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The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code sections 2B.5A and 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay or suspension imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515)281-3355 or (515)242-6873

Agriculture and Land Stewardship Department[21]

Replace Chapter 67

Utilities Division[199]

Replace Analysis

Replace Chapter 9

Economic Development Authority[261]

Replace Analysis

Replace Chapter 197

Replace Chapter 199

Replace Chapter 220

Remove Reserved Chapters 406 to 410 and Chapters 411 and 412

Insert Reserved Chapters 406 to 412

Iowa Finance Authority[265]

Replace Chapter 12

Human Services Department[441]

Replace Analysis

Replace Chapter 170

Replace Chapter 204

Inspections and Appeals Department[481]

Replace Analysis

Replace Chapter 6

Replace Chapter 41

Replace Chapters 50 and 51

Replace Chapters 57 and 58

Replace Chapters 60 and 61

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Environmental Protection Commission[567]

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Public Health Department[641]

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Replace Chapters 41 and 42

Replace Chapter 69

Professional Licensure Division[645]

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Replace Chapter 21

Public Safety Department[661]

Replace Chapter 83

Replace Chapter 159

Replace Chapter 211

Revenue Department[701]

Replace Chapter 12

Replace Chapter 70

Replace Chapter 78

Replace Chapter 82

CHAPTER 67
ANIMAL WELFARE

[Prior to 7/27/88 see Agriculture Department 30—Ch 20]

21—67.1(162) Definitions.

“Acclimated” means the animal is accustomed to a climate or environment and has the ability to maintain its body temperature.

“Adequate feed” means the provision at suitable intervals of not more than 24 hours or longer if the dietary requirements of the species so require, of a quantity of wholesome foodstuff suitable for the species and age, sufficient to maintain a reasonable level of nutrition in each animal. The foodstuff shall be served in a clean receptacle, dish or container.

“Adequate space” means the animals contained within the primary enclosure all must have the ability to comfortably turn about, stand erect, sit or lie with limbs fully extended.

“Adequate water” means reasonable access to a supply of clean, fresh, potable water provided in a sanitary manner or provided at suitable intervals for the species and not to exceed 24 hours at any interval.

“Animal shelter” means a facility which is used to house or contain dogs or cats, or both, and which is owned, operated, or maintained by an incorporated humane society, animal welfare society, society for the prevention of cruelty to animals, or other nonprofit organization devoted to the welfare, protection, and humane treatment of such animals.

“Animal warden” means any person employed, contracted, or appointed by the state, municipal corporation, or any political subdivision of the state, for the purpose of aiding in the enforcement of the provisions of Iowa Code chapter 162 or any other law or ordinance relating to the licensing of animals, control of animals or seizure and impoundment of animals and includes any peace officer, animal control officer, or other employee whose duties in whole or in part include assignments which involve the seizure or taking into custody of any animal.

“Animal Welfare Act” means the federal Animal Welfare Act, 7 U.S.C. Ch. 54, and regulations promulgated by the United States Department of Agriculture and published in 9 C.F.R. Ch. 1.

“Authorization” means a state license, certificate of registration, or permit issued or renewed by the department to a commercial establishment as provided in Iowa Code section 162.2A.

“Boarding kennel” means a place or establishment other than a pound or animal shelter where dogs or cats not owned by the proprietor are sheltered, fed, and watered in return for a consideration.

“Breeding male or female” means any sexually intact adult dog or cat over 12 months of age.

“Cleaning” means the mechanical removal of organic matter and waste through the application of soap, detergent or other cleaning agent followed by the rinsing of all surfaces with clean water.

“Commercial breeder” means a person, engaged in the business of breeding dogs or cats, who sells, exchanges, or leases dogs or cats in return for consideration, or who offers to do so, whether or not the animals are raised, trained, groomed, or boarded by the person. A person who owns or harbors three or fewer breeding males or females is not a commercial breeder. However, a person who breeds any number of breeding male or female greyhounds for the purposes of using them for pari-mutuel wagering at a racetrack as provided in Iowa Code chapter 99D shall be considered a commercial breeder irrespective of whether the person sells, leases, or exchanges the greyhounds for consideration or offers to do so.

“Commercial establishment” or *“establishment”* means an animal shelter, boarding kennel, commercial breeder, commercial kennel, dealer, pet shop, pound, public auction, or research facility.

“Commercial kennel” means a kennel which performs grooming, boarding, or training services for dogs or cats in return for a consideration.

“Commingle” means to combine animals from different owners in a common area or enclosure.

“Common area” means any area where dogs are commingled for exercise or social interaction.

“Dealer” means any person who is engaged in the business of buying for resale or selling or exchanging dogs or cats, or both, as a principal or agent, or who claims to be so engaged.

“Department” means the department of agriculture and land stewardship.

“Direct and immediate visual supervision” means a person providing visual supervision is located on the premises and within the line of sight of the animal and is available to provide immediate attention to the animals within the group.

“Distemper” means canine distemper virus or feline panleukopenia virus.

“Dog day care” means a facility licensed as a commercial kennel or a boarding kennel and designed and operated with the intention that a dog admitted to the facility is allowed, in compliance with this chapter, to mingle and interact with other dogs in one or more playgroups operating in the facility.

“Euthanasia” means the humane destruction of an animal accomplished by a method that involves instantaneous unconsciousness and immediate death or by a method that involves anesthesia, produced by an agent which causes painless loss of consciousness, and death during the loss of consciousness.

“Facility” means all buildings, yards, pens and other areas, or any portion thereof, at a single location in which any animal is kept, handled, or transported for the purpose of adoption, breeding, boarding, grooming, handling, selling, sheltering, trading, rescuing or otherwise transferring.

“Federal license” means a license issued by the United States Department of Agriculture to a person classified as a dealer or exhibitor pursuant to the federal Animal Welfare Act.

“Federal licensee” means a person to whom a federal license as a dealer or exhibitor is issued.

“Foster care home” means a private residence that is authorized to provide temporary shelter and care for an animal that has been accepted by a foster oversight organization.

“Foster oversight organization” means a registered animal shelter or pound or licensed dealer which has been authorized by the department to utilize foster care homes in its operation.

“Group housing” means more than two animals housed together within the same primary enclosure.

“Housing facilities” means any room, building, or area used to contain a primary enclosure or enclosures.

“Identification” means breed, color, markings, sex, and age of the dog or cat. If applicable, identification can also include a microchip number, rabies tag number, tattoo, or other similar form of identification.

“In-home facility” means an individual required to be licensed as a boarding kennel, commercial breeder, commercial kennel, or dealer who maintains or harbors animals within the individual’s residence.

“Isolation” means the separation, for the period of communicability, of infected animals from other animals in such a place and under such conditions to prevent the direct or indirect transmission of the infectious agent from those infected to those that are susceptible or that may spread the agent to others.

“Isolation facility” means the location where animals infected with disease may be placed to contain, control and limit the spread of disease.

“Kennel” means a facility, location, or area where dogs or cats are brought together or commingled for the purpose of, but not limited to, boarding, grooming, or training.

“Licensee” means any person or facility authorized to operate pursuant to Iowa Code chapter 162.

“Parvo” means canine parvovirus or feline panleukopenia virus.

“Permittee” means a commercial breeder, dealer, or public auction to whom a permit is issued by the department as a federal licensee pursuant to Iowa Code section 162.2A.

“Person” means person as defined in Iowa Code chapter 4.

“Pet shop” means an establishment where a dog, cat, rabbit, rodent, nonhuman primate, fish other than live bait, bird, or other vertebrate animal is bought, sold, exchanged, or offered for sale. However, a pet shop does not include an establishment if one of the following applies:

1. The establishment receives less than \$500 from the sale or exchange of vertebrate animals during a 12-month period.

2. The establishment sells or exchanges less than six animals during a 12-month period.

“Potable water” means liquid water suitable for drinking.

“Pound” means a facility for the prevention of cruelty to animals operated by the state, a municipal corporation, or other political subdivision of the state for the purpose of impounding or harboring seized stray, homeless, abandoned, or unwanted dogs, cats, or other animals; or a facility operated for such a purpose under a contract with any municipal corporation or incorporated society.

“*Primary enclosure*” means any structure used to immediately restrict an animal to a limited amount of space, such as a room, pen, cage, or compartment.

“*Public auction*” means any place or location where dogs or cats, or both, are sold at auction to the highest bidder regardless of whether the dogs or cats are offered as individuals, as a group, or by weight.

“*Registrant*” means a pound, animal shelter, or research facility to whom a certificate of registration is issued by the department pursuant to Iowa Code section 162.2A.

“*Rescue*” means a person or group of persons, licensed as a dealer, who holds itself out as an animal rescue, or who accepts, purchases, exchanges or solicits for dogs or cats with the intention of finding permanent adoptive homes or providing lifelong care for such dogs and cats or who uses foster homes as a primary means of housing dogs or cats.

“*Rescue manager*” means any person designated by a rescue to carry out the responsibilities of the rescue.

“*Research facility*” means any school or college of medicine, veterinary medicine, pharmacy, dentistry, or osteopathic medicine, or hospital, diagnostic or research laboratories, or other educational or scientific establishment situated in this state concerned with the investigation of, or instruction concerning the structure or function of living organisms, the cause, prevention, control or cure of diseases or abnormal conditions of human beings or animals.

“*Residence*” means any area or space where a person lives or resides.

“*Sanitize*” means to disinfect inanimate objects to eliminate as many or all pathogenic microorganisms, except bacterial spores.

“*Seizure and impoundment,*” as used in this chapter, means either of the following:

1. The confinement of the animals to the property of the owner or custodian of the animals with provisions being made for the care of the animals pending review and final disposition.
2. The physical removal of the animals to another facility for care pending review and final disposition.

“*State fiscal year*” means the fiscal year described in Iowa Code section 3.12.

“*State licensee*” means any of the following:

1. A boarding kennel, commercial kennel, or pet shop to whom a state license is issued by the department pursuant to Iowa Code section 162.2A.
2. A commercial breeder, dealer, or public auction to whom a state license is issued in lieu of a permit by the department pursuant to Iowa Code section 162.2A.

“*Transfer*” means to adopt, sell, give away, trade, barter, exchange, return or convey ownership of an animal.

“*Vertebrate animal*” means those vertebrate animals other than members of the equine, bovine, ovine, and porcine species, and ostriches, rheas, or emus.

“*Veterinarian*” means a person who is validly and currently licensed to practice veterinary medicine in the state of Iowa.

[ARC 4789C, IAB 12/4/19, effective 1/8/20; ARC 5713C, IAB 6/16/21, effective 7/21/21]

21—67.2(162) Animals included in rules. “Dog,” as that term is used in the rules, includes hybrid dog mixtures. “Animals,” as that term is used in rules relating to boarding kennels, commercial kennels, commercial breeders, dealers, public auctions, animal shelters, and pounds, means dogs and cats. “Animals,” as that term is used in rules relating to pet shops, means dogs, cats, rabbits, rodents, nonhuman primates, birds, fish other than live bait, or other vertebrate animals. This chapter does not apply to livestock as defined in Iowa Code section 717.1 or any other agricultural animal used in agricultural production as provided in Iowa Code chapter 717A.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.3(162) Housing facilities and primary enclosures.

67.3(1) Housing facilities.

a. Buildings shall be of adequate structure and maintained in good repair so as to ensure protection of animals from injury.

b. Shelter shall be provided to allow access to shade from direct sunlight and regress from exposure to wind, rain or snow. Heat, insulation, or clean and dry bedding adequate to provide comfort shall be provided when the atmospheric temperature is below 50°F or the temperature to which the particular animals are acclimated. Indoor housing facilities shall be provided for dogs and cats under the age of eight weeks and for dogs and cats within two weeks of whelping. Dogs and cats that are not acclimated to the temperatures prevalent in the area or region where they are kept and sick, aged, young or infirm dogs and cats cannot be housed in outdoor facilities.

c. Temperature.

(1) Indoor housing facilities for dogs and cats must be capable of controlling the temperature in the housing facility and sufficiently heated and cooled when necessary to protect dogs and cats from temperature or humidity extremes and to provide for their well-being.

(2) When dogs and cats are present, the ambient temperature in the indoor housing facility cannot fall below 50°F for dogs and cats not acclimated to lower temperatures, for breeds that cannot tolerate lower temperatures without stress or discomfort, and for sick, aged, young or infirm dogs and cats except as approved by the attending veterinarian. Heat, insulation, clean and dry bedding or other methods of conserving body heat that are adequate to provide comfort shall be provided when the atmospheric temperature is below 50°F. The ambient temperature must not fall below 45°F or rise above 85°F for more than four consecutive hours when dogs or cats are present.

d. Ventilation. Indoor and outdoor housing facilities shall at all times be provided with ventilation by means of doors, windows, vents, air conditioning or direct flow of fresh air that is adequate to provide for the good health and comfort of the animals. Such ventilation shall be environmentally provided so as to maintain adequate temperature and minimize drafts, moisture condensation, odors or stagnant vapors of excreta. Auxiliary ventilation, such as fans, blowers or air conditioning, must be provided when the ambient temperature is above 85°F. Relative humidity must be maintained at a level that ensures the health and well-being of the animals housed in the housing facility. Indoor housing facilities must be capable of the following:

(1) Maintaining humidity levels between 30 percent and 70 percent; and

(2) Rapidly eliminating odors from within the building.

e. Adequate lighting shall be provided by natural or artificial means, or both, during sunrise to sunset hours to allow efficient cleaning of the facilities and routine inspection of the facilities and animals contained therein.

f. Ceilings, walls and floors shall be constructed so as to lend themselves to efficient cleaning and sanitizing. Such surfaces shall be kept in good repair and maintained so that they are substantially impervious to moisture. Floors and walls to a height of four feet shall have finished surfaces. No sharp or jagged edges may be present that may injure an animal. Animal contact surfaces must be free of excessive rust that prevents required cleaning and sanitizing or that affects the structural strength of the surface or that may be detrimental to the health of the animal.

g. Food supplies and bedding materials shall be stored so as to adequately protect them from contamination or infestation by vermin or other factors which would render the food or bedding unclean. Separate storage facilities shall be used to store cleaning and sanitizing equipment and supplies.

h. Washrooms, basins or sinks for maintaining cleanliness among animal caretakers and the sanitizing of food and water utensils shall be provided within or be readily accessible to each housing facility.

i. Equipment shall be available for removal and disposal of all waste materials from housing facilities to minimize vermin infestation, odors and disease hazards. Drainage systems shall be functional to effect the above purposes.

j. Group housing is permitted for animals that are compatible with one another, except as otherwise stated herein. Adequate space shall be provided to prevent crowding and to allow freedom of movement and comfort to animals of the size which are housed in the facility. Females in estrus shall not be housed with males except for breeding purposes.

k. Facilities shall be provided to isolate diseased animals and to prevent exposure to healthy animals.

l. Outdoor dog runs and exercise areas shall be of sound construction and kept in good repair so as to safely contain the animal(s) therein without injury. Floors shall be concrete, gravel or materials which can be regularly cleaned and kept free of waste accumulation. Grass runs and exercise areas are permissible provided that adequate ground cover is maintained, holes are kept filled and the ground cover is not allowed to become overgrown. Dog runs and exercise areas utilizing wire floors are permissible provided that the wire floors are not injurious to the animals and are adequately maintained. Wire flooring cannot cause injury to any animal contained in a dog run or exercise area that has wire flooring and must:

- (1) Have a solid resting surface of adequate size for an animal to lay on its side;
- (2) Be in good repair, free of excessive rust that prevents required cleaning and sanitizing or that affects the structural strength of the surface or that may be detrimental to the health of the animal;
- (3) Be free of jagged or sharp edges, and constructed so as to lend itself to efficient cleaning and sanitizing; and
- (4) Be of a gauge and construction to prevent bending and sagging and to prevent physical harm to an animal or entrapment of the feet of an animal housed within the primary enclosure.

m. Housing facilities and areas used for storage of food or bedding must be free of trash, garbage, waste, weeds, debris and other materials potentially harmful to animals.

n. Animal areas must be kept clean, neat, and free of clutter.

o. The department may limit the number of animals allowed in any housing facility based on, but not limited to, the number of available primary enclosures, the animal care space available within a facility, or lack of available personnel to care for the animals.

67.3(2) Primary enclosures.

a. Primary enclosures shall be of sound construction and maintained in good repair to protect the animals from injury. No sharp points or jagged edges may be present that may cause injury to an animal. Animal contact surfaces must be free of excessive rust that prevents required cleaning and sanitizing or that affects the structural strength of the surface or that may be detrimental to the health of the animal. Animal contact surfaces must also be free of jagged edges, sharp points and anything that may cause injury to an animal.

b. Construction materials and maintenance shall allow the animals to be kept clean and dry. Walls and floors shall be impervious to urine and other moisture and lend themselves to efficient cleaning and sanitizing.

c. A primary enclosure shall provide for adequate space appropriate for the age, size, weight, breed, and temperament of the animal.

d. The shape and size of the enclosure shall afford adequate space for the individual animals within the enclosure. Adequate space includes, but is not limited to, allowing the animal the ability to comfortably reposition, turn about, stand erect, sit or lie while limbs are fully extended. Cats must have adequate space for a litter box so that litter does not contaminate food and water.

e. A nursing bitch or queen must be provided additional space. The amount of additional space required should be based on the breed and behavioral characteristics of the animal.

f. The department may limit the number of animals housed in a primary enclosure based on, but not limited to, the amount of available and usable floor space, personnel available to care for the animals and the compatibility of the animals within the enclosure.

g. Group housing.

(1) Group housing for animal shelters, pounds, commercial breeders, pet shops, dealers, public auctions or research facilities is permitted for animals that are compatible with one another, except as otherwise stated herein. Adequate space shall be provided to prevent crowding and to allow freedom of movement and comfort to animals of the size which are housed within the primary enclosure. No more than 12 adult dogs or cats may be housed in the same primary enclosure. Dogs and cats shall not be housed in the same primary enclosure.

(2) Group housing in boarding kennels and commercial kennels is permitted only if the animals are owned by the same person and are compatible or by operating as a dog day care as required in rule 21—67.8(162).

h. Elevated resting surfaces are required for cats housed in groups of four or more. Elevated resting surfaces must be collectively large enough to simultaneously hold all occupants of a primary enclosure and must be impervious to moisture, easily cleaned and sanitized, easily replaced, and of sufficient elevation for the cats enclosed in the primary enclosure to comfortably lay under the elevated surfaces.

i. Litter boxes containing clean litter shall be provided at all times for kittens and cats. Adequate litter boxes must be provided for the number of cats within a primary enclosure. Litter boxes must:

(1) Be cleaned at minimum once daily or more often as necessary to prevent the accumulation of animal waste;

(2) Contain adequate litter and be of adequate size; and

(3) Be cleaned and sanitized in a separate sink from food and water receptacles. If a separate sink is not available, then the sink must be cleaned and sanitized after the litter boxes are washed and before anything else is washed in the sink.

j. Animal waste, including used cat litter, must be removed from primary enclosures at minimum once daily or more frequently to prevent the accumulation of waste and contamination of the animals contained within the primary enclosure and must be discarded in accordance with state, county and local ordinances.

k. Means shall be provided to maintain the temperature and ventilation that are comfortable for the species within the primary enclosure. Lighting shall be adequate to allow observation of the animals, but the animals shall be protected from excessive illumination.

l. Animals shall be removed from their primary enclosures at least twice in each 24-hour period and exercised unless the primary enclosure is of sufficient size to provide for sufficient exercise. The amount of exercise should be appropriate for the age, breed, and health condition of the animal. Impounded animals, animals deemed too dangerous to be removed from the primary enclosure, and animals undergoing rabies quarantine may be exempt from removal from their primary enclosure but must be housed in a primary enclosure large enough to allow for exercise within the primary enclosure. Animals under the medical supervision of a veterinarian may be exempt in writing from exercise if exemption is deemed medically appropriate by the attending veterinarian.

m. Doghouses with tethered restraints, including but not limited to chains, cannot be used as primary enclosures for dogs but may be used for the purpose of exercise. The tethered restraint used shall be placed or attached so that it cannot become entangled with the tethered restraints of other dogs or any other objects. Such tethered restraints shall be of a type commonly used for the size of dog involved and shall be attached to the dog by means of a well-fitted collar. Such tethered restraints shall be at least three times the length of the dog as measured from the tip of the dog's nose to the base of its tail and shall allow the dog convenient access to the doghouse.

n. Primary enclosures containing wire flooring cannot cause injury to any animal contained in the primary enclosure, and the wire flooring must:

(1) Have a solid resting surface of adequate size for an animal to lay on its side;

(2) Be in good repair, free of excessive rust that prevents required cleaning and sanitizing or that affects the structural strength of the surface or that may be detrimental to the health of the animal;

(3) Be free of jagged or sharp edges, and constructed so as to lend itself to efficient cleaning and sanitizing; and

(4) Be of a gauge and construction to prevent bending and sagging and to prevent physical harm to an animal or entrapment of the feet of an animal housed within the primary enclosure.

o. When primary enclosures are stacked, all stacked enclosures must be secured so that the upper primary enclosure(s) cannot fall in a manner which may cause injury or harm to any animal. A means to prevent urine, feces, and other debris from passing into or being discharged into the underlying primary enclosure(s) is required.

p. All enclosures must be impermeable to water and easily cleaned and sanitized.

q. Bedding within primary enclosures must be easily cleaned and sanitized or disposable.

[ARC 4789C, IAB 12/4/19, effective 1/8/20; ARC 5713C, IAB 6/16/21, effective 7/21/21]

21—67.4(162) General care and husbandry standards.**67.4(1) Feeding and watering.**

a. All species covered under Iowa Code chapter 162 shall be provided with adequate feed and adequate water.

b. Young animals and animals under veterinary care shall be fed and given water at more frequent intervals and with specific diets as their needs dictate.

c. Water must be provided as often as necessary for the health and comfort of the animal. The frequency of providing water should be appropriate to the species, age, condition, and size of the animal as well as the environmental conditions.

d. Water for dogs and cats must be made available at minimum two times daily for at least one hour each time.

e. The receptacles for food and water must be:

- (1) Readily accessible;
- (2) Located to minimize contamination with excreta;
- (3) Made of durable material that can easily be cleaned and sanitized or be disposable;
- (4) Appropriate for the species, size, age and breed of animal; and
- (5) Replaced after a single use if the receptacles are disposable.

67.4(2) Cleaning and sanitation.

a. Housing facilities and primary enclosures shall be cleaned a minimum of once in each 24-hour period and more frequently as may be necessary to reduce disease hazards and odors. Dirt, hair, excreta (including but not limited to urine and feces), food waste, and other debris shall be removed from a primary enclosure daily or at a frequency to prevent their accumulation and the contamination of the animals contained within the primary enclosure.

(1) When primary enclosures are stacked, a means to prevent urine, feces and other debris from passing into or being discharged into the underlying primary enclosure(s) is required.

(2) Pressure water systems or live steam may be used for cleaning if animals are removed while the cleaning takes place.

b. Housing facilities and primary enclosures shall be sanitized at intervals not to exceed two weeks or sanitized more frequently as may be necessary to reduce disease hazards. Sanitizing shall be done by washing the surfaces with hot water and soap or detergent, followed by the application of a safe and effective disinfectant. Runs and exercise areas having gravel or other nonpermanent surface materials shall be sanitized by periodic removal of soiled materials, application of suitable disinfectants, and replacement of the soiled materials with clean surface materials. Dirt, hair, excreta, food waste, and other debris shall be removed before sanitizing begins. Manufacturer labels shall be followed for dilution and contact time for all soaps, detergents, disinfectants, or other chemicals used for sanitization.

c. An effective program shall be established and maintained for the control of vermin infestation.

d. Before a primary enclosure, food receptacle or water receptacle is used for another animal, the primary enclosure, food receptacle or water receptacle shall be cleaned and sanitized.

67.4(3) Veterinary care.

a. Programs of disease prevention and control shall be established in writing and maintained.

b. Sick, diseased or injured animals shall be provided with prompt veterinary care or disposed of by euthanasia. Euthanasia must be performed in a manner deemed acceptable by and published in the American Veterinary Medical Association Guidelines for Euthanasia of Animals: 2020 Edition.

c. All species regulated under Iowa Code chapter 162 that are infected with contagious diseases shall be immediately placed into isolation facilities as provided for in this paragraph to prevent exposure to healthy animals. Isolation facilities must be an area separate from the remainder of the animals in a facility with the ability to contain disease and to reduce the risk of disease spread. Animals in isolation must be cared for separately from the remainder of the animals in a facility. All equipment and supplies used for animals in an isolation facility must be cleaned and disinfected prior to removal from the isolation facility or discarded in a manner that prevents disease spread.

d. Dogs and cats within all commercial establishments must be vaccinated for rabies when age-appropriate unless exempted by Iowa Code section 351.42.

e. All dogs and cats taken into the care of a dealer, or transported into housing facilities regulated under Iowa Code chapter 162, excluding pounds and animal shelters, shall have been vaccinated against distemper, parvo and rabies, unless exempted by direct written recommendation of the owner's veterinarian or exempted by Iowa Code section 351.42 before entering the housing facility or being taken into the care of a dealer. Rabies titers shall not be accepted by a commercial establishment in lieu of a rabies vaccination.

f. Animal shelters and pounds must vaccinate dogs and cats in their care for rabies, distemper and parvo within a reasonable time of the dog or cat entering the animal shelter or pound. Animal shelters and pounds must also keep dogs and cats current on vaccinations for rabies, distemper and parvo.

g. Vaccine titers shall not be accepted as a form of vaccine verification. Vaccine records and written vaccine exemptions shall be kept on file. Acceptable forms of documentation for vaccine verification for admittance of a dog or cat into a commercial establishment, excluding animal shelters and pounds, include the following:

- (1) Written documentation of vaccination from a veterinarian.
- (2) A rabies certificate signed by a veterinarian.

h. Dogs and cats brought into the state of Iowa must meet importation requirements under rule 21—65.10(163).

i. Commercial establishments, excluding commercial kennels and boarding kennels, shall enter into a written agreement with a veterinarian licensed by the state of Iowa to provide veterinary care for the animals maintained in the facility. The agreement shall include a requirement that the veterinarian visit the facility at least once every 12 months for the purpose of viewing all the animals in the facility, making a general determination concerning the health/disease status of the animals, and reviewing the facility's program for disease prevention and control. If during the course of the visit the veterinarian identifies an animal that requires a more detailed individual examination to determine the specific condition of the animal or to determine an appropriate course of treatment, then such examination shall be undertaken.

j. Commercial kennels and boarding kennels must have a written agreement with a veterinarian licensed by the state of Iowa to provide veterinary care for an animal in their care should veterinary care be required.

k. If during an inspection of a facility the department finds an animal which appears to have a physical condition or disease that, in the opinion of the inspector, requires a veterinarian's attention, the department may order that the licensee subject the animal to a veterinarian's examination at the licensee's expense. The department may require the licensee to submit written proof of the veterinarian's examination and results of the examination within a time frame set by the department.

67.4(4) Personnel.

a. The owner or personnel shall be present at least once in each 24-hour period to supervise and ascertain that the care of animals and maintenance of facilities conform to all of the provisions of Iowa Code chapter 162.

b. A sufficient number of qualified personnel shall be utilized to provide the required care of animals and maintenance of facilities during normal business hours.

[ARC 4789C, IAB 12/4/19, effective 1/8/20; ARC 5713C, IAB 6/16/21, effective 7/21/21]

21—67.5(162) Transportation.

67.5(1) Primary enclosures for transportation. Primary enclosures are required within transportation vehicles.

a. Primary enclosures utilized in transportation shall:

- (1) Be of sound construction, maintained in good repair to ensure protection of animals from injury, and readily cleaned and sanitized;
- (2) Be free of sharp points, jagged edges or protrusions that could injure the animal; and
- (3) Securely contain the animal so that the animal cannot injure itself, its handler or any persons or animals nearby.

b. Floors and lower sides shall be constructed or covered on the inner surfaces so as to contain excreta and bedding materials.

c. Adequate space shall be provided so that the animal(s) contained in the primary enclosure may comfortably turn about, stand erect, sit and lie.

d. Openings shall be provided in primary enclosures so that adequate ventilation can be maintained when the primary enclosures are positioned in the transporting vehicle.

e. Primary enclosures shall be cleaned and sanitized before each trip and between animals.

f. The temperature within primary enclosures shall not be allowed to exceed the atmospheric temperature. During transportation, the ambient temperature inside the primary enclosure cannot exceed 85°F for a period of more than four hours, nor may the temperature fall below 45°F for a period of more than four hours. Auxiliary ventilation, such as fans, blowers or air conditioning, must be used in the animal space when the ambient temperature in the space reaches 85°F.

67.5(2) Vehicles.

a. Protection shall be afforded to primary enclosures transported in the vehicle, sheltering the animals from drafts and extremes of hot or cold temperatures to which they are not acclimated.

b. Primary enclosures used in transportation shall be securely positioned in the vehicle to protect the animals from injury.

67.5(3) Care in transit.

a. Animals in transit shall be provided adequate feed and adequate water as defined in rule 21—67.1(162).

b. Incompatible animals shall not be placed together during shipment. Females in estrus shall not be placed in the same primary enclosure with a male.

c. Animals shall be inspected at least once in each four-hour period and the primary enclosures cleaned if necessary and the emergency needs of the animals attended to immediately.

d. Animals shall be removed for exercise and their enclosures cleaned if the animals have been en route for a 12-hour period.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.6(162) Purchase, sale, trade and adoption.

67.6(1) Records shall be made and retained for a period of 12 months for any change of ownership of a dog, cat or nonhuman primate, including but not limited to any sale, exchange, transfer, trade, or adoption from any commercial establishment. Records shall be similarly kept on other small vertebrate animals sold or transferred, except that individual identifications shall not be required. Records shall include the following:

- a.* Date of change of ownership;
- b.* Identification of animal;
- c.* Names, mailing addresses, telephone numbers, and email addresses, if available, of seller and purchaser or transferor and recipient;
- d.* State of Iowa animal welfare license number of the seller or transferor;
- e.* Source of the animal;
- f.* Date animal entered the care of and left the care of the commercial establishment;
- g.* Method and date of euthanasia, if applicable;
- h.* Transfer of animal within or between commercial establishments;
- i.* List of prophylactic immunization(s) given, including date(s) administered (if applicable);
- j.* List of internal parasite medication(s) given and date(s) administered (if applicable); and
- k.* Description of other medical care provided to the animal, including type of medical care received and date(s) of medical care.

67.6(2) All commercial establishments shall furnish a statement of sale, exchange, transfer, trade, or adoption to each purchaser or recipient of a dog, cat, nonhuman primate, bird, or other vertebrate animal. This statement shall include the following:

- a.* Names, mailing addresses, telephone numbers, and email addresses, if available, of the seller or transferor and the purchaser or recipient;
- b.* State of Iowa animal welfare license number of the seller or transferor;
- c.* Date of sale, transfer, trade, adoption, exchange or any other change of ownership;

- d. Description or identification of vertebrate sold;
- e. List of prophylactic immunization(s) given, including date(s) administered (if applicable);
- f. List of internal parasite medication(s) given and date(s) administered (if applicable); and
- g. Description of other medical care provided to the animal, including type of medical care received and date(s) of medical care.

67.6(3) All vertebrate animals regulated under Iowa Code chapter 162 which are known to be exposed to or show symptoms of having infectious and contagious diseases or which show symptoms of parasitism or malnutrition sufficient to adversely affect the health of the animals are restricted from sale or transfer. The secretary of agriculture may order quarantine on premises or housing facilities in which any of the conditions listed in this subrule exist. Quarantine shall be removed when at the discretion of the secretary or the secretary's designee, the disease conditions for which quarantined are no longer evident and the apparent health of the animals indicates absence of contagion.

67.6(4) For the purposes of determining an individual's obligation to be licensed under Iowa Code section 162.8, "breeding animal" includes any sexually intact animal over the age of 12 months.
[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.7(162) Boarding kennels, commercial kennels, animal shelters, pounds and dealers.

67.7(1) *Boarding kennels and commercial kennels.*

a. Records shall be made and retained for a period of 12 months for each animal boarded, groomed or trained. Records shall include the following:

- (1) Owner's name, address, telephone number and email address;
- (2) Identification of animal;
- (3) Duration of animal's stay;
- (4) Service(s) provided;
- (5) Any illnesses which have occurred and veterinary treatment the animal received; and
- (6) Written documentation of the animal's vaccinations or vaccination exemptions from a veterinarian.

b. All dogs and cats transported into boarding kennels and commercial kennels regulated under Iowa Code chapter 162 shall have been vaccinated against distemper, parvo and rabies, unless exempted by Iowa Code section 351.42 or the direct written recommendation of a qualified veterinarian. Vaccine records and exemptions must be kept on file for a period of 12 months for each animal boarded, groomed, or trained.

c. Vaccine titers shall not be accepted as a form of vaccine verification. Vaccine records and written vaccine exemptions shall be kept on file. Acceptable forms of documentation for vaccine verification include the following:

- (1) Written documentation of vaccination from a veterinarian;
- (2) A rabies certificate signed by a veterinarian.

d. Animals exhibiting symptoms of disease shall be promptly examined and treated by a veterinarian.

e. Group housing is permitted only if the animals are owned by the same person and are compatible or by operating as a dog day care as required in rule 21—67.8(162).

f. Grooming and training utensils and equipment shall be cleaned and sanitized between use on animals owned by different persons.

g. Primary enclosures shall be cleaned and sanitized between use in containing animals owned by different persons. Primary enclosures must be cleaned at least once daily and sanitized weekly for animals staying overnight.

h. Primary enclosures shall utilize latches that cannot be inadvertently opened or shall be equipped with some form of locking device so as to prevent the accidental release of the animal contained in the primary enclosure.

67.7(2) *Animal shelters and pounds.*

a. Dogs, cats and other vertebrates upon which euthanasia may be permitted by law shall be destroyed only by euthanasia in a manner deemed acceptable by and published in the American Veterinary Medical Association Guidelines for Euthanasia of Animals: 2020 Edition.

b. Animal shelters and pounds shall develop and implement a plan providing for the surgical sterilization of all dogs and cats released, unless exempted from this provision in accordance with Iowa Code section 162.20(5).

c. Sterilization agreements shall contain the following:

- (1) The name, address and signature of the person receiving custody of the dog or cat.
- (2) A complete description of the animal, including any identification.
- (3) The signature of the representative of the pound or animal shelter.
- (4) The date that the agreement is executed and the date by which sterilization must be completed.
- (5) A statement which states the following:
 1. Sterilization of the animal is required pursuant to Iowa Code section 162.20.
 2. Ownership of the dog or cat is conditioned upon the satisfaction of the terms of the agreement.
 3. Failure to satisfy the terms of the agreement constitutes a breach of contract, requiring the return

of the dog or cat.

4. A person failing to satisfy the sterilization provisions of the agreement is guilty of a simple misdemeanor.

d. In addition to maintaining the records required by subrule 67.6(1), animal shelters and pounds shall maintain, for a period of 12 months, the following records:

- (1) Euthanasia records, including date of entry, source of animal, and date of euthanasia.
- (2) Sterilization agreements, including confirmation in the form of a receipt furnished by the office of the attending veterinarian.
- (3) Disposition records of all animals lawfully claimed by owners, research facilities, or Class B federal dealers.

e. A pound or animal shelter may apply in writing for an enforcement waiver pursuant to Iowa Code section 162.20(5) “*b.*” The application shall include the specific guidelines under which the waiver is being requested and a certified copy of the ordinance providing the basis for the waiver application. A waiver application fee of \$10 shall accompany the application.

f. A pound or animal shelter shall be subject to civil penalties as provided in Iowa Code section 162.20(3) “*c.*” for not procuring and maintaining required records documenting compliance with the sterilization agreement, successfully seeking return of the animal from a noncompliant custodian, failing to effect a sterilization agreement when required for an animal which is released, or seeking legal recourse as provided in Iowa Code section 162.20(4). The pound or animal shelter shall be entitled to appeal pursuant to Iowa Code chapter 17A.

67.7(3) Dealers.

a. A dealer license is required to operate as a dealer in Iowa. This requirement applies to residents and nonresidents of Iowa, including dealer foster homes in Iowa.

b. All dogs and cats taken in by or in the possession of a dealer must be vaccinated and kept current against distemper, parvo and rabies, unless exempted by Iowa Code section 351.42 or the direct written recommendation of a qualified veterinarian. A signed rabies certificate or other written documentation from a veterinarian is required to verify vaccination compliance. Vaccine titers are not sufficient for demonstrating vaccine compliance. Dealers must provide vaccine records or exemptions to the department upon request.

c. Dogs and cats brought into the state of Iowa must meet the importation requirements stated in rule 21—65.10(163).

d. A dealer with housing facilities must meet the requirements provided for housing facilities and primary enclosures in rule 21—67.3(162) and in-home facilities in rule 21—67.9(162).

e. A dealer must maintain records and statement of sales as provided for in rule 21—67.6(162).

f. A dealer approved by the department to act as a fostering oversight organization must meet the requirements for fostering oversight organizations and foster care homes provided in rule

21—67.11(162). A dealer may not utilize or oversee a foster home without prior written authorization of the department.

[ARC 4789C, IAB 12/4/19, effective 1/8/20; ARC 5713C, IAB 6/16/21, effective 7/21/21]

21—67.8(162) Dog day cares.

67.8(1) Purpose. The purpose of a dog day care is to allow dogs participating in the day care to become socialized through interaction in playgroups with other compatible dogs.

67.8(2) Subclassification of license. Dog day cares can operate as a subclassification of a commercial kennel license or boarding kennel license by complying with rule 21—67.8(162).

67.8(3) Approval based on number of dogs. The department will approve a dog day care for a maximum number of dogs based on, but not limited to, available space, available staff, and staff's ability to supervise dogs.

67.8(4) Facility requirements. A facility licensed to be a dog day care shall meet the housing facility and primary enclosure requirements provided for in rule 21—67.3(162). The dog day care shall also comply with the following facility requirements:

a. Group interaction is permitted for dogs, including dogs owned by different owners, that are compatible with one another. A facility licensed as a dog day care shall comply with all requirements in this rule during all hours of operation.

b. The play area for dogs shall provide for a minimum of 50 square feet per dog. Play areas must have a sign placed at the entry of the play area stating the maximum number of dogs allowed in the play area at any one time.

c. Each dog attending a dog day care must have a primary enclosure. When not under direct supervision, dogs at a dog day care must be housed within a primary enclosure at all times. Group housing within a primary enclosure is permitted for dogs from the same household that are compatible with one another.

67.8(5) Sanitation requirements. A facility licensed to be a dog day care shall comply with the cleaning and sanitation standards provided for in rule 21—67.4(162) and the following requirements:

a. All areas to which a dog has access shall be cleaned and sanitized a minimum of once in each 24-hour period and more frequently as may be necessary to reduce disease hazards and odors.

b. Used primary enclosures and food and water receptacles must be cleaned and sanitized before they can be used to house, feed or water another animal.

67.8(6) Operations. A facility licensed to be a dog day care shall comply with the following operational standards:

a. A dog, including a dog owned by the dog day care owner or a dog day care employee, shall be admitted into a dog day care only after the day care has:

(1) Subjected the dog to a pre-entry screening process that adequately evaluates the temperament of the dog, the dog's ability to interact with other dogs in a positive manner, and the dog's ability to interact with humans in a positive manner. The screening shall include, but not be limited to, obtaining a social history of the dog from the dog's owner. A written record of the testing shall be maintained by the facility for the time the dog is enrolled in the day care. The day care shall not admit any dog into the day care if the dog has a predisposition to be possessive of either the facility or a person owning or working in the facility. The day care shall not admit any dog that is known to have a predisposition of aggression toward other dogs or people.

(2) Obtained from the dog's owner written documentation of the medical history of the dog, including the dog's current vaccination status against distemper, parvo and rabies, unless exempted by direct, written recommendation of the owner's veterinarian or exempted by Iowa Code section 351.42.

(3) Obtained written documentation that the dog has been spayed or neutered, if the dog is over six months of age.

(4) Obtained a written acknowledgment from the dog's owner that the owner understands the inherent risk of injury or disease when dogs owned by different people are allowed to commingle. This written acknowledgment shall be separately signed or initialed by the dog's owner.

b. The dog day care shall separate dogs in the dog day care into playgroups comprised of compatible dogs. Dogs of incompatible personalities or temperaments shall be maintained separately.

c. The dog day care shall make advance arrangements in writing with a veterinarian to provide emergency veterinary care for dogs at the dog day care. This agreement must be updated annually.

d. A sick, diseased or injured dog shall be immediately removed from the playgroup and isolated. If circumstances indicate that immediate veterinary care is required, the dog shall be taken to a veterinarian or a veterinarian shall be called to examine the dog. The veterinarian can be either a veterinarian whose services have been contracted for by the dog day care or the veterinarian designated by the dog's owner, if a timely examination by that veterinarian is feasible.

e. The feeding of a dog and giving of snacks to a dog shall only be provided when the dog receiving the food or snack is contained within a primary enclosure. Treats for the purpose of training or managing a group of dogs are permissible.

f. A dog day care shall not establish a playgroup composed of more than 30 dogs.

g. A dog day care shall employ sufficient staffing so that there is a minimum of one person assigned to each playgroup with 15 or fewer dogs and two people assigned to each playgroup with 16 to 30 dogs. The person(s) supervising a playgroup must provide direct and immediate visual supervision at all times.

h. At all times, a dog day care must ensure that dogs are safe within the dog day care group.

i. Rest time within a primary enclosure must be provided for a minimum of two hours per day.

Direct supervision is not required while dogs are housed within primary enclosures.

[ARC 4789C, IAB 12/4/19, effective 1/8/20; see Delay note at end of chapter; ARC 5713C, IAB 6/16/21, effective 7/21/21]

21—67.9(162) In-home facilities.

67.9(1) *Maximum number of animals.* An in-home facility may not maintain or harbor more than six adult animals, including both breeding dogs or cats and surgically sterilized dogs or cats, in the individual's residence.

67.9(2) *Standards.* Notwithstanding subrules 67.4(1) and 67.4(2), an in-home facility shall comply with the following standards:

a. Food supplies and bedding shall be stored so as to adequately protect them from contamination or infestation by vermin or other factors which would render the food or bedding unclean. Separate storage facilities shall be used to store cleaning and sanitizing equipment and supplies.

b. Adequate lighting shall be provided by natural or artificial means, or both, during sunrise to sunset hours. Animals shall be protected from excessive illumination.

c. The building shall be of adequate structure and maintained in good repair so as to ensure protection of animals from injury.

d. Facilities shall be available to isolate diseased animals to prevent exposure to healthy animals.

e. Outdoor dog runs and exercise areas shall be of sound construction and kept in good repair so as to safely contain the animal(s) therein without injury. Floors shall be concrete, gravel or materials which can be regularly cleaned and kept free of waste accumulation. Grass runs and exercise areas are permissible provided that adequate ground cover is maintained, holes are kept filled and the ground cover is not allowed to become overgrown.

f. Group housing is permitted for animals that are compatible with one another. Adequate space shall be provided to prevent crowding and to allow freedom of movement and comfort to animals of the size which are housed within the facility. Females in estrus shall not be housed with males, except for breeding purposes.

g. Every animal in an in-home facility must have a designated primary enclosure.

h. Litter boxes containing clean litter shall be provided at all times for kittens and cats. Litter boxes must be maintained as provided for in paragraph 67.3(2) "j."

i. Means shall be provided to maintain the temperature and ventilation that are comfortable for the species at all times.

j. Animals shall be removed from their primary enclosures at least twice in each 24-hour period and exercised. The amount of exercise should be appropriate for the age, breed and health condition of the animal.

k. Housing facilities shall be cleaned as set out in subrule 67.4(2) to reduce disease hazards, and an effective program shall be established and maintained for the control of vermin infestation. All surfaces within the in-home facility must be readily cleaned and maintained in good repair.

[ARC 4789C, IAB 12/4/19, effective 1/8/20; ARC 5713C, IAB 6/16/21, effective 7/21/21]

21—67.10(162) Rescues.

67.10(1) *Rescue manager.* A rescue must designate a rescue manager to carry out the responsibilities of the rescue. The responsibilities of a rescue manager include, but are not limited to, the following:

- a.* Establishing criteria for approving foster homes;
- b.* Approving foster homes;
- c.* Supervising dogs and cats taken into the care of the rescue;
- d.* Monitoring and ensuring all foster homes under the rescue's oversight are providing proper care and compliance with relevant laws and rules; and
- e.* Maintaining rescue records. Such records shall include, but are not limited to, the following:
 - (1) Source of the dog or cat;
 - (2) Date of placement of the dog or cat into a foster home;
 - (3) Adoption records;
 - (4) Disposition of dog or cat (if applicable);
 - (5) Medical care received by the dog or cat; and
 - (6) Vaccination and deworming records.

67.10(2) *Records.* Rescue records must be made available to the department upon request. A rescue must maintain records and statement of the sale, exchange, transfer, trade or adoption as provided for in rule 21—67.6(162).

67.10(3) *Vaccine requirements.* All dogs and cats taken in by or in the possession of a rescue shall have been vaccinated against distemper, parvo and rabies and kept current on distemper, parvo and rabies vaccinations, unless exempted by Iowa Code section 351.42 or by direct written recommendation of a qualified veterinarian. A signed rabies certificate and written documentation of parvo and distemper vaccinations from a veterinarian are required to verify vaccination. Titers are not an acceptable form of vaccine verification. Vaccine titers are not sufficient for demonstrating vaccine compliance. Dealers must provide vaccine records or written exemptions to the department upon request.

67.10(4) *Importation requirements.* Dogs and cats brought into the state of Iowa must meet the importation requirements stated in rule 21—65.10(163).

67.10(5) *Housing facilities and primary enclosures.* A rescue with housing facilities must meet the requirements for housing facilities and primary enclosures in rule 21—67.3(162). Rescues operating as in-home facilities must meet the requirements in rule 21—67.9(162).

67.10(6) *Foster care homes.* A rescue approved by the department to act as a foster oversight organization must meet the requirements for foster oversight organizations and foster care homes provided in rule 21—67.11(162). A dealer may not utilize or oversee a foster care home without prior written authorization of the department.

67.10(7) *General care and husbandry.* A rescue must meet the general care and husbandry standards provided for in rule 21—67.4(162).

67.10(8) *Transportation.* A rescue transporting animals must meet the requirements provided in rule 21—67.5(162).

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.11(162) Foster oversight organizations and foster care homes.

67.11(1) A registered animal shelter, registered pound or licensed dealer shall not operate a foster care home or operate an organization that utilizes a foster care home unless the shelter, pound or dealer is in compliance with this rule and other applicable provisions of this chapter and Iowa Code chapter 162. If an out-of-state organization is utilizing foster care homes in Iowa, that organization must also be licensed or registered in the state of Iowa as an animal shelter, pound or dealer.

67.11(2) A registered animal shelter, registered pound or licensed dealer may apply to the department for a permit authorizing the shelter, pound or dealer to utilize one or more foster care homes in carrying

out its mission of providing for the care and maintenance of an animal that has been taken in or entrusted to the animal shelter, pound or dealer. For purposes of this rule, an animal shelter, pound or dealer that has been granted such authorization shall be considered a foster oversight organization.

67.11(3) A registered animal shelter, registered pound or licensed dealer may not utilize a foster care home unless the shelter, pound or dealer has been granted authorization by the department to be a foster oversight organization. An animal shelter, pound or dealer that uses a foster care home without first obtaining a permit authorizing the shelter, pound or dealer to be a foster oversight organization shall be considered to be operating illegally, shall be subject to suspension or revocation of its license to operate, and may be subject to other penalties authorized in Iowa Code chapter 162.

67.11(4) A registered animal shelter, registered pound or licensed dealer seeking to obtain a permit to be a foster oversight organization shall make application to the department on a form prescribed by the department. When feasible, the application shall be submitted to the department at the same time that the registered animal shelter, registered pound or licensed dealer submits its certificate of registration renewal or license renewal application. The permit application shall provide sufficient information to allow the department to determine the ability of the proposed foster oversight organization to provide adequate screening and oversight of any foster care home operating under the authority of the foster oversight organization.

a. Such application shall include, but not be limited to, the following information:

(1) The proposed foster oversight organization's plan for providing oversight of the foster care home. The plan shall include the frequency of inspections of the foster care home by the foster oversight organization and the criteria to be used by the foster oversight organization in reviewing the foster care home during periodic inspections. The plan shall also include the actions to be taken by the foster oversight organization in the event that the foster oversight organization determines that the foster care home is not adequately providing for the animals in the foster care home. Foster oversight organizations shall inspect foster care homes annually, at minimum, and an annual written inspection report must be on file with the foster oversight organization. Annual inspection reports shall be retained for a minimum of two years.

(2) The name, mailing address, email address and telephone number of the staff person connected with the proposed foster oversight organization who will have primary responsibility for administering the proposed foster care program.

(3) The name, mailing address, email address and telephone number of a secondary staff person connected with the proposed foster oversight organization who will have responsibility for administering the proposed foster care program in the absence of the primary administrator.

(4) The number of foster care homes the foster oversight organization is applying for and currently oversees. During the first year of application, the foster oversight organization will be limited to a maximum of 20 foster care homes. Upon renewal of the foster oversight organization permit, the foster oversight organization may apply for more than 20 foster care homes, subject to the approval of the department.

(5) Copies of all forms utilized by the foster oversight organization. This includes, but is not limited to, inspection forms and applications.

(6) The number of paid employees, both full-time and part-time, working for the foster oversight organization, the number of volunteers serving the foster oversight organization, and the number of volunteer hours utilized per week.

(7) The criteria used to determine if a foster care home is capable of caring for an animal.

(8) The actions taken by the foster oversight organization if the foster care home is unable to care for an animal.

b. If the foster oversight organization changes locations, a new application must be submitted.

c. If the primary or secondary contact listed on the application is no longer associated with the foster oversight organization, the department must be notified and provided with the name, mailing address, email address and telephone number of the staff person administering the foster care program.

d. The foster oversight organization must provide documentation to demonstrate that the foster oversight organization has sufficient infrastructure to adequately supervise all foster care homes and the care of the animals within the foster care homes.

67.11(5) The initial approval of a foster oversight organization shall be in effect only until the next expiration date of the registered animal shelter's, registered pound's, or licensed dealer's license. Thereafter, a foster oversight organization permit renewal shall be concurrent with the facility's certificate of registration or license renewal, unless circumstances otherwise require.

Foster oversight agreements must be renewed yearly at the same time that the registered animal shelter, registered pound, or licensed dealer submits its certificate of registration renewal application. The renewal agreement must contain the number of foster care homes for which the animal shelter or pound is requesting approval.

67.11(6) A foster oversight organization shall require that all persons seeking to operate a foster care home under the foster oversight organization submit a written application to the foster oversight organization specifying the proposed foster care home's qualifications, including but not limited to the ability of the foster care home to provide adequate care, exercise, feed, water, shelter, space, and veterinary care.

67.11(7) A foster oversight organization shall not be authorized to approve more than 20 foster care homes during the first year of operation. In granting a permit to a foster oversight organization, the department may further restrict the number of foster care homes a particular foster oversight organization may utilize if the department determines that the foster oversight organization does not have adequate personnel to supervise the number of foster care homes for which authorization was sought or the adequate ability to care for all animals in foster care. The department may authorize the foster oversight organization to approve more than 20 foster care homes only if the department finds that the foster oversight organization has and maintains adequate personnel assigned to provide sufficient oversight of foster care homes.

67.11(8) A foster oversight organization shall not authorize a foster care home to have in its care more than six animals, including animals owned by the foster care home, with the exception of a litter of puppies or kittens under 16 weeks of age. A litter of puppies or kittens under 16 weeks of age is considered the equivalent of one dog or cat. The mother of the litter of puppies or kittens is considered one dog or cat. No more than two litters of puppies or kittens under 16 weeks of age may be in a foster home at any given point in time.

67.11(9) A person who has been found to have engaged in or participated in an act constituting animal abandonment, neglect, cruelty, or abuse shall not be authorized to operate a foster care home. In addition, if a person has had a license or permit issued under Iowa Code chapter 162 or under the United States Department of Agriculture's animal care program revoked or has surrendered that person's license in lieu of revocation, then that person shall not be authorized to operate a foster care home.

67.11(10) A foster oversight organization shall not place a sexually intact animal in a foster care home where there is a sexually intact animal of the opposite sex of the same species unless the foster oversight organization determines that the fostered animal is too young to breed. If the foster oversight organization determines that a sexually intact animal may be placed in a foster care home with another sexually intact animal of the opposite sex of the same species because the fostered animal is too young to breed, then the foster oversight organization shall monitor the physical development of the fostered animal to either remove the animal before it is capable of breeding or to neuter or spay the fostered animal.

67.11(11) The foster oversight organization shall retain a copy of all the following documents for a period of 24 months and shall make such documents available for inspection by the department during regular business hours:

a. Applications to operate a foster care home, including any written approvals, conditional approvals, or denials.

b. Inspections or other reports relating to the operation of a foster care home. Inspection forms must be kept on file for each foster home. Inspections of a foster care home must be conducted by the foster oversight organization at minimum yearly.

c. Any written complaints or notes written by staff of the foster oversight organization relating to an oral complaint against a foster care home.

d. Any documents relating to the investigation or other resolution of a complaint regarding a foster care home.

e. Any documents relating to the revocation or suspension of a foster care home's authorization.

f. A current list of animals in foster care homes.

67.11(12) The foster oversight organization shall maintain detailed records as to which animals have been placed in a foster care home, when each animal was placed in a foster care home, and the ultimate disposition of each animal.

67.11(13) All adoptions and euthanasias of animals placed in a foster care home shall be the responsibility of the foster oversight organization and shall not be performed by the foster care home unless an emergency euthanasia must be performed by a licensed veterinarian to prevent the needless suffering of the animal.

67.11(14) All deaths, injuries, or emergency euthanasias occurring within a foster care home shall be reported to the foster oversight organization within 24 hours of the event.

67.11(15) It is the primary responsibility of the foster oversight organization to provide for oversight and regulation of its foster care homes; however, the department may choose to inspect a foster care home if the department determines that it would be in the best interests of the animals being maintained in the foster care home to conduct the inspection or if the department deems an inspection desirable to determine whether a foster oversight organization is properly fulfilling its role of screening and oversight of foster care homes. If the department determines that either serious or chronic problems exist in a foster care home, the department may order the foster oversight organization to suspend or rescind the authorization of the foster care home. The foster oversight organization shall immediately obtain physical examinations of all animals previously placed in the foster care home.

67.11(16) If the department determines that a foster oversight organization is not providing adequate screening or oversight of its foster care homes, the department may suspend or rescind the foster oversight organization's authorization to use foster care homes.

67.11(17) If the department suspends or revokes the license of an animal shelter, pound or dealer that is also a foster oversight organization, then the authorization to operate of the foster oversight organization and that of the foster care homes operating under the foster oversight organization shall immediately cease.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.12(162) Public health.

67.12(1) Animal wardens aiding in the enforcement of the provisions of Iowa Code chapter 162 shall enlist veterinary aid in programming control measures to protect the public from zoonotic diseases which may be suspected to be on the premises of a licensee or registrant.

67.12(2) Animals, housing facilities, or premises may be placed under quarantine by order of the secretary of agriculture when it is deemed necessary to protect the public from zoonotic diseases.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.13(162) Access, seizure and impoundment.

67.13(1) *Access to facilities and records.* The premises, housing facilities and records required by Iowa Code chapter 162 and this chapter shall be open for inspection by authorized personnel of the department during normal business hours.

67.13(2) *Seizure and impoundment.*

a. Failure of any pound, animal shelter, pet shop, boarding kennel, commercial kennel, commercial breeder, public auction or dealer to adequately house, feed, water or care for the animals in the person's or facility's possession or custody may subject the animals to seizure and impoundment. Seizure and impoundment shall be at the discretion of the secretary of agriculture. Standards to guide discretion shall include, but not be limited to, the following:

(1) An assessment of the condition of the animals, including but not limited to direct visual examination. Such assessment may include procedures and testing necessary to accurately determine disease, nutritional, and health status.

(2) An assessment as to the likelihood that the condition of the animals will deteriorate if action is not taken.

(3) An assessment as to the degree of failure to provide for the animals. Primary consideration will be based on the general health of the animals and the adequacy with which the animals are being fed, watered and sheltered.

(4) An assessment as to the history, if any, of the facility's compliance, noncompliance, and willingness to take corrective action. Such an assessment will be based on past inspection reports completed by regulatory personnel from the appropriate licensing agency.

(5) Court determination, if any, as to the existence of cruelty, abuse or neglect under Iowa Code chapter 717B.

(6) The willingness of the facility to allow frequent monitoring and the ability of the department or local law enforcement officers to provide this service.

(7) A determination as to whether adequate impoundment facilities or resources exist and are available for use by the department for the seizure and impoundment of animals.

b. In proceeding under this subrule, the department may either:

(1) Petition the court in the county where the facility is located for an ex parte court order authorizing seizure and impoundment, either separately or as part of an action commenced pursuant to Iowa Code chapter 717B. The petition shall request an expedited hearing within seven days of the order for seizure and impoundment. The expedited hearing shall determine final disposition of the animals seized and impounded.

(2) Issue an administrative order authorizing seizure and impoundment. The order shall state the finding of facts on which issuance of the order was based. The order shall be personally served upon the owner or manager of the facility. If the owner or manager cannot be found after a reasonable effort to locate, the notice shall be posted conspicuously at the facility. The notice shall state the time and place of an administrative hearing to determine the appropriateness of the seizure and impoundment; and if such seizure and impoundment is upheld, then the hearing shall determine final disposition of the animals seized and impounded.

The administrative hearing shall be held within three days of the seizure unless a continuance is agreed upon by the department and the owner. A decision at the administrative hearing will not be stayed by the department for more than 48 hours pending appeal without a court order. However, the department may delay the disposition if the department determines the delay is desirable for the orderly disposition of the animals. Unless otherwise provided in this subrule, the department will follow adopted departmental rules on the conduct of the administrative hearing.

c. The release of animals for final disposition to the department will allow for the sale, adoption or euthanasia of the animals. Determination of the most appropriate option for final disposition of a specific animal shall reside with the department and be based on, but not limited to, the animal's physical health, the presence of any condition which would necessitate treatment of significant duration or expense, and the appropriateness of the animal as a pet. All due consideration shall be given to the sale or adoption of an animal as the preferable option of disposition.

d. Any moneys generated from the sale or adoption of animals shall be used to provide compensation for the cost of care of the animals while impounded or the cost of disposition. Any residual moneys shall be directed to the owner. If the moneys generated from the sale and adoption of the animals are insufficient to meet the costs incurred in caring for the animals, the difference may be recovered in an action against the owner of the animals.

e. The department may arrange for impoundment services, including final disposition, with any licensed facility able to adequately provide for the care and disposition of the animals. Animals for which an order is issued authorizing seizure and impoundment shall be individually identified and records maintained relating to their care and final disposition. The department, or its representatives, shall be allowed access during normal business hours to the records and impounded animals.

f. In lieu of seizure and impoundment, the secretary of agriculture may authorize a one-time dispersal of animals, including by sale, as a remedial option. The owner may petition the department in writing for full or partial dispersal. The petition shall address the terms and conditions for dispersal which are being requested. The department may require additional terms and conditions. The terms and conditions governing dispersal will be contingent upon department approval. Such approval shall be in writing.

g. Conditions of this subrule and subrule 67.13(1) and Iowa Code sections 162.13 and 162.14 shall likewise apply to all eligible licensees and registrants, whether or not they have been properly licensed by Iowa Code chapter 162.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.14(162) Loss of license or denial of license.

67.14(1) If the license of a licensee is revoked or is relinquished by the licensee while a revocation action is pending, the licensee shall not be eligible to reapply for a new license for at least three years from the date of the revocation or relinquishment. If a licensee has been found in court to have committed an act of animal cruelty or neglect, the licensee shall not be eligible for a new license for at least five years from the date of the revocation or relinquishment. If an applicant has been found in court to have committed an act of animal cruelty or neglect, the applicant shall not be eligible for a license for at least five years from the date of the conviction or guilty plea. The prohibition against relicensure or licensure in this subrule shall include any partnership, firm, corporation, or other legal entity in which the person has a substantial interest, financial or otherwise, and any person who has been or is an officer, agent or employee of the licensee if the person was responsible for or participated in the violation upon which the revocation or conviction was based. The department may waive the three-year bar to relicensure arising from a revocation or relinquishment of a license where a revocation action was pending. Such waiver shall be made on a case-by-case basis. Such waiver shall only be given if the department finds that the conditions which resulted in the revocation or revocation action have been addressed and there is little likelihood that they will be replicated.

67.14(2) If the license of a licensee is revoked or if the license is voluntarily relinquished by the licensee, the licensee shall file with the department a written plan detailing the numbers and types of animals in its facilities and how these animals are going to be legally disposed of to ensure that the animals are being humanely handled and to ensure that the remaining animals are being maintained properly. The licensee shall submit this plan to the department no later than ten calendar days from the date of revocation or relinquishment of the license.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.15(162) Applicability to commercial establishments with federal licenses. In addition to obtaining the permit from the department, any person who operates a commercial establishment under a current and valid federal license shall provide care ensuring adequate feed, water, and housing facilities and appropriate sanitary control, grooming practices and veterinary care. The department has the authority to inspect the premises and the required records.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

21—67.16(162) Acceptable forms of euthanasia. The euthanasia of all animals kept in facilities regulated under Iowa Code chapter 162 and these rules shall be performed in a manner deemed acceptable by and published in the American Veterinary Medical Association Guidelines for Euthanasia of Animals: 2020 Edition. A copy of this report is on file with the department.

[ARC 4789C, IAB 12/4/19, effective 1/8/20; ARC 5713C, IAB 6/16/21, effective 7/21/21]

21—67.17(162) Greyhound breeder or farm fee. A person who owns, keeps, breeds, or transports a greyhound dog for pari-mutuel wagering at a racetrack as provided in Iowa Code chapter 99D shall pay a fee of \$40 for the issuance or renewal of a state license.

[ARC 4789C, IAB 12/4/19, effective 1/8/20]

These rules are intended to implement Iowa Code chapter 162.

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¹ January 8, 2020, effective date of paragraph 67.8(4)“b” delayed until the adjournment of 2020 session of the General Assembly by the Administrative Rules Review Committee at its meeting held December 10, 2019.

UTILITIES DIVISION[199]

Former Commerce Commission[250] renamed Utilities Division[199]
under the “umbrella” of Commerce Department[181] by 1986 Iowa Acts, Senate File 2175, section 740.

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CHAPTER 9
RESTORATION OF AGRICULTURAL LANDS DURING AND AFTER PIPELINE
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199—9.1(479,479B) General information.

9.1(1) Authority and purpose. The rules in this chapter are adopted by the Iowa utilities board pursuant to the authority granted to the board in Iowa Code sections 479.29 and 479B.20 to establish standards for the restoration of agricultural lands during and after pipeline construction. These rules constitute the minimum standards for restoration of agricultural lands disturbed by pipeline construction. These rules do not apply to land located within city boundaries, unless the land is used for agricultural purposes, or to interstate natural gas pipelines.

When a project-specific land restoration plan is required pursuant to Iowa Code section 479.29(9) or 479B.20(9), following notice and comment, the board may impose additional or more stringent standards as necessary to address issues specific to the nature and location of the particular pipeline project. Where a project-specific land restoration plan is not required pursuant to Iowa Code section 479.29(9) or 479B.20(9), the rules in this chapter shall constitute the minimum land restoration standards for any pipeline construction.

9.1(2) Definitions. The following words and terms, when used in these rules, shall have the meanings indicated below:

“Affected person” means any person with a legal right or interest in the property, including, but not limited to, a landowner, a contract purchaser of record, a person possessing the property under a lease, a record lienholder, and a record encumbrancer of the property.

“Agricultural land” means any land devoted to agricultural use, including, but not limited to, land used for crop production, cleared land capable of being cultivated, hay land, pasture land, managed woodlands and woodlands of commercial value, truck gardens, farmsteads, commercial agricultural-related facilities, feedlots, rangeland, livestock confinement systems, land on which farm buildings are located, and land used to implement management practices and structures for the improvement or conservation of soil, water, air, and related plant and animal resources.

“Board” means the utilities board within the utilities division of the department of commerce.

“County inspector” means a professional engineer who is licensed under Iowa Code chapter 542B, who is familiar with agricultural and environmental inspection requirements, and who is designated by the county board of supervisors to be responsible for completing an on-site inspection for compliance with this chapter and Iowa Code chapters 479 and 479B.

“Drainage structures” or *“underground improvements”* means any permanent structure used for draining agricultural lands, including tile systems and buried terrace outlets.

“Hazardous liquid” means crude oil, refined petroleum products, liquefied petroleum gases, anhydrous ammonia, liquid fertilizers, liquefied carbon dioxide, alcohols, and coal slurries.

“Person” means individual, corporation, limited liability company, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity as defined in Iowa Code section 4.1(20).

“Pipeline” means any pipe, pipes, or pipelines used for the transportation or transmission of any solid, liquid, or gaseous substance, except water, or hazardous liquid, within or through Iowa.

“Pipeline company” means any person engaged in or organized for the purpose of owning, operating, or controlling pipelines.

“Pipeline construction” means activity associated with installation, relocation, replacement, removal, or operation or maintenance of a pipeline that disturbs agricultural land, but shall not include work performed during an emergency, tree clearing, or topsoil surveying completed on land under easement with written approval from the landowner. Emergency means a condition involving clear and immediate danger to life, health, or essential services, or a risk of a potentially significant loss of property. When the emergency condition ends, pipeline construction will be in accordance with these rules.

“*Proper notice to the county inspector*” means that the pipeline company and its contractors shall keep the county inspector continually informed of the work schedule and any changes to the schedule, and shall provide at least 24 hours’ written notice before commencing or continuing any construction activity which requires inspection by the county inspector, including, but not limited to, right-of-way staking, clearing, boring, topsoil removal and stockpiling, trenching, tile marking, tile screening, tile repairs, backfilling, decompaction, cleanup, restoration, or testing at any project location. The pipeline company may request that the county inspector designate a person to receive such notices. If proper notice is given, construction shall not be delayed due to a county inspector’s failure to be present on site.

“*Soil conservation practices*” means any land conservation practice recognized by federal or state soil conservation agencies, including, but not limited to, grasslands and grassed waterways, hay land planting, pasture, and tree plantings.

“*Soil conservation structures*” means any permanent structure recognized by federal or state soil conservation agencies, including, but not limited to, toe walls, drop inlets, grade control works, terraces, levees, and farm ponds.

“*Surface drains*” means any surface drainage system, such as shallow surface field drains, grassed waterways, open ditches, or any other conveyance of surface water.

“*Till*” means to loosen the soil in preparation for planting or seeding by plowing, chiseling, discing, or similar means. For the purposes of this chapter, agricultural land planted using no-till planting practices is also considered tilled.

“*Topsoil*” means the uppermost layer of the soil with the darkest color or the highest content of organic matter, generally referred to as the “A” horizon. In areas where the “A” horizon is determined by a certified professional soil scientist to be less than 12 inches, the topsoil depth shall include both the “A” and the “Bw” horizons as determined by the March 2017 United States Department of Agriculture Soil Survey Manual. Topsoil depth is to be determined under the supervision of a certified professional soil scientist.

“*Underground storage*” means storage of either natural gas or hazardous liquid in a subsurface stratum or formation of the earth.

“*Wet conditions*” means adverse soil conditions due to rain events, antecedent moisture, or ponded water, where the passage of construction equipment may cause rutting that mixes topsoil and subsoil, may prevent the effective removal or replacement of topsoil and subsoil, may prevent proper decompaction, or may damage underground tile lines.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.2(479,479B) Filing of land restoration plans. Pursuant to Iowa Code sections 479.29 and 479B.20, a land restoration plan is required for any pipeline construction that requires a permit from the board and for any proposed amendment to an existing permit that involves pipeline construction, relocation, or replacement. The land restoration plan shall be filed with the appropriate petition and be identified as Exhibit I. For pipelines that do not need a permit from the board and that are constructed across agricultural land, the pipeline company shall have on file with the board a general land restoration plan covering pipelines that do not need a permit from the board.

9.2(1) Content of plan. A land restoration plan shall include, but not be limited to, the following:

- a. A brief description of the purpose and nature of the pipeline construction project.
- b. A description of the sequence of events that will occur during pipeline construction.
- c. A description of how the pipeline company will comply with rules 199—9.4(479,479B) and 199—9.5(479,479B).
- d. The point of contact for landowner inquiries or claims as provided for in rule 199—9.5(479,479B).
- e. A unique identification number that follows a linearly sequential pattern on each parcel of land over which the pipeline will be constructed.

9.2(2) Plan variations. The board may by waiver allow variations from the requirements in this chapter if the pipeline company requesting a waiver is able to satisfy the standards set forth in rule

199—1.3(17A,474,476) and if the alternative methods proposed by the pipeline company would restore the land to a condition as good or better than provided for in this chapter.

9.2(3) *Mitigation plans and agreements.* Preparation of a separate land restoration plan may be waived by the board where a pipeline company enters into an agricultural impact mitigation plan or similar agreement with the appropriate agencies of the state of Iowa that satisfies the requirements of this chapter. If a mitigation plan or agreement is used to fully or partially meet the requirements of a land restoration plan, the statement or agreement shall be filed with the board and shall be considered to be, or to be part of, the land restoration plan for purposes of this chapter.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.3(479,479B) Procedure for review of plan.

9.3(1) *Timing.* The board will review the proposed land restoration plan, as established in rule 199—9.2(479,479B), at the same time it reviews the petition. Objections to the proposed plan shall be filed as part of the permit proceeding. The pipeline company shall modify the plan as required by the board.

9.3(2) *Distributing approved plan.* After the board has approved the plan as part of the board's review and approval of the petition, but prior to construction, the pipeline company shall provide copies of the final plan approved by the board to all landowners of property and persons in possession of the property under a lease that will be disturbed by the construction, the county board of supervisors in each county affected by the project, the county engineer of each affected county, and to the county inspector in each affected county.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.4(479,479B) Staking and clearing of agricultural land.

9.4(1) *Easement staking.* The pipeline company shall allow the county inspector and the landowner to be present during the staking of the easement. Written notice of the staking shall be provided to the landowner and the county inspector in the same manner as provided for in proper notice to the county inspector. Pipeline construction may not occur until seven days after the easement is staked unless the landowner waives the seven-day period after the easement staking has been completed. If proper notice is given, easement staking shall not be delayed due to a county inspector or landowner's failure to be present on site.

9.4(2) *Trees and brush.* If trees are to be removed from the easement, the pipeline company shall consult with the landowner to determine if there are trees of commercial or other value to the landowner.

a. If there are trees of commercial or other value to the landowner, the pipeline company shall allow the landowner the right to retain ownership of the trees with the disposition of the trees to be negotiated prior to commencement of land clearing, or if the landowner does not want to retain ownership of the trees, the pipeline company shall hire a forester with local expertise to appraise the commercial value of any timber to be cut for construction of the pipeline. The pipeline company shall compensate the landowner for the full appraised commercial value of any timber removed. The pipeline company shall remove all cleared trees and debris left on or adjacent to the easement.

b. If the trees to be cleared have been determined to have no commercial or other value to the landowner and there is no negotiated agreement between the pipeline company and the landowner for the disposition of the trees in advance of clearing of the easement, removal and disposal of the material shall be completed at the discretion of the pipeline company.

9.4(3) *Fencing.* The pipeline company may remove all field fences and gates, located within the pipeline company's easement, during clearing of the easement and may construct temporary fences and gates where necessary. Upon completion of the pipeline construction, the pipeline company shall replace any temporary field fences or gates with permanent field fences or gates. The pipeline company and landowner may negotiate separate agreements regarding field fences and gates. If livestock is present, the pipeline company shall construct any temporary or permanent fences and gates in a manner which will contain livestock.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.5(479,479B) Restoration of agricultural lands.**9.5(1) Topsoil survey.**

a. Prior to the removal of any topsoil, the pipeline company shall direct that a topsoil survey be performed under the supervision of a certified professional soil scientist across the full extent of the easement for any pipeline that requires a board permit. A minimum of three soil depths shall be physically measured in the field at each cross section as follows: (1) one on the left edge of the easement; (2) one at 15 feet of the centerline of the pipeline on the working side of the right-of-way; and (3) one on the right edge of the working easement. Cross sections shall be taken a minimum of every 500 linear feet for the full extent of the easement. Each parcel of land shall have a minimum of two cross sections.

b. The pipeline company shall provide the results of the topsoil survey to the county board of supervisors, county inspector, county engineer, and affected persons at least six weeks prior to commencing construction.

9.5(2) Topsoil separation and replacement.

a. *Removal.* Topsoil removal and replacement in accordance with this rule is required for any open excavation associated with pipeline construction unless otherwise provided in these rules. The actual depth of the topsoil, as determined by a topsoil survey, shall be stripped from the full extent of the easement. Topsoil shall also be removed and replaced in accordance with these rules at any location where land slope or contour is significantly altered to facilitate construction. Topsoil removal shall not occur during wet conditions.

b. *Soil storage.* The topsoil and subsoil shall be segregated, stockpiled, and preserved separately during subsequent construction operations. The stored topsoil and subsoil shall have sufficient separation to prevent mixing during the storage period. Topsoil shall not be used to construct field entrances or drives, or be otherwise removed from the property, without the written consent of the landowner. Topsoil shall not be stored or stockpiled at locations that will be used as a traveled way by construction equipment without the written consent of the landowner.

c. *Stockpile stabilization.* Topsoil stockpiles shall be stabilized with seeding and mulch within 14 calendar days of stockpiling. Between October 15 and March 15, soil tackifier shall be used in place of seeding and mulch.

d. *Topsoil removal not required.* Topsoil removal is not required where the pipeline is installed by plowing, jacking, boring, or other methods that do not require the opening of a trench. If provided for in a written agreement between the pipeline company and the landowner, topsoil removal is not required if the pipeline can be installed in a trench with a top width of 18 inches or less.

e. *Backfill.* The topsoil and subsoil shall be replaced in the reverse order in which they were excavated from the trench. The depth of the replaced topsoil shall conform as near as possible to the depth of topsoil that was removed. Where excavations are made for road, stream, drainage ditch, or other crossings, the original depth of topsoil shall be replaced as near as possible.

9.5(3) Pumping of water from open trenches.

a. In the event it becomes necessary to pump water from open trenches, the pipeline company shall pump the water in a manner that avoids damaging adjacent agricultural land. Damages from pumping water from trenches include, but are not limited to, inundation of crops and depositing of sediment in fields, pastures, and surface drains.

b. If water-related damages result from pumping water from trenches, the pipeline company shall either compensate the landowner for the damages or restore the land, pasture, surface drains, or similar land, to their preconstruction condition, at the landowner's discretion.

c. Written permission from the landowner is required before the pipeline company can pump water from trenches onto land outside of the pipeline company's easement.

d. All pumping of water shall comply with existing state drainage laws, local ordinances, and federal statutes.

9.5(4) Temporary and permanent repair of drain tile.

a. *Pipeline clearance from drain tile.* Where underground drain tile is encountered, the pipeline shall be installed in such a manner that the permanent tile repair can be installed with at least 12 inches of clearance from the pipeline.

b. Temporary repair. The following standards shall be used to determine if temporary repair of agricultural drainage tile lines encountered during pipeline construction is required.

(1) Any underground drain tile damaged, cut, or removed and found to be flowing or which subsequently begins to flow shall be temporarily repaired as soon as practicable, and the repair shall be maintained as necessary to allow for its proper function during construction of the pipeline. The temporary repairs shall be maintained in good condition until permanent repairs are made.

(2) Any underground drain tile damaged, cut, or removed and found to not be flowing shall have the upstream exposed tile line screened or otherwise protected to prevent the entry of foreign material and small animals into the tile system. The downstream tile line entrance shall be capped or filtered to prevent entry of mud or foreign material into the line if water level rises in the trench.

c. Marking. Any underground drain tile damaged, cut, or removed shall be marked by placing a highly visible flag in the trench spoil bank directly over or opposite such tile. This marker shall not be removed until the tile has been permanently repaired and the repairs have been approved and accepted by the county inspector. If proper notice is given, construction shall not be delayed due to an inspector's failure to be present on the site.

d. Permanent repairs. Tile disturbed or damaged by pipeline construction shall be repaired to its original or better condition. Permanent repairs shall be completed within 14 days after the pipeline is installed in the trench and prior to backfilling of the trench over the tile line. The county inspector shall inspect each permanent repair for compliance with this chapter. If proper notice is given, construction shall not be delayed due to a county inspector's failure to be present on site. Permanent repair and replacement of damaged drain tile shall be performed in accordance with the following requirements:

(1) All damaged, broken, or cracked tile shall be removed.

(2) Only unobstructed tile shall be used for replacement.

(3) The tile furnished for replacement purposes shall be of a quality, size, and flow capacity at least equal to that of the tile being replaced.

(4) Tile shall be replaced using a laser transit, or similar instrument or method, to ensure that the tile's proper gradient and alignment are restored, except where relocation or rerouting is required for angled crossings. Tile lines at a sharp angle to the trench shall be repaired in the manner shown on Drawing No. IUB PL-1 at the end of this chapter.

(5) The replaced tile shall be firmly supported to prevent loss of gradient or alignment due to soil settlement. The method used shall be comparable to that shown on Drawing No. IUB PL-1 at the end of this chapter.

e. Inspection. Prior to backfilling of the applicable trench area, each permanent tile repair shall be inspected for compliance by the county inspector. If proper notice is given, construction shall not be delayed due to an inspector's failure to be present on site prior to backfilling.

f. Backfilling. The backfill surrounding the permanently repaired drain tile shall be completed at the time of the repair and in a manner that ensures that any further backfilling will not damage or misalign the repaired section of the tile line. The county inspector shall inspect that backfill for compliance with this chapter. If proper notice is given, construction shall not be delayed due to an inspector's failure to be present on the site.

g. Subsurface drainage. Subsequent to pipeline construction and permanent repair, if it becomes apparent the tile line in the area disturbed by construction is not functioning correctly or that the land adjacent to the pipeline is not draining properly, which can reasonably be attributed to the pipeline construction, the pipeline company shall make further repairs or install additional tile as necessary to restore subsurface drainage.

9.5(5) Removal of rocks and debris from the easement.

a. Removal. The topsoil, when backfilled, and the easement area shall be free of all rock larger than three inches in average diameter not native to the topsoil prior to excavation. Where rocks over three inches in size are present, their size and frequency shall be similar to adjacent soil not disturbed by construction. The top 24 inches of the trench backfill shall not contain rocks in any greater concentration or size than exist in the adjacent natural soils. Consolidated rock removed by blasting or mechanical means shall not be placed in the backfill above the natural bedrock profile or above the frost line. In

addition, the pipeline company shall examine areas adjacent to the easement and along access roads and shall remove any large rocks or debris that may have rolled or blown from the right-of-way or fallen from vehicles.

b. Disposal. Rock that cannot remain in or be used as backfill shall be disposed of at locations and in a manner mutually satisfactory to the company and the landowner. Soil from which excess rock has been removed may be used for backfill. All debris attributable to the pipeline construction and related activities shall be removed and disposed of properly. For the purposes of this rule, debris shall include spilled oil, grease, fuel, or other petroleum or chemical products. Such products and any contaminated soil shall be removed for proper disposal or treated by appropriate in situ remediation.

9.5(6) *Restoration after soil compaction and rutting.*

a. Agricultural restoration. Agricultural land, including off right-of-way access roads traversed by heavy construction equipment that will be removed, shall be deep tilled to alleviate soil compaction upon completion of construction on the property. If the topsoil was removed from the area to be tilled, the tillage shall precede replacement of the topsoil. At least three passes with the deep tillage equipment shall be made. Tillage shall be at least 18 inches deep in land used for crop production and 12 inches deep on other lands and shall be performed under soil moisture conditions that result in a maximum standard penetration test (SPT) reading of 300 psi pursuant to ASTM D1586-11 performed by a qualified person. Decompaction shall not occur in wet conditions. Upon agreement, this tillage may be performed by the landowners or tenants using their own equipment.

b. Rutted land restoration. Rutted land shall be graded and tilled until restored as near as practical to its preconstruction condition. Rutting shall be remedied before any topsoil that was removed is replaced.

9.5(7) *Restoration of terraces, waterways, and other erosion control structures.* Existing soil conservation practices and structures damaged by the construction of a pipeline shall be restored to the elevation and grade existing prior to the time of pipeline construction. Any drain tiles or flow diversion devices impacted by pipeline construction shall be repaired or modified as needed. Soil used to repair embankments intended to retain water shall be well compacted. Disturbed vegetation shall be reestablished, including a cover crop when appropriate. Restoration of terraces shall be in accordance with Drawing No. IUB PL-2 at the end of this chapter. The county inspector shall inspect restoration of terraces, waterways, and other erosion control structures for compliance with this chapter. If proper notice is given, construction shall not be delayed due to an inspector's failure to be present on the site.

9.5(8) *Revegetation of untilled land.*

a. Crop production. Agricultural land not in row crop or small grain production at the time of construction, including hay ground and land in conservation or set-aside programs, shall be reseeded, including use of a cover crop when appropriate, following completion of deep tillage and replacement of the topsoil. The seed mix used shall restore the original or a comparable ground cover unless otherwise requested by the landowner. If the land is to be placed in crop production the following year, paragraph 9.5(9) "b" shall apply.

b. Delayed crop production. Agricultural land used for row crop or small grain production which will not be planted in that calendar year due to the pipeline construction shall be seeded with an appropriate cover crop following replacement of the topsoil and completion of deep tillage. However, cover crop seeding may be delayed if construction is completed too late in the year for a cover crop to become established and in such instances is not required if the landowner or tenant proposes to till the land the following year. The landowner may request ground cover where the construction is completed too late in the year for a cover crop to become established to prevent soil erosion.

c. Weed control. On any easement, including, but not limited to, construction easements and easements relating to valve sites, metering stations, and compression stations, the pipeline company shall provide for weed control in a manner that prevents the spread of weeds onto adjacent lands used for agricultural purposes. Spraying shall be done by a pesticide applicator that is appropriately licensed for spraying of pesticide in Iowa. If the pipeline company fails to control weeds within 45 days after

receiving written notice from the landowner, the pipeline company shall be responsible for reimbursing all reasonable costs of weed control incurred by owners of adjacent land.

9.5(9) *Future installation of drain tile or soil conservation practices and structures.*

a. Future drain tile. The pipeline company shall consult with affected persons regarding plans for future drain tile installation. Where an affected person provides the pipeline company with written plans prepared by a qualified tile technician for future drain tile improvements before an easement is secured, the pipeline shall be installed at a depth which will allow proper clearance between the pipeline and the proposed future tile installation.

b. Future practices and structures. The pipeline company shall consult with any affected person's plans for future use or installation of soil conservation practices or structures. Where an affected person provides the pipeline company with a design for such practice or structure prepared by a qualified technician before an easement is secured, the pipeline shall be installed at a depth that will allow for future installation of the planned soil conservation practice or structure and that will retain the integrity of the pipeline.

9.5(10) *Restoration of land slope and contour.* Upon completion of construction, the slope, contour, grade, and drainage pattern of the disturbed area shall be restored as near as possible to its preconstruction condition. However, the trench may be crowned to allow for anticipated settlement of the backfill. Excessive or insufficient settlement of the trench area, which visibly affects land contour or undesirably alters surface drainage, shall be remediated by the pipeline company by means such as regrading and, if necessary, import of appropriate fill material. Disturbed areas in which erosion causes formation of rills or channels, or areas of heavy sediment deposition, shall be regraded as needed. On steep slopes, methods such as sediment barriers, slope breakers, or mulching shall be used as necessary to control erosion until vegetation can be reestablished. The county inspector shall inspect restoration of land slope and contour for compliance with this chapter.

9.5(11) *Restoration of areas used for field entrances or temporary roads.* Upon completion of construction and land restoration, field entrances or temporary roads built as part of the construction project shall be removed and the land made suitable for return to its previous use. Areas affected shall be regraded as required by subrule 9.5(10) and deep tilled as required by subrule 9.5(6). If by agreement, or at landowner request, and subject to any necessary approval by local public road authorities, a field entrance or road is to be left in place, it shall be left in a graded and serviceable condition. The county inspector shall inspect restoration of areas used for field entrances or temporary roads for compliance with this chapter.

9.5(12) *Construction in wet conditions.* The county inspector, in consultation with the pipeline company and the landowner or person in possession of the land pursuant to a lease, if present, shall determine when construction should not proceed in a given area due to wet conditions. The county inspector shall have the sole authority to determine whether construction should be halted due to wet conditions. Construction in wet soil conditions shall not commence or continue at times when or locations where the passage of heavy construction equipment may cause rutting to the extent that the topsoil and subsoil are mixed or underground drainage structures may be damaged. To facilitate construction in wet soils, the pipeline company may elect to remove and stockpile the topsoil from the traveled way, install mats or padding, or use other methods acceptable to the county inspector. Topsoil removal, storage, and replacement shall comply with subrule 9.5(2).

9.5(13) *Access to land.* Nothing in this rule shall prohibit a landowner or person in possession of the land pursuant to a lease from having access to the property. A landowner or person in possession of the land pursuant to a lease shall not disrupt ongoing construction and shall not compromise the safety considerations of the construction. A landowner or person in possession of the land pursuant to a lease shall abide by any and all safety instructions established by the pipeline company during construction.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.6(479,479B) Designation of a pipeline company point of contact for landowner inquiries or claims.

9.6(1) For each pipeline construction project subject to this chapter, the pipeline company shall designate a point of contact for inquiries or claims from affected persons. The designation shall include the name of an individual to contact and a toll-free telephone number, an email address, and an address through which that person can be reached. The pipeline company shall also provide the name of and contact information for the county inspector. This information shall be provided to all affected persons prior to commencement of construction. Any change in the point of contact shall be promptly communicated in writing to affected persons. A designated point of contact shall remain available for all affected persons for at least one year following project completion and for affected persons with unresolved damage claims until such time as those claims are settled.

9.6(2) If requested by an affected person, any notice required to be given to the county inspector shall also be given to the affected person.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.7(479,479B) Separate agreements. This chapter does not preclude the application of provisions for protecting or restoring property that are different from those contained in this chapter, or in a land restoration plan, which are contained in easements or other agreements independently executed by the pipeline company and the landowner. The alternative provision shall not be inconsistent with state law or these rules. The agreement shall be in writing, and the pipeline company shall provide a copy to the county inspector and the board.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.8(479,479B) Notice of violation and halting construction.

9.8(1) Notice of violation. If the county inspector identifies a violation of the standards adopted in this chapter, Iowa Code section 479.29 or 479B.20, or a separate agreement between the pipeline company and the landowner, the county inspector shall give verbal notice, followed by written notice, to the pipeline company and the pipeline company's contractor and require the pipeline company to take corrective action.

9.8(2) Halting construction. A county inspector may temporarily halt construction at the location of the dispute if construction is not in compliance with the standards adopted in this chapter, the land restoration plan, or the terms of an independent agreement between the pipeline company and landowner regarding land restoration or line location until the county inspector consults with a supervisor of the pipeline company or contractor. If, after consultation with a supervisor of the pipeline company or contractor, agreement on corrective action to address the violation cannot be reached, the county inspector may submit a request to the county board of supervisors for resolution of the issue. Construction may not resume at the disputed location either (1) until the county inspector and supervisor of the pipeline company reach an agreement on a resolution or (2) where the board of supervisors has been contacted, until the board of supervisors has responded or after one business day after contact by the county inspector. If a resolution is not reached, construction may continue; however, the pipeline company will be responsible for any damages or for correcting any violation.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.9(479,479B) Enforcement. A pipeline company shall fully cooperate with county inspectors in the performance of their duties under Iowa Code sections 479.29 and 479B.20, including giving proper notice before staking, clearing, boring, topsoil removal and stockpiling, trenching, tile marking, silt screening, tile repair or backfilling, decompaction, cleanup, restoration, or testing of any easement. The pipeline company shall pay the reasonable costs for any work provided during the pipeline construction by the county inspector. If the pipeline company or its contractor does not comply with the requirements of Iowa Code section 479.29 or 479B.20, with the land restoration plan, or with an independent agreement on land restoration or line location, the county board of supervisors may petition the utilities board for an order requiring corrective action to be taken. The county board of supervisors may also file a complaint with the board seeking imposition of civil penalties.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

199—9.10(479,479B) Project completion. The county inspector for each county affected by the pipeline project shall recommend to the county board of supervisors that the pipeline project be considered complete upon completion of restoration of all affected agricultural lands and 70 percent growth is established in locations requiring seeding after receiving written notification by the pipeline company to the same effect. The county board of supervisors shall determine whether the project is completed.

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

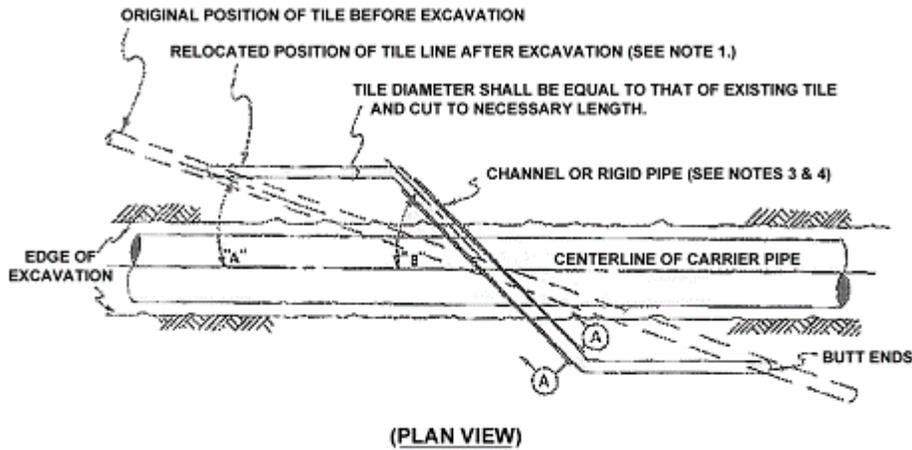
199—9.11(479,479B) Document submittal. Once a project is completed, project documents shall be submitted as follows:

9.11(1) Document turnover. The county inspector shall submit to the county board of supervisors and the pipeline company copies of inspection reports; tile reports and maps; punch lists; notice of violation documents; decompaction agreements; separate agreements, including those that excuse the pipeline company from certain construction responsibilities; and landowner agreements. The documents shall also be available for inspection by the board or an affected person upon request.

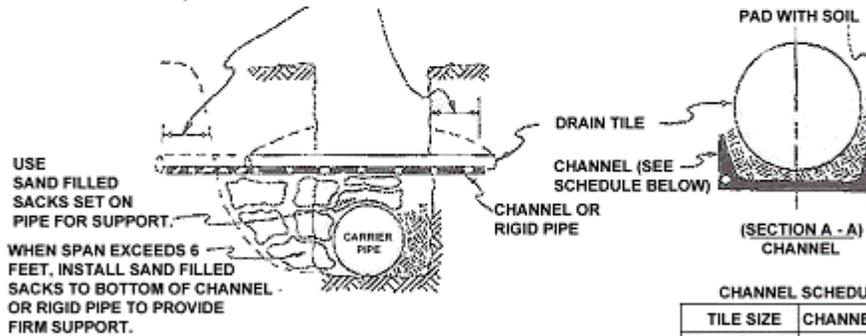
9.11(2) As-built drawings. The pipeline company shall provide the county inspector and affected landowners with copies of pipe alignment as-built drawings and underground drain tile as-built drawings, including the Global Positioning System location of drain tile.

Drawing No. IUB PL-1

RESTORATION OF DRAIN TILE



20" MINIMUM LENGTH OF CHANNEL OR RIGID PIPE SUPPORT ON SOLID SOIL, EACH SIDE OF EXCAVATION.

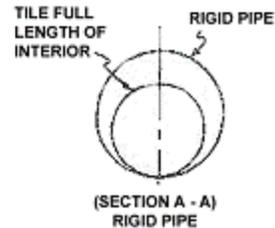


CHANNEL SCHEDULE

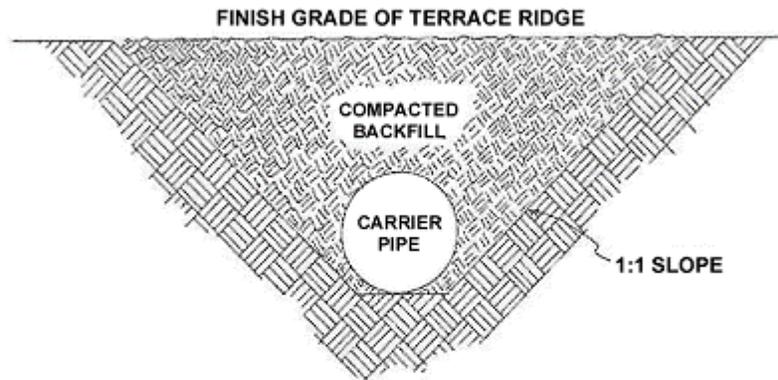
TILE SIZE	CHANNEL SIZE
3"	4" AT 5.4#
4" - 5"	5" AT 6.7#
6" - 9"	7" AT 9.8#
10" & LARGER	10" AT 15.3#

NOTES:

1. TILE SHALL BE RELOCATED AS SHOWN WHEN ANGLE "A" BETWEEN PIPELINE AND ORIGINAL TILE IS LESS THAN 20° UNLESS OTHERWISE AGREED TO BY LANDOWNER AND COMPANY.
2. ANGLE "B" SHALL BE 45° FOR USUAL WIDTHS OF TRENCH. FOR EXTRA WIDTHS, IT MAY BE GREATER.
3. DIAMETER OF RIGID PIPE SHALL BE OF ADEQUATE SIZE TO ALLOW FOR THE INSTALLATION OF THE TILE FOR THE FULL LENGTH OF THE RIGID PIPE.
4. OTHER METHODS OF SUPPORTING DRAIN TILE MAY BE USED IF THE ALTERNATE PROPOSED IS EQUIVALENT IN STRENGTH TO THE CHANNEL SECTIONS SHOWN AND IF APPROVED BY THE LANDOWNER.



Drawing No. IUB PL-2

RESTORATION OF TERRACE**NOTE:**

COMPACTION OF BACKFILL TO BE EQUAL TO THAT OF THE UNDISTURBED ADJACENT SOIL.

IUB PL-2

[ARC 5685C, IAB 6/16/21, effective 7/21/21]

These rules are intended to implement Iowa Code sections 479.29 and 479B.20.

[Filed 1/4/80, Notice 10/17/79—published 1/23/80, effective 2/27/80]

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[Filed emergency 9/18/86—published 10/8/86, effective 9/18/86]

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[Filed ARC 5685C (Notice ARC 5266C, IAB 11/4/20), IAB 6/16/21, effective 7/21/21]

ECONOMIC DEVELOPMENT AUTHORITY[261]

[Created by 1986 Iowa Acts, chapter 1245]

[Prior to 1/14/87, see Iowa Development Commission[520] and Planning and Programming[630]]

[Prior to 9/7/11, see Economic Development, Iowa Department of[261];
renamed Economic Development Authority by 2011 Iowa Acts, House File 590]

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CHAPTER 197
PETITION FOR RULE MAKING

[Prior to 7/19/95, see 261—Ch 2]
[Prior to 9/6/00, see 261—Ch 102]
[Prior to 7/4/07, see 261—Ch 171]

261—197.1(17A) Petition for rule making. Any person or state agency may file a petition for rule making with the authority at the Director’s Office, Iowa Economic Development Authority, 1963 Bell Avenue, Suite 200, Des Moines, Iowa 50315, Attn: Legal Counsel. Petitions for rule making may be delivered, mailed, or sent by email or other electronic means reasonably calculated to reach the intended recipient. A petition is deemed filed when it is received by the authority. The authority must provide the petitioner with a file-stamped copy of the petition if the petitioner provides the authority an extra copy for this purpose. The petition must be typewritten, or legibly handwritten in ink, and must substantially conform to the following form:

BEFORE THE IOWA ECONOMIC DEVELOPMENT AUTHORITY
Petition by (Name of Petitioner) for
the (adoption, amendment, or repeal)
of rules relating to (state subject matter). } PETITION FOR
RULE MAKING

The petition must provide the following information:

- 1. A statement of the specific rule-making action sought by the petitioner including the text or a summary of the contents of the proposed rule or amendment to a rule and, if it is a petition to amend or repeal a rule, a citation and the relevant language to the particular portion or portions of the rule proposed to be amended or repealed.
2. A citation to any law deemed relevant to the authority to take the action urged or to the desirability of that action.
3. A brief summary of petitioner’s arguments in support of the action urged in the petition.
4. A brief summary of any data supporting the action urged in the petition.
5. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the proposed action which is the subject of the petition.
6. Any request by petitioner for a meeting provided for by subrule 197.4(1).

197.1(1) The petition must be dated and signed by the petitioner or the petitioner’s representative. It must also include the name, mailing address, and telephone number of the petitioner and petitioner’s representative, and a statement indicating the person to whom communications concerning the petition should be directed.

197.1(2) The authority may deny a petition because it does not substantially conform to the required form.
[ARC 5691C, IAB 6/16/21, effective 7/21/21]

261—197.2(17A) Briefs. The petitioner may attach a brief to the petition in support of the action urged in the petition. The authority may request a brief from the petitioner or from any other person concerning the substance of the petition.
[ARC 5691C, IAB 6/16/21, effective 7/21/21]

261—197.3(17A) Inquiries. Inquiries concerning the status of a petition for rule making may be made to the address indicated in rule 261—197.1(17A).
[ARC 5691C, IAB 6/16/21, effective 7/21/21]

261—197.4(17A) Authority consideration.

197.4(1) Meeting. Upon request by the petitioner in the petition, the authority shall schedule a brief and informal meeting between the petitioner and authority staff to discuss the petition. The authority may request the petitioner to submit additional information or argument concerning the petition. The authority may also solicit comments from any person on the substance of the petition. Also, comments on the substance of the petition may be submitted to the authority by any person.

197.4(2) *Action on petition.* Within 60 days after the filing of the petition, or within any longer period agreed to by the petitioner, the authority shall, in writing, deny the petition, and notify petitioner of its action and the specific grounds for the denial, or grant the petition and notify petitioner that it has instituted rule-making proceedings on the subject of the petition. Petitioner shall be deemed notified of the denial or grant of the petition on the date when the authority mails or delivers the required notification to petitioner. The authority shall submit the petition and the disposition of the petition to the administrative rules review committee.

197.4(3) *Denial of petition for nonconformance with form.* Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for rejection of the petition.

[ARC 5691C, IAB 6/16/21, effective 7/21/21]

These rules are intended to implement Iowa Code section 17A.7.

[Filed emergency 12/19/86—published 1/14/87, effective 12/19/86]

[Filed 6/26/95, Notice 5/10/95—published 7/19/95, effective 8/23/95]

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[Filed emergency 6/15/07—published 7/4/07, effective 6/15/07]

[Filed 8/22/07, Notice 7/4/07—published 9/26/07, effective 10/31/07]

[Filed ARC 5691C (Notice ARC 5536C, IAB 3/24/21), IAB 6/16/21, effective 7/21/21]

CHAPTER 199
UNIFORM WAIVER RULES

[Prior to 9/6/00, see 261—Ch 104]

[Prior to 7/4/07, see 261—Ch 173]

261—199.1(17A,15) Applicability. This chapter outlines a uniform process for the granting of waivers from rules adopted by the authority. The intent of this chapter is to allow persons to seek exceptions to the application of rules issued by the authority.

199.1(1) Definitions.

“*Authority*” means the economic development authority created in Iowa Code section 15.105.

“*Board*” means the members of the economic development authority board appointed by the governor and in whom the powers of the authority are vested pursuant to Iowa Code section 15.105.

“*Director*” means the director of the authority or the director’s designee.

“*Director/board*” means either the director or the board depending on which one has decision-making authority pursuant to rule 261—199.2(17A,15).

“*Person*” means an individual, corporation, limited liability company, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any legal entity.

“*Waiver*” means an agency action which suspends in whole or in part the requirements or provisions of a rule as applied to an identified person on the basis of the particular circumstances of that person.

199.1(2) Authority.

a. A waiver from rules adopted by the authority may be granted in accordance with this chapter if (1) the authority has exclusive rule-making authority to promulgate the rule from which waiver is requested or has final decision-making authority over a contested case in which a waiver is requested; and (2) no statute or rule otherwise controls the grant of a waiver from the rule from which waiver is requested.

b. No waiver may be granted from a requirement which is imposed by statute. Any waiver must be consistent with statute.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.2(17A,15) Director/board discretion. The decision on whether the circumstances justify the granting of a waiver shall be made at the discretion of the director upon consideration of all relevant factors. The director may refer a petition for waiver to the board for decision. In the case of petition referred to the board by the director, the board shall make the decision on whether the circumstances justify the granting of a waiver, upon consideration of all relevant factors.

199.2(1) Criteria for waiver. The director/board may, in response to a completed petition, grant a waiver from a rule, in whole or in part, as applied to the circumstances of a specified situation if the director/board finds each of the following:

- a.* Application of the rule to the person at issue would result in undue hardship to that person; and
- b.* Waiver on the basis of the particular circumstances relative to that specified person would be consistent with the public interest; and
- c.* Waiver in the specific case would not prejudice the substantial legal rights of any person; and
- d.* Where applicable, substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.

In determining whether waiver should be granted, the director/board shall consider whether the underlying public interest policies and legislative intent of the rules are substantially equivalent to full compliance with the rule. When the rule from which a waiver is sought establishes administrative deadlines, the director/board shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all licensees, grantees and constituents.

199.2(2) Special waiver rules not precluded. These uniform waiver rules shall not preclude the director/board from granting waivers in other contexts or on the basis of other standards if a statute or other rule authorizes the director/board to do so, and the director/board deems it appropriate to do so.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.3(17A,15) Requester's responsibilities in filing a waiver petition.

199.3(1) *Petition.* All petitions for waiver must be submitted in writing to the Iowa Economic Development Authority, Office of the Director, 1963 Bell Avenue, Suite 200, Des Moines, Iowa 50315, Attention: Legal Counsel. Petitions for waiver may be delivered, mailed, or sent by email or other electronic means reasonably calculated to reach the intended recipient. If the petition relates to a pending contested case, a copy of the petition shall also be filed in the contested case proceeding.

199.3(2) *Content of petition.* A petition for waiver shall include the following information where applicable and known to the requester (for an example of a petition for waiver, see Exhibit A at the end of this chapter):

- a. A description and citation of the specific rule from which a waiver is requested.
- b. The specific waiver requested, including the precise scope and operative period that the waiver will extend.
- c. The relevant facts that the petitioner believes would justify a waiver.
- d. A signed statement from the petitioner attesting to the accuracy of the facts provided in the petition, and a statement of reasons that the petitioner believes will justify a waiver.
- e. A history of any prior contacts between the authority and the petitioner relating to the regulated activity, license, grant, loan or other financial assistance affected by the proposed waiver, including a description of each affected license, grant, loan or other financial assistance held by the requester, any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, grant or loan within the last five years.
- f. Any information known to the requester regarding the authority's treatment of similar cases.
- g. The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question, or which might be affected by the grant of a waiver.
- h. The name, address, and telephone number of any person or entity who would be adversely affected by the grant of a petition.
- i. The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver.
- j. Signed releases of information authorizing persons with knowledge regarding the request to furnish the authority with information relevant to the waiver.

199.3(3) *Burden of persuasion.* When a petition is filed for a waiver from a rule, the burden of persuasion shall be on the petitioner to demonstrate by clear and convincing evidence that the director/board should exercise its discretion to grant the petitioner a waiver.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.4(17A,15) Notice. The authority shall acknowledge a petition upon receipt. The authority shall ensure that notice of the pendency of the petition and a concise summary of its contents have been provided to all persons to whom notice is required by any provision of law, within 30 days of the receipt of the petition. In addition, the authority may give notice to other persons. To accomplish this notice provision, the authority may require the petitioner to serve the notice on all persons to whom notice is required by any provision of law or who may be impacted by the requested waiver, and provide a written statement to the authority attesting that notice has been provided.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.5(17A,15) Authority responsibilities regarding petition for waiver.

199.5(1) *Additional information.* Prior to issuing an order granting or denying a waiver, the director/board may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the director/board may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the director/board, the director's/board's designee, a committee of the board, or a quorum of the board.

199.5(2) *Hearing procedures.* The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply in three situations: (a) to any petition for a waiver of rule filed within a contested case; (b) when the director/board so provides by rule or order; or (c) when a statute so requires.

199.5(3) Ruling. An order granting or denying a waiver shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and operative period of the waiver if one is issued.

199.5(4) Conditions. The director/board may condition the grant of the waiver on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means.

199.5(5) Time for ruling. The director/board shall grant or deny a petition for a waiver as soon as practicable, but in any event, shall do so within 120 days of its receipt, unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the director/board shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

199.5(6) When deemed denied. Failure of the director/board to grant or deny a petition within the required time period shall be deemed a denial of that petition by the director/board.

199.5(7) Service of order. Within seven days of its issuance, any order issued under this chapter shall be transmitted to the petitioner or the person to whom the order pertains, and to any other person entitled to such notice by any provision of law.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.6(17A,15) Submission of waiver information. Within 60 days of granting or denying a waiver, the authority shall make a submission on the Internet site established pursuant to Iowa Code section 17A.9A for the submission of waiver information. The submission shall identify the rule(s) for which a waiver has been granted or denied, the number of times a waiver was granted or denied for each rule, a citation to the statutory provisions implemented by these rules, and a general summary of the reasons justifying the authority's actions on waiver requests. If practicable, the report shall detail the extent to which granting a waiver has established a precedent for additional waivers and the extent to which the granting of a waiver has affected the general applicability of the rule itself.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.7(17A,15) Voiding or cancellation. A waiver is void if the material facts upon which the request is based are not true or if material facts have been withheld. The director/board may at any time cancel a waiver upon appropriate notice if the director/board finds that the facts as stated in the request are not true, material facts have been withheld, the alternative means of compliance provided in the waiver have failed to achieve the objectives of the statute, or the requester has failed to comply with the conditions of the order.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.8(17A,15) Violations. Violation of conditions in the waiver approval is the equivalent of violation of the particular rule for which the waiver is granted and is subject to the same remedies or penalties.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.9(17A,15) Defense. After the director/board issues an order granting a waiver, the order is a defense within its terms and the specific facts indicated therein for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

261—199.10(17A,15) Appeals. Granting or denying a request for waiver is final agency action under Iowa Code chapter 17A. An appeal to district court shall be taken within 30 days of the issuance of the ruling in response to the request unless a contrary time is provided by rule or statute.

Exhibit A

Sample Petition (Request) for Waiver

BEFORE THE IOWA ECONOMIC DEVELOPMENT AUTHORITY

Petition by (insert name of petitioner) for the waiver of (insert rule citation) relating to (insert the subject matter).



PETITION FOR WAIVER

Requests for waiver from an authority rule shall include the following information in the petition for waiver where applicable and known:

- a. Provide the petitioner’s (person asking for a waiver) name, address, and telephone number.
b. Describe and cite the specific rule from which a waiver is requested.
c. Describe the specific waiver requested; include the exact scope and time period that the waiver will extend.
d. Explain the important facts that the petitioner believes justify a waiver. Include in your answer why (1) applying the rule will result in undue hardship or injustice to the petitioner; and (2) granting a waiver to the petitioner is consistent with the public interest; and (3) granting the waiver will not prejudice the substantial legal rights of any person; and (4) where applicable, how substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.
e. Provide history of prior contacts between the authority and petitioner relating to the regulated activity, license, grant, loan or other financial assistance that would be affected by the waiver; include a description of each affected license, grant, loan or other financial assistance held by the petitioner, any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, grant or loan within the last five years.
f. Provide information known to the petitioner regarding the authority’s treatment of similar cases.
g. Provide the name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question, or which might be affected by the grant of a waiver.
h. Provide the name, address, and telephone number of any person or entity who would be adversely affected or disadvantaged by the grant of the waiver.
i. Provide the name, address, and telephone number of any person with knowledge of the relevant or important facts relating to the requested waiver.
j. Provide signed releases of information authorizing persons with knowledge regarding the request to furnish the authority with information relevant to the waiver.

I hereby attest to the accuracy and truthfulness of the above information.

Petitioner’s signature

Date

Petitioner should note the following when requesting or petitioning for a waiver:

- 1. The petitioner has the burden of proving, by clear and convincing evidence, the following to the director/board: (a) application of the rule to the petitioner would result in undue hardship or injustice to the petitioner; and (b) waiver on the basis of the particular circumstances relative to the petitioner would be consistent with the public interest; and (c) waiver in the specific case would not prejudice the substantial legal rights of any person; and (d) where applicable, how substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.
2. The authority may request additional information from or request an informal meeting with the petitioner prior to issuing a ruling granting or denying a request for waiver.

3. All petitions for waiver must be submitted in writing to the Iowa Economic Development Authority, Office of the Director, 1963 Bell Avenue, Suite 200, Des Moines, Iowa 50315, Attention: Legal Counsel. If the petition relates to a pending contested case, a copy of the petition shall also be filed in the contested case proceeding.

[ARC 5692C, IAB 6/16/21, effective 7/21/21]

These rules are intended to implement Iowa Code section 17A.9A and chapter 15.

[Filed 6/23/00, Notice 1/12/00—published 7/12/00, effective 8/16/00]

[Filed without Notice 8/18/00—published 9/6/00, effective 10/11/00]

[Filed emergency 6/15/07—published 7/4/07, effective 6/15/07]

[Filed 8/22/07, Notice 7/4/07—published 9/26/07, effective 10/31/07]

[Filed ARC 5692C (Notice ARC 5438C, IAB 2/24/21), IAB 6/16/21, effective 7/21/21]

CHAPTER 220
RURAL HOUSING NEEDS ASSESSMENT GRANT PROGRAM

261—220.1(88GA,SF608) Purpose. Pursuant to 2019 Iowa Acts, Senate File 608, the authority is directed to establish a rural housing needs assessment grant program to support the interpretation and implementation of hard data and housing-related information specific to the communities applying for financial assistance under this program. This grant program is intended to support the use of publicly available information and support community efforts to interpret hard data with supplemental information and to help communities implement changes to development codes, local ordinances, and housing incentives according to the community's needs.

[ARC 5092C, IAB 7/15/20, effective 8/19/20]

261—220.2(88GA,SF608) Definitions. For purposes of this chapter, unless the context otherwise requires:

“*Agreement*” means a contract for financial assistance under the program describing the terms on which financial assistance is to be provided.

“*Applicant*” means an Iowa community applying for financial assistance under the program.

“*Authority*” means the economic development authority created in Iowa Code section 15.105.

“*Community*” means a county, an incorporated city, or a community designee.

“*Community designee*” means a legal entity established or designated by a county or incorporated city in an agreement pursuant to Iowa Code chapter 28E for the purposes of evaluating housing needs.

“*Director*” means the director of the authority.

“*Financial assistance*” means a grant made by the authority to an applicant approved for funding under the program.

“*Program*” means the procedures, agreement, terms, and assistance established and provided pursuant to this chapter.

[ARC 5092C, IAB 7/15/20, effective 8/19/20; ARC 5693C, IAB 6/16/21, effective 7/21/21]

261—220.3(88GA,SF608) Program description.

220.3(1) Amount, form, and timing of assistance. This program provides financial assistance to applicants to support the interpretation and implementation of hard data and housing-related information specific to the communities applying for a grant under this program. The amount of assistance awarded will be determined by the authority and will be based on the total amount of funds available to the authority for the program and the costs specified in the application. Each award shall not be less than \$1,000.

220.3(2) Application.

a. Forms. All applications and other filings related to the program shall be on such forms and in accordance with such instructions as may be established by the authority. Information about the program, the application, and application instructions may be obtained by contacting the authority or by visiting the authority's website: Iowa Economic Development Authority, Community Development Division, 1963 Bell Avenue, Suite 200, Des Moines, Iowa 50315, (515)348-6200, iowaeda.com.

b. Application period. Each fiscal year during which funding is available, applications for financial assistance will only be accepted during the established application period, or periods, as identified by the authority on its website.

c. Complete application required. An application shall not be considered submitted for review until the application is completed and all required supporting documentation and information are provided to the authority.

220.3(3) Approval of assistance. Authority staff will review applications for financial assistance under the program, and a grant committee will score and recommend applications to the director in accordance with subrule 220.4(2). A project that does not receive funding may reapply.

220.3(4) Agreement required. The authority shall enter into an agreement with each applicant for the receipt of a grant under this chapter. The agreement must state the terms on which financial assistance

is to be provided. The authority may negotiate the terms of the agreement. The applicant shall execute the agreement before funds are disbursed under the program.

220.3(5) *Form of financial assistance.* The authority will provide financial assistance in the form of a grant to the applicant. The amount of the grant and any other terms shall be included in the agreement required pursuant to this chapter.

220.3(6) *Use of funds.*

a. An applicant shall use funds only for reimbursement of the costs directly related to the project. The authority may require documentation or other information establishing the actual costs incurred for a project. Failure to use the funds for reimbursement of the costs directly related to a project shall be grounds for default under the agreement required pursuant to this chapter.

b. For purposes of this subrule, “costs directly related” does not include any expenses specified as ineligible in the agreement required pursuant to this chapter.

[ARC 5092C, IAB 7/15/20, effective 8/19/20; ARC 5693C, IAB 6/16/21, effective 7/21/21]

261—220.4(88GA,SF608) Program eligibility, application scoring, and funding decisions.

220.4(1) *Program eligibility.* An applicant must meet the following eligibility criteria to qualify for financial assistance under this program:

a. The applicant must be an Iowa community as defined in rule 261—220.2(88GA,SF608).

b. An applicant that is an incorporated city must have a population of 20,000 or fewer and shall not be contiguous to a city with a population of 40,000 or greater. An applicant that is a county shall be one of the 88 least populous counties in the state. An applicant that is a community designee shall have entered an agreement pursuant to Iowa Code chapter 28E with an incorporated city or county meeting the population criteria in this paragraph.

c. An eligible applicant will be allowed to submit only one application per application period.

d. The applicant must demonstrate the capacity for administering a grant.

e. The applicant must demonstrate the feasibility of the project’s proposed scope and timeline with the funds requested.

f. The applicant must identify and describe other sources of funding for the proposed assessment and related activities.

g. The applicant must identify any partner organizations that will be utilized in interpreting and implementing the data collected through the assessment.

h. The applicant must provide a cash match of at least 50 cents for every dollar awarded as a grant under this program.

220.4(2) *Application scoring criteria.* All completed applications will be reviewed and scored. Each application will be scored using criteria set forth by the authority.

220.4(3) *Funding decisions.* Funding decisions will be made using the following process:

a. Staff review. Each application will be reviewed by staff for eligibility and completeness. Complete applications meeting all eligibility requirements will be sent to a grant committee.

b. Grant committee review and recommendation. Following staff review, a grant committee will review and score applications using the criteria set forth by the authority pursuant to subrule 220.4(2) and will make funding recommendations. The committee may utilize an outside technical panel if the committee determines additional expertise is necessary to review and score the application. The application and score will be referred to the director with a recommendation as to whether to fund the project and, if funding is recommended, a recommendation as to the amount of the grant.

c. Director’s decision. The director will make the final funding decision on each application, taking into consideration the amount of available funding and the grant committee’s recommendation. The director may approve, deny, or defer funding for any application.

d. Notification. Each applicant will be notified in writing of the funding decision within 15 days of the director’s decision.

[ARC 5092C, IAB 7/15/20, effective 8/19/20; ARC 5693C, IAB 6/16/21, effective 7/21/21]

261—220.5(88GA,SF608) Agreement required.

220.5(1) Each applicant that is approved for financial assistance under the program shall enter into an agreement with the authority for the provision of such financial assistance. The agreement will establish the terms on which the financial assistance is to be provided and may include any other terms reasonably necessary for the efficient administration of the program.

220.5(2) The authority and the applicant may amend the agreement at any time upon the mutual agreement of both the authority and the applicant.

220.5(3) The agreement may require an applicant that has been approved for financial assistance under the program to submit information reasonably required by the authority to make reports to the authority's board, the governor's office, or the general assembly.

[ARC 5092C, IAB 7/15/20, effective 8/19/20]

These rules are intended to implement 2019 Iowa Acts, Senate File 608.

[Filed ARC 5092C (Notice ARC 4774C, IAB 11/20/19), IAB 7/15/20, effective 8/19/20]

[Filed ARC 5693C (Notice ARC 5535C, IAB 3/24/21), IAB 6/16/21, effective 7/21/21]

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CHAPTER 410
BOARD STRUCTURE AND PROCEDURES
Rescinded **ARC 1573C**, IAB 8/20/14, effective 9/24/14

CHAPTER 411
IOWA BROADBAND DEPLOYMENT PROGRAM
Rescinded **ARC 5691C**, IAB 6/16/21, effective 7/21/21

CHAPTER 412
FAIR INFORMATION PRACTICES, WAIVER AND VARIANCE,
AND PETITION FOR RULE MAKING
Rescinded **ARC 5691C**, IAB 6/16/21, effective 7/21/21

CHAPTER 12
LOW-INCOME HOUSING TAX CREDITS

265—12.1(16) Qualified allocation plans.

12.1(1) Four percent qualified allocation plan. The qualified allocation plan titled Iowa Finance Authority Low-Income Housing Tax Credit Program 2020-21 4% Qualified Allocation Plan (“4% QAP”) dated November 6, 2019, shall be the qualified allocation plan for the allocation of 4 percent low-income housing tax credits consistent with IRC Section 42 and the applicable Treasury regulations and Iowa Code section 16.35. The 4% QAP is incorporated by reference pursuant to Iowa Code section 17A.6 and 265—subrules 17.4(2) and 17.12(2). The 4% QAP does not include any amendments or editions created subsequent to November 6, 2019.

12.1(2) Nine percent qualified allocation plan. The qualified allocation plan titled Iowa Finance Authority Low-Income Housing Tax Credit Program 2020-21 9% Qualified Allocation Plan (“9% QAP”) shall be the qualified allocation plan for the allocation of 9 percent low-income housing tax credits awarded in 2020, consistent with IRC Section 42 and the applicable Treasury regulations and Iowa Code section 16.35. The qualified allocation plan titled Iowa Finance Authority Low-Income Housing Tax Credit Program 2020-21 First Amended 9% Qualified Allocation Plan (“first amended 9% QAP”) shall be the qualified allocation plan for the allocation of 9 percent low-income housing tax credits awarded in 2021, consistent with IRC Section 42 and the applicable Treasury regulations and Iowa Code section 16.35. The 9% QAP and the first amended 9% QAP are incorporated by reference pursuant to Iowa Code section 17A.6 and 265—subrules 17.4(2) and 17.12(2). The 9% QAP does not include any amendments or editions created subsequent to November 6, 2019. The first amended 9% QAP does not include any amendments or editions created subsequent to February 3, 2021.

[ARC 8266B, IAB 11/4/09, effective 12/9/09; ARC 8947B, IAB 7/28/10, effective 7/6/10; ARC 9279B, IAB 12/15/10, effective 1/19/11; ARC 9950B, IAB 12/28/11, effective 2/1/12; ARC 0427C, IAB 10/31/12, effective 12/5/12; ARC 1139C, IAB 10/30/13, effective 12/4/13; ARC 1700C, IAB 10/29/14, effective 12/3/14; ARC 2225C, IAB 10/28/15, effective 12/2/15; ARC 2723C, IAB 9/28/16, effective 11/2/16; ARC 3338C, IAB 9/27/17, effective 11/1/17; ARC 4037C, IAB 9/26/18, effective 10/31/18; ARC 4794C, IAB 12/4/19, effective 1/8/20; ARC 5717C, IAB 6/16/21, effective 5/28/21]

265—12.2(16) Location of copies of the plans.

12.2(1) 4% QAP. The 4% QAP can be reviewed and copied in its entirety on the authority’s website at www.iowafinanceauthority.gov. Copies of the 4% QAP, application, and all related attachments and exhibits shall be deposited with the administrative rules coordinator and at the state law library and shall be available on the authority’s website. The 4% QAP incorporates by reference IRC Section 42 and the regulations in effect as of November 6, 2019. Additionally, the 4% QAP incorporates by reference Iowa Code section 16.35. These documents are available from the state law library, and information about these statutes, regulations and rules is on the authority’s website.

12.2(2) 9% QAP. The 9% QAP and the first amended 9% QAP can be reviewed and copied in their entirety on the authority’s website at www.iowafinance.com. Copies of the 9% QAP and the first amended 9% QAP, the application, and all related attachments and exhibits shall be deposited with the administrative rules coordinator and at the state law library and shall be available on the authority’s website. The 9% QAP incorporates by reference IRC Section 42 and the regulations in effect as of November 6, 2019. The first amended 9% QAP incorporates by reference IRC Section 42 and the regulations in effect as of February 3, 2021. Additionally, both the 9% QAP and the first amended 9% QAP incorporate by reference Iowa Code section 16.35. These documents are available from the state law library, and information about these statutes, regulations and rules is on the authority’s website. [ARC 8266B, IAB 11/4/09, effective 12/9/09; ARC 8947B, IAB 7/28/10, effective 7/6/10; ARC 9279B, IAB 12/15/10, effective 1/19/11; ARC 9950B, IAB 12/28/11, effective 2/1/12; ARC 0427C, IAB 10/31/12, effective 12/5/12; ARC 1139C, IAB 10/30/13, effective 12/4/13; ARC 1700C, IAB 10/29/14, effective 12/3/14; ARC 2225C, IAB 10/28/15, effective 12/2/15; ARC 2723C, IAB 9/28/16, effective 11/2/16; ARC 3338C, IAB 9/27/17, effective 11/1/17; ARC 4037C, IAB 9/26/18, effective 10/31/18; ARC 4794C, IAB 12/4/19, effective 1/8/20; ARC 5717C, IAB 6/16/21, effective 5/28/21]

265—12.3(16) Compliance manual. Rescinded ARC 1700C, IAB 10/29/14, effective 12/3/14.

265—12.4(16) Location of copies of the manual. Rescinded **ARC 1700C**, IAB 10/29/14, effective 12/3/14.

These rules are intended to implement Iowa Code section 16.35.

[Filed 6/23/88, Notice 12/30/87—published 7/13/88, effective 8/17/88]

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[Filed emergency 10/14/08—published 11/5/08, effective 10/14/08]

[Filed 12/10/08, Notice 11/5/08—published 12/31/08, effective 2/4/09]

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[Filed ARC 8723B (Notice ARC 8508B, IAB 2/10/10), IAB 5/5/10, effective 6/9/10]

[Filed Emergency ARC 8947B, IAB 7/28/10, effective 7/6/10]

[Filed ARC 9279B (Notice ARC 9160B, IAB 10/20/10), IAB 12/15/10, effective 1/19/11]

[Filed ARC 9950B (Notice ARC 9837B, IAB 11/2/11), IAB 12/28/11, effective 2/1/12]

[Filed ARC 0427C (Notice ARC 0284C, IAB 8/22/12), IAB 10/31/12, effective 12/5/12]

[Filed ARC 1139C (Notice ARC 0929C, IAB 8/7/13), IAB 10/30/13, effective 12/4/13]

[Filed ARC 1700C (Notice ARC 1585C, IAB 8/20/14), IAB 10/29/14, effective 12/3/14]

[Filed ARC 2225C (Notice ARC 2077C, IAB 8/5/15), IAB 10/28/15, effective 12/2/15]

[Filed ARC 2723C (Notice ARC 2659C, IAB 8/3/16), IAB 9/28/16, effective 11/2/16]

[Filed ARC 3338C (Notice ARC 3225C, IAB 8/2/17), IAB 9/27/17, effective 11/1/17]

[Filed ARC 4037C (Notice ARC 3917C, IAB 8/1/18), IAB 9/26/18, effective 10/31/18]

[Filed ARC 4794C (Notice ARC 4665C, IAB 9/25/19), IAB 12/4/19, effective 1/8/20]

[Filed Emergency After Notice ARC 5717C (Notice ARC 5468C, IAB 2/24/21), IAB 6/16/21,
effective 5/28/21]

HUMAN SERVICES DEPARTMENT[441]

Rules transferred from Social Services Department[770] to Human Services Department[498],
see 1983 Iowa Acts, Senate File 464, effective July 1, 1983.

Rules transferred from agency number [498] to [441] to conform with the reorganization
numbering scheme in general, IAC Supp. 2/11/87.

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TITLE XV
*INDIVIDUAL AND FAMILY SUPPORT
AND PROTECTIVE SERVICES*

CHAPTER 170
CHILD CARE SERVICES

[Prior to 7/1/83, Social Services[770] Ch 132]
[Previously appeared as Ch 132—renumbered IAB 2/29/84]
[Prior to 2/11/87, Human Services[498]]

PREAMBLE

The intent of this chapter is to establish requirements for the payment of child care services. Child care services are for children of low-income parents who are in academic or vocational training; or employed or looking for employment; or for a limited period of time, unable to care for children due to physical or mental illness; or needing protective services to prevent or alleviate child abuse or neglect. Services may be provided in a licensed child care center, a registered child development home, the home of a relative, the child's own home, or a nonregistered family child care home.

[ARC 2169C, IAB 9/30/15, effective 1/1/16]

441—170.1(237A) Definitions.

“Agency error” means child care assistance incorrectly paid for the client because of action attributed to the department as the result of one or more of the following circumstances:

1. Loss or misfiling of forms or documents.
2. Errors in typing or copying.
3. Computer input errors.
4. Mathematical errors.
5. Failure to determine eligibility correctly or to certify assistance in the correct amount when all essential information was available to the department.
6. Failure to make timely changes in assistance following amendments of policies that require the changes by a specific date.

“Child care” means a service that provides child care in the absence of parents for a portion of the day, but less than 24 hours. Child care supplements parental care by providing care and protection for children who need care in or outside their homes for part of the day. Child care provides experiences for each child's social, emotional, intellectual, and physical development. Child care may involve comprehensive child development care or it may include special services for a child with special needs. Components of this service shall include supervision, food services, program and activities, and may include transportation.

“Child with protective needs” means a child who is not in foster care and has a case file that identifies child care as a safety or well-being need to prevent or alleviate the effects of child abuse or neglect. Child care is provided as part of a safety plan during a child abuse or child in need of assistance assessment or as part of the service plan established in the family's case plan. The child must have:

1. An open child abuse assessment;
2. An open child in need of assistance assessment;
3. An open child welfare case as a result of a child abuse assessment;
4. A petition on file for a child in need of assistance adjudication; or
5. Adjudication as a child in need of assistance.

“Child with special needs” means a child with one or more of the following conditions:

1. The child has been diagnosed by a physician or by a person endorsed for service as a school psychologist by the Iowa department of education to have a developmental disability which substantially limits one or more major life activities, and the child requires professional treatment, assistance in self-care, or the purchase of special adaptive equipment.

2. The child has been determined by a qualified intellectual disability professional to have a condition which impairs the child's intellectual and social functioning.

3. The child has been diagnosed by a mental health professional to have a behavioral or emotional disorder characterized by situationally inappropriate behavior which deviates substantially from behavior appropriate to the child's age, or which significantly interferes with the child's intellectual, social, or personal adjustment.

"Client" means a current or former recipient of the child care assistance program.

"Client error" means and may result from:

1. False or misleading statements, oral or written, regarding the client's income, resources, or other circumstances which affect eligibility or the amount of assistance received;
2. Failure to timely report changes in income, resources, or other circumstances which affect eligibility or the amount of assistance received;
3. Failure to timely report the receipt of child care units in excess of the number approved by the department;
4. Failure to comply with the need for service requirements.

"Department" means the Iowa department of human services.

"Food services" means the preparation and serving of nutritionally balanced meals and snacks.

"Fraudulent means" means knowingly making or causing to be made a false statement or a misrepresentation of a material fact, knowingly failing to disclose a material fact, or committing a fraudulent practice.

"In-home" means care which is provided within the child's own home.

"Migrant seasonal farm worker" means a person to whom all of the following conditions apply:

1. The person performs seasonal agricultural work which requires travel so that the person is unable to return to the person's permanent residence within the same day.
2. Most of the person's income is derived from seasonal agricultural work performed during the months of July through October. Most shall mean the simple majority of the income.
3. The person generally performs seasonal agricultural work in Iowa during the months of July through October.

"On-line or distance learning" means training such as, but not limited to, training conducted over the Iowa communications network, on-line courses, or web conferencing. The training includes:

1. Interaction between the instructor and the student, such as required chats or message boards;
2. Mechanisms for evaluation and measurement of student achievement.

"Overpayment" means any benefit or payment received in an amount greater than the amount the client or provider is entitled to receive.

"Parent" means the parent or the person who serves in the capacity of the parent of the child receiving child care assistance services.

"Program and activities" means the daily schedule of experiences in a child care setting.

"PROMISE JOBS" means the department's training program, promoting independence and self-sufficiency through employment job opportunities and basic skills, as described in 441—Chapter 93.

"Provider" means a licensed child care center, a registered child development home, a relative who provides care in the relative's own home solely for a related child, a caretaker who provides care for a child in the child's home, or a nonregistered child care home.

"Provider error" means and may result from:

1. Presentation for payment of any false or fraudulent claim for services or merchandise;
2. Submittal of false information for the purpose of obtaining greater compensation than that to which the provider is legally entitled;
3. Failure to report the receipt of a child care assistance payment in excess of that approved by the department;
4. Charging the department an amount for services rendered over and above what is charged private pay clients for the same services;
5. Failure to maintain a copy of Form 470-4535, Child Care Assistance Billing/Attendance Provider Record, signed by the parent and the provider.

“*Recoupment*” means the repayment of an overpayment by a payment from the client or provider or both.

“*Relative*” means an adult aged 18 or older who is a grandparent, aunt or uncle to the child being provided child care.

“*Supervision*” means the care, protection, and guidance of a child.

“*Transportation*” means the movement of children in a four or more wheeled vehicle designed to carry passengers, such as a car, van, or bus, between home and facility.

“*Unit of service*” means a half day which shall be up to 5 hours of service per 24-hour period.

“*Vocational training or education*” means a training plan which includes a specific goal, that is, high school completion, improved English skills, or development of specific academic or vocational skills.

Training may be approved for high school completion activities, high school equivalency, adult basic education, English as a second language, or postsecondary education, up to and including an associate or a baccalaureate degree program.

[ARC 8506B, IAB 2/10/10, effective 3/1/10; ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 1525C, IAB 7/9/14, effective 7/1/14; ARC 1606C, IAB 9/3/14, effective 10/8/14; ARC 2169C, IAB 9/30/15, effective 1/1/16; ARC 2555C, IAB 6/8/16, effective 7/1/16]

441—170.2(237A,239B) Eligibility requirements. A person deemed eligible for benefits under this chapter is subject to all other state child care assistance requirements including, but not limited to, provider requirements under Iowa Code chapter 237A and provider reimbursement methodology. The department shall determine the number of units of service to be approved.

170.2(1) Financial eligibility. Financial eligibility for child care assistance shall be based on federal poverty levels as determined by the Office of Management and Budget and on Iowa’s median family income as determined by the U.S. Census Bureau. Poverty guidelines and median family income amounts are updated annually. Changes shall go into effect for the child care assistance program on July 1 of each year.

a. Income limits.

(1) For initial eligibility, an applicant family’s nonexempt gross monthly income as established in paragraph 170.2(1) “c” cannot exceed the amounts in this subparagraph.

1. 145 percent of the federal poverty level applicable to the family size for children needing basic care; or

2. 200 percent of the federal poverty level applicable to the family size for children needing special-needs care; or

3. 85 percent of Iowa’s median family income, if that figure is lower than the standard in numbered paragraph “1” or “2.”

(2) For ongoing eligibility, at the time of a family’s annual eligibility redetermination as described in subrule 170.3(5), the family’s nonexempt gross monthly income as established in paragraph 170.2(1) “c” cannot exceed the amounts in this subparagraph.

1. 225 percent of the federal poverty level applicable to the family size for children needing basic care or special-needs care; or

2. 85 percent of Iowa’s median family income, if that figure is lower than the standard in numbered paragraph “1.”

b. Exceptions to income limits.

(1) A person who is participating in activities approved under the PROMISE JOBS program is eligible for child care assistance without regard to income if there is a need for child care services.

(2) A person who is part of the family investment program or whose earned income was taken into account in determining the needs of a family investment program recipient is eligible for child care assistance without regard to income if there is a need for child care services.

(3) Protective child care services are provided without regard to income.

(4) In certain cases, the department will provide child care services directed in a court order.

c. Determining gross income. Eligibility shall be determined using a projection of income based on the best estimate of future income. In determining a family’s gross monthly income, the department

shall consider all income received by a family member from sources identified by the U.S. Census Bureau in computing median income, unless excluded under paragraph 170.2(1)“d.”

(1) Income considered shall include wages or salary, net profit from farm or nonfarm self-employment, social security, dividends, interest, income from estates or trusts, net rental income and royalties, public assistance or welfare payments, pensions and annuities, unemployment compensation, workers' compensation, alimony, child support, veterans pensions, cash payments, casino profits, railroad retirement, permanent disability insurance, strike pay and living allowance payments made to participants of the AmeriCorps program. “Net profit from self-employment” means gross income less the costs of producing the income other than depreciation. A net loss in self-employment income cannot be offset from other earned or unearned income.

(2) For migrant seasonal farm workers, the monthly gross income shall be determined by calculating the total amount of income earned in a 12-month period preceding the date of application and dividing the total amount by 12.

(3) When income received weekly or once every two weeks is projected for future months, income shall be projected by adding all income received in the period being used for the projection and dividing the result by the number of instances of income received in that period. The result shall be multiplied by four if the income is received weekly, or by two if the income is received biweekly, regardless of the number of weekly or biweekly payments to be made in future months.

d. Income exclusions. The following sources are excluded from the computation of monthly gross income:

(1) Per capita payments from or funds held in trust in satisfaction of a judgment of the Indian Claims Commission or the court of claims.

(2) Payments made pursuant to the Alaska Claims Settlement Act, to the extent the payments are exempt from taxation under Section 21(a) of the Act.

(3) Money received from the sale of property, unless the person was engaged in the business of selling property.

(4) Withdrawals of bank deposits.

(5) Money borrowed.

(6) Tax refunds.

(7) Gifts.

(8) Lump-sum inheritances or insurance payments or settlements.

(9) Capital gains.

(10) The value of the food assistance allotment under the Food and Nutrition Act of 2008.

(11) The value of USDA donated foods.

(12) The value of supplemental food assistance under the Child Nutrition Act of 1966 and the special food program for children under the National School Lunch Act.

(13) Earnings of a child 14 years of age or younger.

(14) Loans and grants obtained and used under conditions that preclude their use for current living expenses.

(15) Any grant or loan to any undergraduate student for educational purposes made or insured under the Higher Education Act.

(16) Home produce used for household consumption.

(17) Earnings received by any youth under the Workforce Investment Act (WIA).

(18) Stipends received for participating in the foster grandparent program.

(19) The first \$65 plus 50 percent of the remainder of income earned in a sheltered workshop or work activity setting.

(20) Payments from the Low-Income Home Energy Assistance Program.

(21) Agent Orange settlement payments.

(22) The income of the parents with whom a teen parent resides.

(23) For children with special needs, income spent on any regular ongoing cost that is specific to that child's disability.

(24) Moneys received under the federal Social Security Persons Achieving Self-Sufficiency (PASS) program or the Income-Related Work Expense (IRWE) program.

(25) Income received by a Supplemental Security Income recipient if the recipient's earned income was considered in determining the needs of a family investment program recipient.

(26) The income of a child who would be in the family investment program eligible group except for the receipt of Supplemental Security Income.

(27) Any adoption subsidy payments received from the department.

(28) Federal or state earned income tax credit.

(29) Payments from the Iowa individual assistance grant program (IIAGP).

(30) Payments from the transition to independence program (TIP).

(31) Payments to volunteers participating in the Volunteers in Service to America (VISTA) program.

EXCEPTION: This exemption will not be applied when the director of ACTION determines that the value of all VISTA payments, adjusted to reflect the number of hours the volunteer is serving, is equivalent to or greater than the minimum wage then in effect under the Fair Labor Standards Act of 1938 or the minimum wage under the laws of the state where the volunteer is serving, whichever is greater.

(32) Reimbursement from the employer for job-related expenses.

(33) Stipends from the preparation for adult living (PAL) program.

(34) Payments from the subsidized guardianship waiver program.

(35) The earnings of a child aged 18 or under who is a full-time student.

(36) Census earnings received by temporary workers from the Bureau of the Census.

(37) Payments for major disaster and emergency assistance provided under the Disaster Relief Act of 1974 as amended by Public Law 100-707, the Disaster Relief and Emergency Assistance Amendments of 1988.

e. Family size. The following people shall be included in the family size for the determination of eligibility:

(1) Legal spouses (including common law) who reside in the same household.

(2) Natural mother or father, adoptive mother or father, or stepmother or stepfather, and children who reside in the same household.

(3) A child or children who live with a person or persons not legally responsible for the child's support.

f. Effect of temporary absence. The composition of the family does not change when a family member is temporarily absent from the household. "Temporary absence" means:

(1) An absence for the purpose of education or employment.

(2) An absence due to medical reasons that is anticipated to last less than three months.

(3) Any absence when the person intends to return home within three months.

g. Resource limits. For initial and ongoing eligibility, family resources may not exceed \$1 million.

170.2(2) General eligibility requirements. In addition to meeting financial requirements, the child needing services must meet age, citizenship, and residency requirements. Each parent in the household must have at least one need for service and shall cooperate with the department's quality control review and with investigations conducted by the department of inspections and appeals.

a. Age. Child care shall be provided only to children up to age 13, unless they are children with special needs, in which case child care shall be provided up to age 19. When a child reaches the age of 13, or, as applicable, the age of 19, during the certification period, eligibility shall continue until the end of the approved certification period.

b. Need for service. Except for assistance provided under subparagraph 170.2(2)"b"(3), assistance shall be provided to a two-parent family only during the parents' coinciding hours of participation in training, employment, or job search. Each parent in the household shall meet one or more of the following requirements:

(1) The parent is in academic or vocational training. Training shall be on a full-time basis. The training facility shall define what is considered as full-time. Part-time training may be approved only if the number of credit hours to complete training is less than that required for full-time status, the required prerequisite credits or remedial course work is less than that required for full-time status, or training is not

offered on a full-time basis. Child care services may be provided for the parent's hours of participation in the academic or vocational training and for actual travel time between the child care location and the training facility.

1. Child care provided while the parent participates in postsecondary education leading up to and including a baccalaureate degree program or vocational training shall be limited to a 24-month lifetime limit. A month is defined as a fiscal month or part thereof and shall generally have starting and ending dates that fall within two adjacent calendar months but shall only count as one month. Time spent in high school completion, adult basic education, high school equivalency, or English as a second language does not count toward the 24-month limit. PROMISE JOBS child care allowances provided while the parent is a recipient of the family investment program and participating in PROMISE JOBS components in postsecondary education or training shall count toward the 24-month lifetime limit.

2. Payment shall not be approved for child-care during training in the following circumstances:

- Labor market statistics for a local area indicate low employment potential for workers with that training. Exceptions may be made when the parent has a job offer before entering the training or if a parent is willing to relocate after training to an area where there is employment potential. Parents willing to relocate must provide documentation from the department of workforce development, private employment agencies, or employers that jobs paying at least minimum wage for which training is being requested are available in the locale specified by the parent.

- The training is for jobs paying less than minimum wage.

- A parent who possesses a baccalaureate degree wants to take additional college coursework unless the coursework is to obtain a teaching certificate or complete continuing education units.

- The course or training is one that the parent has previously completed.

- The parent was previously unable to maintain the cumulative grade point average required by the training or academic facility in the same training for which application is now being made. This does not apply to parents under the age of 18 who are enrolled in high school completion activities.

- The education is in a field in which the parent will not be able to be employed due to known criminal convictions or founded child or dependent adult abuse.

- The parent wants to participate in on-line or distance learning from the parent's own home, and the training facility does not require specified hours of attendance.

(2) The parent is employed 28 or more hours per week or an average of 28 or more hours per week during the month. Child care services may be provided for the hours of employment and for actual travel time between the child care location and the place of employment. If the parent works a shift consisting of at least six hours of employment between the hours of 8 p.m. and 6 a.m. and needs to sleep during daytime hours, child care services may also be provided to allow the parent to sleep during daytime hours.

(3) The parent has a child with protective needs for child care.

(4) The parent is absent from the home due to inpatient hospitalization or outpatient treatment because of physical or mental illness, or is present but due to medical incapacity is unable to care for the child or participate in work or training, as verified by a physician.

1. Eligibility under this paragraph is limited to parents who become medically incapacitated while eligible for child care assistance based on the need criteria in subparagraph 170.2(2) "b"(1) or 170.2(2) "b"(2).

2. Child care assistance shall continue to be available for up to 90 consecutive days after the parent becomes medically incapacitated. Assistance beyond 90 days may be approved by the service area manager or designee if extenuating circumstances are verified by a physician.

3. The number of units of service authorized shall be determined as follows:

- For a single-parent family or for a two-parent family where both parents are incapacitated, the number of units authorized for the period of incapacity shall not exceed the number of units authorized for the family before the onset of incapacity.

- For a two-parent family where only one parent is incapacitated, the units of service authorized shall be based on the need of the parent who is not incapacitated.

(5) The parent is looking for employment. Child care for job search hours shall be limited to only those hours the parent is actually looking for employment, including travel time. Job search shall be limited to a maximum of 90 consecutive calendar days.

1. For applicants, job search shall be approved for a maximum of 90 consecutive calendar days. If the parent has not started employment within 90 days, assistance shall be canceled.

2. For ongoing participants, job search shall be limited to a maximum of 90 consecutive calendar days and will be treated the same as a temporary lapse in need as described at 170.2(2) "b"(9) and (10).

(6) The parent needs child care services due to participation in activities approved under the PROMISE JOBS program.

(7) The family is part of the family investment program and there is a need for child care services due to employment or participation in vocational training or education. A family who meets this requirement due to employment is not required to work a minimum number of hours. If a parent in a family investment program household remains in the home, child care assistance can be paid if that parent receives Supplemental Security Income.

(8) The parent is employed and participating in academic or vocational training for 28 or more hours per week or an average of 28 or more hours per week in the aggregate, during the month. Child care services may be provided for the hours of employment, the hours of participation in academic or vocational training and for actual travel time between the child care location and the place of employment or training. All of the requirements relating to academic or vocational training found at subparagraph 170.2(2) "b"(1), except for the requirement to be enrolled full-time, apply to the part-time training in this subparagraph.

(9) Family eligibility shall continue during an approved certification period when a temporary lapse in need for service for a parent established under this subparagraph occurs. A temporary lapse is defined as:

1. Any time-limited absence from work or a training or education program for a parent due to:
 - Need to care for a family member.
 - An illness.
 - Maternity leave.
 - Family Medical Leave Act (FMLA) situations for household members.
 - Participation in a treatment/rehabilitation program.
2. Any reduction in employment or education/training hours that fall below the minimum number required at 170.2(2) "b"(1), (2) or (8) as long as the parent continues to work or attend training or education.
3. Any student holiday or break for a parent participating in training or education.
4. Any interruption in work for a seasonal worker who is not working between regular industry work seasons.
5. Any other cessation of work or attendance at a training or education program that does not exceed three months.

(10) Family eligibility shall be canceled if the lapse in need is not temporary because the lapse will continue for more than 3 consecutive months.

c. Residency. To be eligible for child care services, the person must be living in the state of Iowa. "Living in the state" shall include those persons living in Iowa for a temporary period, other than for the purpose of vacation.

d. Citizenship. As a condition of eligibility, the applicant shall attest to the child's citizenship or alien status by signing Form 470-3624 or 470-3624(S), Child Care Assistance Application, or Form 470-0462 or 470-0462(S), Health and Financial Support Application. Child care assistance payments may be made only for a child who:

- (1) Is a citizen or national of the United States; or
- (2) Is a qualified alien as defined at 8 U.S.C. Section 1641. The applicant shall furnish documentation of the alien status of any child declared to be a qualified alien. A child who is a qualified alien is not eligible for child care assistance for a period of five years beginning on the date of the child's entry into the United States with qualified alien status.

EXCEPTION: The five-year prohibition from receiving assistance does not apply to:

1. Qualified aliens described at 8 U.S.C. Section 1613; or
2. Qualified aliens as defined at 8 U.S.C. Section 1641 who entered the United States before August 22, 1996.

e. Cooperation. Parents shall cooperate with the department when the department selects the family's case for quality control review to verify eligibility. Parents shall also cooperate with investigations conducted by the department of inspections and appeals to determine whether information supplied by the parent regarding eligibility for child care assistance is complete and correct. (See 481—Chapter 72.)

(1) Failure to cooperate shall serve as a basis for cancellation or denial of the family's child care assistance.

(2) Once denied or canceled for failure to cooperate, the family may reapply but shall not be considered for approval until cooperation occurs.

170.2(3) Priority for assistance. Child care services shall be provided only when funds are available. Funds available for child care assistance shall first be used to continue assistance to families currently receiving child care assistance and to families with protective child care needs. When funds are insufficient, families applying for services must meet the specific requirements in this subrule.

a. Priority groups. As funds are determined available, families shall be served on a statewide basis from a service-area-wide waiting list as specified in subrule 170.3(4) based on the following schedule in descending order of prioritization.

(1) Families with an income at or below 100 percent of the federal poverty level whose members, for at least 28 hours per week in the aggregate, are employed or are participating at a satisfactory level in an approved training program or educational program, and parents with a family income at or below 100 percent of the federal poverty level who are under the age of 21 and are participating in an educational program leading to a high school diploma or equivalent.

(2) Parents under the age of 21 with a family income at or below 100 percent of the federal poverty guidelines who are participating, at a satisfactory level, in an approved training program or in an education program.

(3) Families with an income of more than 100 percent but not more than 145 percent of the federal poverty guidelines whose members, for at least 28 hours per week in the aggregate, are employed or are participating at a satisfactory level in an approved training program or educational program.

(4) Families with an income at or below 200 percent of the federal poverty guidelines whose members are employed at least 28 hours per week with a special-needs child as a member of the family.

b. Exceptions to priority groups. The following are eligible for child care assistance notwithstanding waiting lists for child care services:

- (1) Families with protective child care needs.
- (2) Recipients of the family investment program or those whose earned income was taken into account in determining the needs of family investment program recipients.
- (3) Families that receive a state adoption subsidy for a child.
- (4) Families that are experiencing homelessness.

c. Effect on need for service. Families approved under a priority group are not required to meet the requirements in paragraph 170.2(2) "b" except at review or redetermination.

170.2(4) Reporting changes. The parent may report any changes in circumstances affecting these eligibility requirements and changes in the choice of provider to the department worker or the PROMISE JOBS worker within ten calendar days of the change.

a. If the change is timely reported within ten calendar days, the effective date of the change shall be the date when the change occurred.

b. If the change is not timely reported within ten calendar days, the effective date of the change shall be the date when the change is reported to the department office or the PROMISE JOBS office.

c. Exceptions. The following changes must be reported:

- (1) Changes in income when the family's gross monthly income exceeds 85 percent of Iowa's median family income.

- (2) A lapse in a parent's need for service found in paragraph 170.2(2) "b" that is not temporary.
- (3) A change in residency outside of the state of Iowa.
- (4) No eligible child remains in the home.

d. The department worker shall disregard any reported changes that are not required to be reported unless the change would cause the authorized units to be increased or the family copay amount to be decreased.

[ARC 8506B, IAB 2/10/10, effective 3/1/10; ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 1525C, IAB 7/9/14, effective 7/1/14; ARC 1606C, IAB 9/3/14, effective 10/8/14; ARC 2555C, IAB 6/8/16, effective 7/1/16; ARC 3092C, IAB 6/7/17, effective 7/1/17; ARC 3791C, IAB 5/9/18, effective 7/1/18; ARC 4470C, IAB 6/5/19, effective 7/1/19; ARC 5035C, IAB 5/6/20, effective 7/1/20]

441—170.3(237A,239B) Application and determination of eligibility.

170.3(1) Application process.

a. Application for child care assistance may be made at any local office of the department on:

- (1) Form 470-3624 or 470-3624(S), Child Care Assistance Application,
- (2) Form 470-0462 or 470-0462(S), Health and Financial Support Application, or
- (3) Form 470-4377 or 470-4377(S), Child Care Assistance Review, when returned after the end of the certification period.

b. The application may be filed by the applicant, by the applicant's authorized representative or, when the applicant is incompetent or incapacitated, by a responsible person acting on behalf of the applicant.

c. The date of application is the date a signed application form containing a legible name and address is received in the department office. An electronic or paper application delivered to a closed office is considered to be received on the first day following the day the office was last open that is not a weekend or state holiday.

d. Families who are determined eligible for child care assistance shall be approved for a certification period of at least 12 months. Families who fail to complete the review and redetermination process as described at subrule 170.3(5) will lose eligibility at the end of the certification period.

170.3(2) Exceptions to application requirement. An application is not required for:

- a. A person who is participating in activities approved under the PROMISE JOBS program.
- b. Recipients of the family investment program or those whose earned income was taken into account in determining the needs of family investment program recipients. The date of application is the date the family requests child care assistance from the department.
- c. Children with protective needs.
- d. Child care services provided under a court order.
- e. Families whose application has been denied for failure to provide requested information who have provided all necessary information to determine eligibility within 14 days of the denial of the application, or by the next working day if the fourteenth day falls on a weekend or state holiday.

170.3(3) Application processing. The department shall approve or deny an application as soon as possible, but no later than 30 days following the date the application was received. This time limit shall apply except in unusual circumstances, such as when the department and the applicant have made every reasonable effort to secure necessary information that has not been supplied by the date the time limit expires, or because of emergency situations, such as fire, flood or other conditions beyond the administrative control of the department.

a. The department worker or PROMISE JOBS worker shall determine the number of units of service authorized for each eligible family and shall:

- (1) Inform the family through the notice of decision; and
- (2) Inform the family's provider through the notice of decision or through Form 470-4444, Certificate of Enrollment.

b. The department shall issue a written notice of decision to the applicant by the next working day following a determination of eligibility.

c. The effective date of assistance shall be the date of application or the date the need for service began, whichever is later. When an application is not required as described under subrule 170.3(2), the effective date shall be as follows:

(1) For a person participating in activities under the PROMISE JOBS program, the effective date of child care assistance shall be the date the person becomes a PROMISE JOBS participant as defined in rule 441—93.1(239B) or the date the person has a need for child care assistance to participate in an approved PROMISE JOBS activity as described in 441—Chapter 93, whichever is later.

(2) For a family receiving family investment program benefits, the effective date of child care assistance shall be no earlier than the effective date of family investment program benefits, or 30 days before the date of application for child care assistance, or the date the need for service began, whichever is the latest.

(3) For a family with protective service needs, the effective date of assistance shall be the date the family signs Form 470-0615 or 470-0615(S), Application for All Social Services.

(4) When child care services are provided under a court order, the effective date of assistance shall be the date specified in the court order or the date of the court order if no date is specified.

(5) For a family whose application was denied for failure to provide requested information but who provides all information necessary to determine eligibility, including verification of all changes in circumstances, within 14 days of the denial, the effective date of assistance shall be the date that all information required to establish eligibility is provided. If the fourteenth calendar day falls on a weekend or state holiday, the family shall have until the next business day to provide the information.

170.3(4) *Waiting lists for child care services.* When the department has determined that there may be insufficient funding, applications for child care assistance shall be taken only for the priority groups for which funds have been determined available according to subrule 170.2(3).

a. The department shall maintain a log of families applying for child care services that meet the requirements within the priority groups for which funds may be available.

(1) Each family shall be entered on the logs according to their eligibility priority group and in sequence of their date of application.

(2) If more than one application is received on the same day for the same priority group, families shall be entered on the log based on the day of the month of the birthday of the oldest eligible child. The lowest numbered day shall be first on the log. Any subsequent tie shall be decided by the month of birth, January being month one and the lowest number.

b. When the department determines that there is adequate funding, the department shall notify the public regarding the availability of funds.

170.3(5) *Review and redetermination.* The department shall redetermine a family's financial and general eligibility for child care assistance at least every 12 months. EXCEPTION: The department shall redetermine only general eligibility for recipients of the family investment program (FIP), persons whose earned income was taken into account in determining the needs of FIP recipients, and parents who have children with protective needs, because these families are deemed financially eligible so long as the FIP eligibility or need for protective services continues.

a. If FIP or protective services eligibility ends, the department shall redetermine financial and general eligibility for child care assistance according to the requirements in rule 441—170.2(237A,239B). The redetermination of eligibility shall be completed within 30 days.

b. The department shall use information gathered on Form 470-4377 or 470-4377(S), Child Care Assistance Review, to redetermine eligibility, except when the family is not required to complete a review form as provided in paragraph 170.3(5)“c.”

(1) The department shall issue a notice of expiration for the child care assistance certification period on Form 470-4377 or 470-4377(S).

(2) If the family does not return a complete review form to the department by the end of the certification period, the family must reapply for benefits, except as provided in paragraph 170.3(6)“b.” A complete review form is Form 470-4377 or 470-4377(S) with all items answered that is signed and dated by the applicant and is accompanied by all verification needed to determine continued eligibility.

c. Families who have children with protective needs and families who are receiving child care assistance because the parent is participating in activities under the PROMISE JOBS program are not required to complete Form 470-4377 or 470-4377(S).

(1) The department shall issue a notice of expiration for the child care assistance certification period on the notice of decision when the department approves the family's certification period.

(2) The department shall gather information needed to redetermine general eligibility. If the department needs information from the family, the department will send a written request to the family. If the family does not return the requested information by the due date, the family must reapply for child care assistance, except as provided in paragraph 170.3(6) "b."

d. Families who apply for child care assistance because the parent is seeking employment are not subject to review requirements because eligibility is limited to 90 consecutive calendar days. This waiver of the review requirement applies only when the parent who is seeking employment does not have another need for service.

170.3(6) Reinstatement.

a. Assistance shall be reinstated without a new application when all necessary information is provided before the effective date of cancellation and eligibility can be reestablished. If there is a change in circumstances, the change must be verified before the case will be reinstated.

b. Assistance shall be reinstated without a new application when the case was canceled for failure to provide requested information but all information necessary to determine eligibility, including verification of all changes in circumstances, is provided within 14 days of the effective date of cancellation and eligibility can be reestablished. If the fourteenth calendar day falls on a weekend or state holiday, the family shall have until the next business day to provide the information. The effective date of child care assistance shall be the date that all information required to establish eligibility is provided.

[ARC 8506B, IAB 2/10/10, effective 3/1/10; ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 2555C, IAB 6/8/16, effective 7/1/16; ARC 3092C, IAB 6/7/17, effective 7/1/17]

441—170.4(237A) Elements of service provision.

170.4(1) Case file. The child welfare case file shall document the eligibility for service under 170.2(2) "b"(3).

170.4(2) Fees. Fees for services received shall be charged to clients according to the schedules in this subrule, except that fees shall not be charged to clients receiving services without regard to income. The fee is a per-unit charge that is applied to the child in the family who receives the largest number of units of service. The fee shall be charged for only one child in the family, regardless of how many children receive assistance.

a. Sliding fee schedule.

(1) The fee schedule shown in the following table is effective for eligibility determinations made on or after July 1, 2021:

Level	Monthly Income According to Family Size													Unit Fee Based on Number of Children in Care		
	1	2	3	4	5	6	7	8	9	10	11	12	13+	1	2	3 or more
A	\$1,020	\$1,379	\$1,739	\$2,099	\$2,458	\$2,817	\$3,177	\$3,536	\$3,895	\$4,255	\$4,614	\$4,973	\$5,333	\$0.00	\$0.00	\$0.00
B	\$1,074	\$1,452	\$1,830	\$2,209	\$2,587	\$2,965	\$3,344	\$3,722	\$4,100	\$4,479	\$4,857	\$5,235	\$5,614	\$0.20	\$0.45	\$0.70
C	\$1,104	\$1,493	\$1,881	\$2,271	\$2,659	\$3,048	\$3,438	\$3,826	\$4,215	\$4,604	\$4,993	\$5,382	\$5,771	\$0.45	\$0.70	\$0.95
D	\$1,134	\$1,533	\$1,932	\$2,333	\$2,732	\$3,131	\$3,531	\$3,930	\$4,330	\$4,730	\$5,129	\$5,528	\$5,928	\$0.70	\$0.95	\$1.20
E	\$1,166	\$1,576	\$1,987	\$2,398	\$2,808	\$3,219	\$3,630	\$4,040	\$4,451	\$4,862	\$5,273	\$5,683	\$6,094	\$0.95	\$1.20	\$1.45
F	\$1,198	\$1,619	\$2,041	\$2,463	\$2,885	\$3,306	\$3,729	\$4,151	\$4,572	\$4,995	\$5,416	\$5,838	\$6,260	\$1.20	\$1.45	\$1.70
G	\$1,231	\$1,665	\$2,098	\$2,532	\$2,966	\$3,399	\$3,833	\$4,267	\$4,700	\$5,135	\$5,568	\$6,001	\$6,436	\$1.45	\$1.70	\$1.95
H	\$1,265	\$1,710	\$2,155	\$2,601	\$3,046	\$3,492	\$3,938	\$4,383	\$4,828	\$5,274	\$5,720	\$6,165	\$6,611	\$1.70	\$1.95	\$2.20
I	\$1,300	\$1,758	\$2,215	\$2,674	\$3,132	\$3,589	\$4,048	\$4,506	\$4,963	\$5,422	\$5,880	\$6,337	\$6,796	\$1.95	\$2.20	\$2.45
J	\$1,336	\$1,806	\$2,276	\$2,747	\$3,217	\$3,687	\$4,158	\$4,628	\$5,098	\$5,570	\$6,040	\$6,510	\$6,981	\$2.20	\$2.45	\$2.70
K	\$1,373	\$1,856	\$2,339	\$2,824	\$3,307	\$3,790	\$4,275	\$4,758	\$5,241	\$5,726	\$6,209	\$6,692	\$7,177	\$2.45	\$2.70	\$2.95
L	\$1,410	\$1,907	\$2,403	\$2,901	\$3,397	\$3,894	\$4,391	\$4,888	\$5,384	\$5,882	\$6,378	\$6,874	\$7,372	\$2.70	\$2.95	\$3.20
M	\$1,450	\$1,960	\$2,470	\$2,982	\$3,492	\$4,003	\$4,514	\$5,024	\$5,535	\$6,046	\$6,557	\$7,067	\$7,579	\$2.95	\$3.20	\$3.45
N	\$1,489	\$2,013	\$2,538	\$3,063	\$3,587	\$4,112	\$4,637	\$5,161	\$5,685	\$6,211	\$6,735	\$7,259	\$7,785	\$3.20	\$3.45	\$3.70
O	\$1,531	\$2,070	\$2,609	\$3,149	\$3,688	\$4,227	\$4,767	\$5,306	\$5,845	\$6,385	\$6,924	\$7,463	\$8,003	\$3.45	\$3.70	\$3.95
P	\$1,573	\$2,126	\$2,680	\$3,235	\$3,788	\$4,342	\$4,897	\$5,450	\$6,004	\$6,559	\$7,112	\$7,666	\$8,221	\$3.70	\$3.95	\$4.20
Q	\$1,617	\$2,186	\$2,755	\$3,325	\$3,894	\$4,463	\$5,034	\$5,603	\$6,172	\$6,743	\$7,312	\$7,881	\$8,451	\$3.95	\$4.20	\$4.45
R	\$1,661	\$2,245	\$2,830	\$3,416	\$4,000	\$4,585	\$5,171	\$5,756	\$6,340	\$6,926	\$7,511	\$8,095	\$8,681	\$4.20	\$4.45	\$4.70
S	\$1,707	\$2,308	\$2,909	\$3,512	\$4,112	\$4,713	\$5,316	\$5,917	\$6,518	\$7,120	\$7,721	\$8,322	\$8,924	\$4.45	\$4.70	\$4.95
T	\$1,754	\$2,371	\$2,988	\$3,607	\$4,224	\$4,842	\$5,461	\$6,078	\$6,695	\$7,314	\$7,931	\$8,549	\$9,167	\$4.70	\$4.95	\$5.20
U	\$1,803	\$2,437	\$3,072	\$3,708	\$4,343	\$4,977	\$5,614	\$6,248	\$6,883	\$7,519	\$8,153	\$8,788	\$9,424	\$4.95	\$5.20	\$5.45
V	\$1,852	\$2,504	\$3,156	\$3,809	\$4,461	\$5,113	\$5,766	\$6,418	\$7,070	\$7,724	\$8,375	\$9,027	\$9,681	\$5.20	\$5.45	\$5.70

Level	Monthly Income According to Family Size													Unit Fee Based on Number of Children in Care		
	1	2	3	4	5	6	7	8	9	10	11	12	13+	1	2	3 or more
W	\$1,904	\$2,574	\$3,244	\$3,916	\$4,586	\$5,256	\$5,928	\$6,598	\$7,268	\$7,940	\$8,610	\$9,280	\$9,952	\$5.45	\$5.70	\$5.95
X	\$1,956	\$2,644	\$3,332	\$4,023	\$4,711	\$5,399	\$6,089	\$6,778	\$7,466	\$8,156	\$8,844	\$9,533	\$10,223	\$5.70	\$5.95	\$6.20
Y	\$2,010	\$2,718	\$3,426	\$4,135	\$4,843	\$5,550	\$6,260	\$6,967	\$7,675	\$8,385	\$9,092	\$9,800	\$10,509	\$5.95	\$6.20	\$6.45
Z	\$2,065	\$2,792	\$3,519	\$4,248	\$4,975	\$5,702	\$6,430	\$7,157	\$7,884	\$8,613	\$9,340	\$10,067	\$10,795	\$6.20	\$6.45	\$6.70
AA	\$2,123	\$2,870	\$3,618	\$4,367	\$5,114	\$5,861	\$6,610	\$7,358	\$8,105	\$8,854	\$9,601	\$10,348	\$11,098	\$6.45	\$6.70	\$6.95
BB	\$4,000	\$5,000	\$6,000	\$7,000	\$8,000	\$9,000	\$9,000	\$9,000	\$9,500	\$9,500	\$10,000	\$10,500	\$11,500	\$6.70	\$6.95	\$7.20

(2) To use the chart:

1. Find the family size used in determining income eligibility for service.
2. Move across the monthly income table to the column headed by that number.
3. Move down the column for the applicable family size to the highest figure that is equal to or less than the family's gross monthly income. Income at or above that amount (but less than the amount in the next row) corresponds to the fees in the last three columns of that row.

4. Choose the fee that corresponds to the number of children in the family who receive child care assistance.

b. Collection. The provider shall collect fees from clients.

(1) The provider shall maintain records of fees collected. These records shall be available for audit by the department or its representative.

(2) When a client does not pay the fee, the provider shall demonstrate that a reasonable effort has been made to collect the fee. "Reasonable effort to collect" means an original billing and two follow-up notices of nonpayment.

c. Inability of client to pay fees. Child care assistance may be continued without a fee, or with a reduced fee, when a client reports in writing the inability to pay the assessed fee due to the existence of one or more of the conditions set forth below. Before reducing the fee, the worker shall assess the case to verify that the condition exists and to determine whether a reduced fee can be charged. The reduced fee shall then be charged until the condition justifying the reduced fee no longer exists. Reduced fees may be justified by:

(1) Extensive medical bills for which there is no payment through insurance coverage or other assistance.

(2) Shelter costs that exceed 30 percent of the household income.

(3) Utility costs not including the cost of a telephone that exceed 15 percent of the household income.

(4) Additional expenses for food resulting from diets prescribed by a physician.

170.4(3) Method of provision. Parents shall be allowed to exercise their choice for in-home care, except when the parent meets the need for service under subparagraph 170.2(2)"b"(3), as long as the conditions in paragraph 170.4(7)"d" are met. When the child meets the need for service under 170.2(2)"b"(3), parents shall be allowed to exercise their choice of licensed, registered, or nonregistered child care provider except when the department service worker determines it is not in the best interest of the child. The provider must meet one of the applicable requirements set forth below.

a. Licensed child care center. A child care center shall be licensed by the department to meet the requirements set forth in 441—Chapter 109 and shall have a current Certificate of License, Form 470-0618.

b. Registered child development home. A child development home shall meet the requirements for registration set forth in 441—Chapter 110 and shall have a current Certificate of Registration, Form 470-3498.

c. Out-of-state provider. A child care provider who is not located in Iowa may be selected by the parent so long as the out-of-state child care provider verifies that the provider meets all of the requirements to be a provider in the state in which the provider operates.

d. Relative care. Rescinded IAB 2/6/02, effective 4/1/02.

e. In-home care. The adult caretaker selected by the parent to provide care in the child's own home shall be sent Form 470-2890 or 470-2890(S), Payment Application for Nonregistered Providers. The provider shall complete and sign Form 470-2890 or 470-2890(S) and return the form to the department before payment may be made. An identifiable application is an application that contains a legible name and address and that has been signed. Signature on the form certifies the provider's understanding of and compliance with the conditions and requirements for nonregistered in-home care providers that include:

(1) Professional development. The provider shall complete:

1. Prior to provider agreement and every five years thereafter, minimum health and safety trainings, approved by the department, in the following content areas:

- Prevention and control of infectious disease, including immunizations.

- Prevention of sudden infant death syndrome and use of safe sleep practices.
- Administration of medication, consistent with standards for parental consent.
- Prevention of and response to emergencies due to food and allergic reactions.
- Building and physical-premises safety, including identification of and protection from hazards that can cause bodily injury, such as electrical hazards, bodies of water, and vehicular traffic.
- Prevention of shaken baby syndrome and abusive head trauma.
- Emergency preparedness and response planning for emergencies resulting from a natural disaster or a human-caused event.
- Handling and storage of hazardous materials and appropriate disposal of biocontaminants.
- Precautions in transporting children.

Minimum health and safety training may be required prior to the five-year period if content has significant changes which warrant that the training be renewed.

2. Prior to provider agreement, two hours of Iowa's training for mandatory reporting of child abuse.

3. Prior to provider agreement, first-aid and cardiopulmonary resuscitation (CPR) training meeting the following requirements:

- Training shall be provided by a nationally recognized training organization, such as the American Red Cross, American Heart Association, National Safety Council, American Safety and Health Institute or MEDIC First Aid or by an equivalent trainer using curriculum approved by the department.

- First-aid training shall include certification in infant and child first aid.

- The provider shall maintain a valid certificate indicating the date of first-aid training and the expiration date.

- The provider shall maintain a valid certificate indicating the date of CPR training and the expiration date.

(2) Limits on the number of children for whom care may be provided.

(3) Unlimited parental access to the child or children during hours when care is provided, unless prohibited by court order.

(4) Conditions that warrant nonpayment.

f. Nonregistered family child care home. A nonregistered child care home shall meet the requirements set forth in 441—Chapter 120.

g. Iowa records checks for in-home care. If a person who provides in-home care applies to receive public funds as reimbursement for providing child care for eligible clients, the provider shall complete and submit the required authorization form(s) to the department. The department shall use the form(s) to conduct Iowa criminal history record and child abuse record checks.

(1) The purpose of these checks is to determine whether the person has committed a transgression that prohibits or limits the person's involvement with child care.

(2) The department may also conduct criminal and child abuse record checks in other states and may conduct dependent adult abuse, sex offender registry, and other public or civil offense record checks in Iowa or in other states.

(3) Records checks shall be repeated every two years and when the department or provider becomes aware of any new transgressions.

h. National criminal history record checks for in-home care. If a person who provides in-home care applies to receive public funds as reimbursement for providing child care for eligible clients, the provider shall complete Form DCI-45, Waiver Agreement, and Form FD-258, Federal Fingerprint Card.

(1) The provider subject to this check shall submit any other forms required by the department of public safety to authorize the release of records.

(2) The provider subject to this check is responsible for any costs associated with obtaining the fingerprints and for submitting the prints to the department.

(3) Fingerprints may be taken (rolled) by law enforcement agencies or by agencies or companies that specialize in taking fingerprints.

(4) The national criminal history record check shall be repeated for each person subject to the check every four years and when the department or provider becomes aware of any new transgressions committed by that person in another state.

(5) The department may rely on the results of previously conducted national criminal history record checks when a person subject to a record check in one child development home or child care home submits a request for involvement with child care in another child care home, so long as the person's national criminal history record check is within the allowable four-year time frame. All initial or new applications shall require a new national criminal history record check.

i. Transgressions. If any person subject to the record checks in paragraph 170.4(3)“g” or 170.4(3)“h” has a record of founded child abuse, dependent adult abuse, a criminal conviction, or placement on the sex offender registry, the department shall follow the process for prohibition or evaluation defined at 441—subrule 120.11(3).

(1) If any person would be prohibited from registration, employment, or residence, the person shall not provide child care and is not eligible to receive public funds to do so. The department's designee shall notify the applicant.

(2) A person who continues to provide child care in violation of this rule is subject to penalty and injunction under Iowa Code chapter 237A.

170.4(4) Components of service program. Every child eligible for child care services shall receive supervision, food services, and program and activities, and may receive transportation.

170.4(5) Levels of service according to age. Rescinded IAB 9/30/92, effective 10/1/92.

170.4(6) Provider's individual program plan. Rescinded IAB 2/10/10, effective 3/1/10.

170.4(7) Payment. The department shall make payment for child care provided to an eligible family when the family reports their choice of provider to the department and the provider has a completed Form 470-3871 or 470-3871(S), Child Care Assistance Provider Agreement, on file with the department. Both the child care provider and the department worker shall sign this form.

a. Rate of payment. The rate of payment for child care services, except for in-home care which shall be paid in accordance with 170.4(7)“d,” shall be the actual rate charged by the provider for a private individual, not to exceed the maximum rates shown below. When a provider does not have a half-day rate in effect, a rate is established by dividing the provider's declared full-day rate by 2. When a provider has neither a half-day nor a full-day rate, a rate is established by multiplying the provider's declared hourly rate by 4.5. Payment shall not exceed the rate applicable to the provider type and age group as shown in the tables below. To be eligible for the special needs rate, the provider must submit documentation to the child's service worker that the child needing services has been assessed by a qualified professional and meets the definition for “child with special needs,” and a description of the child's special needs, including, but not limited to, adaptive equipment, more careful supervision, or special staff training.

	No QRS		QRS 1 or 2		QRS 3 or 4		QRS 5	
Age Group	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs
Infant and Toddler	\$17.00	\$51.94	\$19.75	\$51.94	\$20.50	\$51.94	\$21.90	\$51.94
Preschool	\$14.75	\$30.43	\$15.50	\$30.43	\$16.40	\$30.43	\$18.69	\$30.43
School Age	\$12.18	\$30.34	\$12.50	\$30.34	\$13.50	\$30.34	\$15.00	\$30.34

Table 2 Half-Day Rate Ceilings for (Child Development Home A/B)								
Age Group	No QRS		QRS 1 or 2		QRS 3 or 4		QRS 5	
	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs
Infant and Toddler	\$12.98	\$19.47	\$13.50	\$20.25	\$13.75	\$20.63	\$14.00	\$21.00
Preschool	\$12.50	\$18.75	\$12.75	\$19.13	\$13.00	\$19.50	\$13.75	\$20.63
School Age	\$10.82	\$16.23	\$11.25	\$16.88	\$12.00	\$18.00	\$12.50	\$18.75

Table 3 Half-Day Rate Ceilings for (Child Development Home C)								
Age Group	No QRS		QRS 1 or 2		QRS 3 or 4		QRS 5	
	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs
Infant and Toddler	\$13.00	\$19.50	\$14.00	\$21.00	\$14.50	\$21.75	\$15.00	\$22.50
Preschool	\$12.50	\$18.75	\$13.00	\$19.50	\$13.50	\$20.25	\$15.00	\$22.50
School Age	\$11.25	\$16.88	\$12.00	\$18.00	\$12.50	\$18.75	\$14.00	\$21.00

Table 4 Half-Day Rate Ceilings for Child Care Home (Not Registered)		
Age Group	Basic	Special Needs
Infant and Toddler	\$8.19	\$12.29
Preschool	\$7.19	\$10.79
School Age	\$7.36	\$11.04

The following definitions apply in the use of the rate tables:

(1) “Licensed center” shall mean those providers as defined in 170.4(3) “a.” “Child development home A/B” or “child development home C” shall mean those providers as defined in 170.4(3) “b.” “Child care home (not registered)” shall mean those providers as defined in 441—Chapter 120.

(2) Under age group, “infant and toddler” shall mean age two weeks to three years; “preschool” shall mean three years to school age; “school age” shall mean a child in attendance in full-day or half-day classes.

(3) “No QRS” shall mean a provider who is not participating in the quality rating system.

(4) A provider who is rated under the quality rating system shall be paid according to the corresponding QRS payment level in the tables above only during the period the rating is valid as defined in 441—Chapter 118. If the provider’s QRS rating expires, the provider shall be paid according to the “No QRS” payment level.

(5) For a provider rated “QRS 1” through “QRS 4,” if the rating period expires before a new QRS level is approved, the provider will be paid according to the “No QRS” payment level until the new QRS level is approved.

(6) For a provider rated “QRS 5,” if a renewal application is received before the current rating period expires, the provider will continue to be paid according to the “QRS 5” payment level until a decision is made on the provider’s application.

(7) “QRS 1 or 2” shall mean a provider who has achieved a rating of Level 1 or Level 2 under the quality rating system.

(8) “QRS 3 or 4” shall mean a provider who has achieved a rating of Level 3 or Level 4 under the quality rating system.

(9) “QRS 5” shall mean a provider who has achieved a rating of Level 5 under the quality rating system.

b. Payment for days of absence. Payment may be made to a child care provider defined in subrule 170.4(3) for an individual child not in attendance at a child care facility not to exceed four days per calendar month providing that the child is regularly scheduled on those days and the provider also charges a private individual for days of absence.

c. Payment for multiple children in a family. When a provider reduces the charges for the second and any subsequent children in a family with multiple children whose care is unsubsidized, the rate of payment made by the department for a family with multiple children shall be similarly reduced.

d. Payment for in-home care. Payment may be made for in-home care when there are three or more children in a family who require child care services. The rate of payment for in-home care shall be the minimum wage amount.

e. Limitations on payment. Payment shall not be made for therapeutic services that are provided in the care setting and include, but are not limited to, services such as speech, hearing, physical and other therapies, individual or group counseling, therapeutic recreation, and crisis intervention.

f. Review of the calculation of the rate of payment. Maximum rate ceilings are not appealable. A provider who is in disagreement with the calculation of the half-day rate as set forth in 170.4(7) “a” may request a review. The procedure for review is as follows:

(1) Within 15 calendar days of notification of the rate in question, the provider shall send a written request for review to the service area manager. The request shall identify the specific rate in question and the methodology used to calculate the rate. The service manager shall provide a written response within 15 calendar days of receipt of the request for review.

(2) When dissatisfied with the response, the provider may, within 15 calendar days of the response, request a review by the chief of the bureau of financial support. The provider shall submit to the bureau chief the original request, the response received, and any additional information desired. The bureau chief shall render a decision in writing within 15 calendar days of receipt of the request.

(3) The provider may appeal the decision to the director of the department or the director’s designee within 15 calendar days of the decision. The director or director’s designee shall issue the final department decision within 15 calendar days of receipt of the request.

g. Submission of claims. The department shall issue payment when the provider submits correctly completed documentation of attendance and charges. The department shall pay for no more than the number of units of service authorized in the notice of decision issued pursuant to subrule 170.3(3). Providers shall submit a claim in one of the following ways:

(1) Using Form 470-4534, Child Care Assistance Billing/Attendance; or

(2) Using an electronic request for payment submitted through the KinderTrack system. Providers using this method shall print Form 470-4535, Child Care Assistance Billing/Attendance Provider Record, to be signed by the provider and the parent. The provider shall keep the signed Form 470-4535 for a period of five years after the billing date.

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441—170.5(237A) Adverse actions.

170.5(1) Provider agreement. The department may refuse to enter into or may revoke the Child Care Assistance Provider Agreement, Form 470-3871 or 470-3871(S), if any of the following occur:

a. The department finds a hazard to the safety and well-being of a child, and the provider cannot or refuses to correct the hazard.

- b. The provider has submitted claims for payment for which the provider is not entitled.
- c. The provider fails to cooperate with an investigation conducted by the department of inspections and appeals to determine whether information the provider supplied to the department regarding payment for child care services is complete and correct. Once the agreement is revoked for failure to cooperate, the department shall not enter into a new agreement with the provider until cooperation occurs.
- d. The provider does not meet one of the applicable requirements set forth in subrule 170.4(3).
- e. The provider fails to comply with any of the terms and conditions of the Child Care Assistance Provider Agreement, Form 470-3871 or 470-3871(S).
- f. The provider submits attendance documentation for payment and the provider knows or should have known that the documentation is false or inaccurate.
- g. An overpayment of CCA funds with a balance of \$3,000 or more exists for a provider and that provider fails to enter into a repayment agreement with the department of inspections and appeals (DIA) or does not make payments according to the repayment agreement on file with DIA.
- h. The provider is found to have more children in care at one time than allowed for the provider type as found at rule 441—110.6(237A) and 441—subrules 110.13(1), 110.14(1), 110.15(1), 120.6(1) and 170.4(3).

170.5(2) Denial. Child care assistance shall be denied when the department determines that:

- a. The client is not in need of service; or
- b. The client is not financially eligible; or
- c. There is another resource available to provide the service or a similar service free of charge that allows parents to select from the full range of eligible providers; or
- d. An application is required and the client or representative refuses or fails to sign the application form; or
- e. Funding is not available; or
- f. The client refuses or fails to supply information or verification requested or to request assistance and authorize the department to secure the required information or verification from other sources (signing a general authorization for release of information to the department does not meet this responsibility); or
- g. The client fails to cooperate with a quality control review or with an investigation conducted by the department of inspections and appeals.

170.5(3) Termination. Child care assistance may be terminated when the department determines that:

- a. The client no longer meets the eligibility criteria in subrule 170.2(2); or
- b. The client's income exceeds the financial guidelines; or
- c. The client refuses or fails to supply information or verification requested or to request assistance and authorize the department to secure the required information or verification from other sources (signing a general authorization for release of information to the department does not meet this responsibility); or
- d. No payment or only partial payment of client fees has been received within 30 days following the issuance of the last billing; or
- e. Another resource is available to provide the service or a similar service free of charge that allows parents to select from the full range of eligible providers; or
- f. Funding is not available; or
- g. The client fails to cooperate with a quality control review or with an investigation conducted by the department of inspections and appeals.

170.5(4) Reduction. Authorized units of service may be reduced when the department determines that:

- a. Continued provision of service at the current level is not necessary to meet the client's service needs; or
- b. Another resource is available to provide the same or similar service free of charge that will meet the client's needs and allow parents to select from the full range of eligible providers; or

c. Funding is not available to continue the service at the current level. When funding is not available, the department may limit on a statewide basis the number of units of child care services for which payment will be made.

170.5(5) Provider agreement sanction. If a Child Care Assistance Provider Agreement, Form 470-3871 or 470-3871(S), is terminated for any of the reasons in subrule 170.5(1), the agreement shall remain terminated for the time periods set forth below:

a. The first time the agreement is terminated, the provider may reapply for another agreement at any time.

b. The second time the agreement is terminated, the provider may not reapply for another agreement for 12 months from the effective date of termination.

c. The third or subsequent time the agreement is terminated, the provider may not reapply for another agreement for 36 months from the effective date of termination.

d. The department shall not act on an application for a child care assistance provider agreement submitted by a provider during the sanction period.

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441—170.6(237A) Appeals. Notice of adverse actions and the right of appeal shall be given in accordance with 441—Chapter 7.

441—170.7(237A) Provider fraud.

170.7(1) Fraud. The department shall consider a child care provider to have committed fraud when:

a. The department of inspections and appeals, in an administrative or judicial proceeding, has found the provider to have obtained by fraudulent means child care assistance payment in an amount in excess of \$1,000; or

b. The provider has agreed to entry of a civil judgment or judgment by confession that includes a conclusion of law that the provider has obtained by fraudulent means child care assistance payment in an amount in excess of \$1,000.

170.7(2) Potential sanctions. Providers found to have committed fraud shall be subject to one or more of the following sanctions, as determined by the department:

a. Special review of the provider's claims for child care assistance.

b. Suspension from receipt of child care assistance payment for six months.

c. Ineligibility to receive payment under child care assistance.

170.7(3) Factors considered in determining level of sanction. The department shall evaluate the following factors in determining the sanction to be imposed:

a. *History of prior violations.*

(1) If the provider has no prior violations, the sanction imposed shall be a special review of provider claims.

(2) If the provider has one prior violation, the sanction imposed shall be a suspension from receipt of child care assistance payment for six months as well as a special review of provider claims.

(3) If the provider has more than one prior violation, the sanction imposed shall be ineligibility to receive payment under child care assistance.

b. *Prior imposition of sanctions.*

(1) If the provider has not been sanctioned before, the sanction imposed shall be a special review of the provider's claims for child care assistance.

(2) If the provider has been sanctioned once before, the sanction imposed shall be a suspension from receipt of child care assistance payment for six months as well as a special review of provider claims.

(3) If the provider has been sanctioned more than once before, the sanction imposed shall be ineligibility to receive payment under child care assistance.

c. *Seriousness of the violation.*

(1) If the amount fraudulently received is less than \$5,000, the sanction level shall be determined according to paragraphs "a" and "b."

(2) If the amount fraudulently received is \$5,000 or more, and the sanction determined according to paragraphs “a” and “b” is review of provider claims, the sanction imposed shall be suspension from receipt of child care assistance payment.

(3) If the amount fraudulently received is \$5,000 or more, and the sanction determined according to paragraphs “a” and “b” is suspension from receipt of child care assistance payment, the sanction imposed shall be ineligibility to receive payment under child care assistance.

d. Extent of the violation.

(1) If the fraudulent claims involve five invoices or less or five months or less, the sanction level shall be determined according to paragraphs “a” and “b.”

(2) If the fraudulent claims involve at least six invoices or six months, and the sanction determined according to paragraphs “a” and “b” is review of provider claims, the sanction imposed shall be suspension from receipt of child care assistance payment.

(3) If the fraudulent claims involve at least six invoices or six months, and the sanction determined according to paragraphs “a” and “b” is suspension from receipt of child care assistance payment, the sanction imposed shall be ineligibility to receive payment under child care assistance.

170.7(4) Mitigating factors.

a. If the sanction determined according to subrule 170.7(3) is suspension from or ineligibility for receipt of child care assistance payment, the department shall determine whether it is appropriate to reduce the level of a sanction for the particular case, considering:

- (1) Prior provision of provider education.
- (2) Provider willingness to obey program rules.

b. If the sanction determined according to subrule 170.7(3) is ineligibility for receipt of child care assistance payment, but consideration of the two factors in paragraph “a” indicates that a lesser sanction will resolve the violation, the sanction imposed shall be:

- (1) Suspension from receipt of child care assistance payment for six months; and
- (2) A special review of provider claims.

c. If the sanction determined according to subrule 170.7(3) is suspension from receipt of child care assistance payment, but consideration of the two factors in paragraph “a” indicates that a lesser sanction will resolve the violation, the sanction imposed shall be a special review of provider claims.

441—170.8(234) Allocation of funds. Rescinded IAB 2/6/02, effective 4/1/02.

441—170.9(237A) Child care assistance overpayments. All child care assistance overpayments shall be subject to recoupment.

170.9(1) Notification and appeals. All clients or providers shall be notified as described at subrule 170.9(6), when it is determined that an overpayment exists. Notification shall include the amount, date and reason for the overpayment. The department shall provide additional information regarding the computation of the overpayment upon the client’s or provider’s request. The client or provider may appeal the computation of the overpayment and any action to recover the overpayment in accordance with 441—paragraph 7.4(3)“i.”

170.9(2) Determination of overpayments. All overpayments due to client, provider, or agency error or due to benefits or payments issued pending an appeal decision shall be recouped. Overpayments shall be computed as if the information had been acted upon timely.

170.9(3) Benefits or payments issued pending appeal decision. Recoupment of overpayments resulting from benefits or payments issued pending a decision on an appeal hearing shall not occur until after a final appeal decision is issued affirming the department.

170.9(4) Failure to cooperate. Failure by the client to cooperate in the investigation of alleged overpayments shall result in ineligibility for the months in question and the overpayment shall be the total amount of assistance received during those months. Failure by the provider to cooperate in the investigation of alleged overpayments shall result in payments being recouped for the months in question.

170.9(5) *Payment agreement.* The client or provider may choose to make a lump-sum payment or make periodic installment payments as agreed to on the notification form issued pursuant to subrule 170.9(6). Failure to negotiate an approved payment agreement may result in further collection action as outlined in 441—Chapter 11.

170.9(6) *Procedures for recoupment.*

a. When the department determines that an overpayment exists, the department shall refer the case to the department of inspections and appeals for investigation, recoupment, or referral for possible prosecution.

b. The department of inspections and appeals shall initiate recoupment by notifying the debtor of the overpayment on Form 470-4530, Notice of Child Care Assistance Overpayment.

c. When financial circumstances change, the department of inspections and appeals has the authority to revise the recoupment plan.

d. Recoupment for overpayments due to client error or due to an agency error that affected eligibility shall be made from the parent who received child care assistance at the time the overpayment occurred. When two parents were in the home at the time the overpayment occurred, both parents are equally responsible for repayment of the overpayment.

e. Recoupment for overpayments due to provider error or due to an agency error that affected benefits shall be made from the provider.

f. Recoupment for overpayments caused by both the provider and client shall be collected from both the provider and client equally, 50 percent from the client and 50 percent from the provider.

170.9(7) *Suspension and waiver.* Recoupment will be suspended on nonfraud overpayments when the amount of the overpayment is less than \$35. Recoupment will be waived on nonfraud overpayments of less than \$35 which have been held in suspense for three years.

[ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 1893C, IAB 3/4/15, effective 7/1/15; ARC 4973C, IAB 3/11/20, effective 4/15/20]

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CHAPTER 204
SUBSIDIZED GUARDIANSHIP PROGRAM

PREAMBLE

This chapter implements a subsidized guardianship program to provide financial assistance to guardians of eligible children who are in foster care but are not able to be adopted and are not able to return home. A subsidized guardianship agreement authorized under this chapter will remain in effect until the agreement is terminated under the terms of this chapter.

[ARC 8914B, IAB 6/30/10, effective 8/4/10; ARC 4167C, IAB 12/5/18, effective 2/1/19]

441—204.1(234) Definitions.

“*Child*” means either a person less than 18 years of age or a person 18, 19, or 20 years of age who meets one or more of the following conditions:

1. Is in full-time attendance at an accredited school pursuing a course of study leading to a high school diploma.
2. Is attending an instructional program leading to a high school equivalency diploma.
3. Has been identified by the director of special education of the area education agency as a child requiring special education as defined in Iowa Code section 256B.2(1).

“*Department*” means the Iowa department of human services.

“*Guardianship subsidy*” means a monthly payment to assist in covering the cost of room, board, clothing, and spending money for the child.

“*Nonrecurring expenses*” means reasonable and necessary guardianship fees, court costs, attorney fees, and other expenses that are directly related to finalizing the legal guardianship of a child. These expenses shall be limited to attorney fees, court filing fees and other court costs.

“*Relative*” means, for this chapter only, a person to whom a child is related by blood, marriage, or adoption, or a person who has a significant, committed, positive relationship with the child.

“*Sibling group*” means at least two children who are whole or half-siblings. A sibling group may include adopted children who have a common parent.

[ARC 4167C, IAB 12/5/18, effective 2/1/19; ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.2(234) Eligibility.

204.2(1) *General conditions of eligibility.* The guardian named in a permanency order under Iowa Code section 232.104(2) “*d*”(1) or Iowa Code chapter 633 for a child who was previously in the custody of the department is eligible for subsidy when all of the following conditions exist:

- a. The child has a documented permanency goal of:
 - (1) Guardianship; or
 - (2) Another planned permanent living arrangement.
- b. The child is either:
 - (1) Ten years of age or older and consents to the guardianship; or
 - (2) Part of a sibling group with a child aged ten or older.
- c. The child has lived in continuous foster family care with the prospective guardian for the six months before initiation of the guardianship subsidy.
- d. The prospective guardian is a licensed relative foster parent who has a significant relationship with the child and demonstrates a willingness to make a long-term commitment to the child’s care.
 - (1) The guardian shall be a relative as defined in this chapter.
 - (2) Placement with that guardian must be in the best interest of the child. The best-interest determination must be documented in the case file.
- e. A child who is part of a sibling group with a child ten years of age or older may be eligible for subsidy if all criteria are met. The following conditions for the younger sibling shall also be met:
 - (1) The sibling is placed as a foster child in the same prospective guardian home.
 - (2) The guardian and the department agree it is appropriate for guardianship to be granted for the sibling.

204.2(2) Residency. The subsidized guardianship applicant or recipient need not reside in Iowa.

204.2(3) Unearned income. The family or the guardian shall provide to the department worker documentation from the source of the child's unearned income.

204.2(4) Other services. Other services available to meet the needs of the child that are free of charge, such as federal, state, and local governmental programs, or private assistance programs, shall be explored and used prior to the expenditure of subsidized guardianship funds.

[ARC 4167C, IAB 12/5/18, effective 2/1/19; ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.3(234) Application. Applications for the subsidized guardianship program may be made at any county office of the department.

204.3(1) Application forms. Application for a subsidized guardianship shall be made on the approved department form.

204.3(2) Eligibility determination. The determination of whether a child meets the eligibility requirements is made by the department. The proposed guardian shall be notified in writing of the decision of the department regarding the child's eligibility for the program and the amount of subsidy to be provided.

204.3(3) Effective date. The effective date of the guardianship subsidy payment shall be the date the guardianship order is signed if all other conditions of eligibility are met.

204.3(4) Redetermination. The department worker shall review the child's eligibility, the needs of the child and the child's unearned income every 12 months. Reviews may be done more often if needed due to the child's need for special services, revision of the subsidy amount because of the child's age, or a request for review by the guardian.

204.3(5) Determination of eligibility after age 18. The department shall review the subsidy agreement when the child reaches the age of 17½ to determine whether the child is eligible to receive subsidy to the age of 21 to complete high school or equivalency or due to the child's physical, intellectual, or mental health disability.

a. A disability shall be diagnosed by a physician, a qualified mental health professional or a qualified intellectual disability professional.

b. The diagnosed disability shall be current within one year prior to the child's eighteenth birthday.

c. Documentation of the child's diagnosed disability shall be provided by the child's guardian to the department to make the determination of continued eligibility to the age of 21.

d. Upon the child's reaching the age of 18, the subsidy may continue until the child completes courses leading to a high school diploma or equivalency or reaches the age of 21. Documentation of school enrollment and completion shall be provided by the child's guardian.

[ARC 8914B, IAB 6/30/10, effective 8/4/10; ARC 4167C, IAB 12/5/18, effective 2/1/19; ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.4(234) Negotiation of amount of subsidy.

204.4(1) Subsidy agreement. The amount of subsidy shall be negotiated between the department and the guardian and shall be based upon the needs of the child and the circumstances of the family.

204.4(2) Amount of subsidy. Each time negotiations are completed, the department worker and the guardian shall complete and sign a new Guardianship Subsidy Agreement.

a. The maximum monthly maintenance payment for a child in subsidized guardianship shall be made pursuant to the foster family care maintenance rates according to the age and special needs of the child as found in 441—subrule 156.6(1) and 441—paragraphs 156.6(4)“*b*” and “*f*.”

(1) The rate for the guardianship subsidy shall not exceed the state's current daily basic foster care rate plus any daily special needs allowance or sibling allowance for which the child is eligible, as found in 441—subrule 156.6(1) and 441—paragraphs 156.6(4)“*b*” and “*f*.”

(2) Rescinded IAB 1/3/07, effective 1/1/07.

b. If the subsidized guardianship payment is less than the maximum amount allowed, the guardian may request an increase if there is a substantial change in the child's needs and circumstances that requires additional resources.

c. Guardianship payments shall continue if the guardian dies or becomes incapacitated and has named a successor guardian in the Guardianship Subsidy Agreement or in any amendments to the agreement.

204.4(3) Placement outside of home. If a child needs to be placed out of the guardian's home and the plan is for the child to return to the guardian within six months, a partial subsidy amount may be negotiated.

204.4(4) Nonrecurring expenses. The nonrecurring expenses necessary to finalize a guardianship shall not exceed \$2,000.

204.4(5) Special services.

a. Reimbursement to the guardian family or direct payment made to a provider is limited to the following services.

(1) Outpatient individual or family services provided from a non-Medicaid provider only with approval from the service area manager or designee and when one of the following applies:

1. The services are not available from a Medicaid provider within a reasonable distance from the family.

2. The child and the family were receiving therapy or counseling from a non-Medicaid provider and it would not be in the child's best interest to disrupt the services.

3. Available Medicaid providers lack experience in working with foster, adopted, or blended families.

(2) Travel-related expenses including transportation, meals and lodging not covered by Medicaid for visitation or family therapy when the child is receiving Medicaid-paid services out of the home.

(3) Supplies and equipment as required by the child's special needs and unavailable through other resources.

(4) Funeral benefits at the amount allowed for a foster child in accordance with rule 441—156.8(234).

b. Any single special service and any special service delivered over a 12-month period costing \$500 or more shall have prior approval from the central office program manager prior to expending program funds.

c. For all Medicaid-covered services, the department shall reimburse at the same rate and duration as Medicaid as set forth in rule 441—79.1(249A).

[ARC 4167C, IAB 12/5/18, effective 2/1/19]

441—204.5(234) Parental liability. These subsidy payments are considered foster care payments for purposes of child support recovery and as such create a support debt for the legally responsible parent or parents.

[ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.6(234) Determination of ongoing subsidy eligibility and suspension of subsidy payments.

204.6(1) Eligibility for continuation of guardianship subsidy shall be evaluated when the department has good cause to suspect the guardian is not providing financial support, or is no longer legally responsible for the child. Good cause includes, but is not limited to, the following circumstances:

a. The child is placed in out-of-home care under Iowa Code chapter 232.

b. A person alleges the guardian is not providing financial support to the child.

c. A person other than the guardian is awarded legal custody of the child.

d. A person other than the guardian is appointed as the guardian of the child.

e. The child has applied for food assistance or other benefits.

f. The child has not resided with the guardian for the past 30 consecutive days.

g. The guardian is incarcerated.

h. The guardian is awaiting trial for criminal charges related to harm caused to a child in the home.

204.6(2) The department shall contact the child's guardian via letter, telephone, or electronic or other means and document such efforts if an evaluation is determined to be necessary.

204.6(3) If such an evaluation occurs, the child's guardian shall provide documentation of support, including receipts, to the department upon request.

204.6(4) Upon completion of the department's evaluation of the child's continued eligibility for guardianship subsidy, the department shall issue a written notice to the guardian documenting required ongoing actions by the guardian, including an expectation of continued cooperation by the guardian to provide documentation of ongoing support to the child at the request of the department.

204.6(5) The department shall suspend guardianship subsidy payments if the guardian refuses to cooperate with any department evaluation designed to determine legal responsibility for the child or to determine whether the guardian is providing financial support for the child.

204.6(6) In the event the evaluation has determined the guardianship subsidy payment will be suspended, modified, or terminated, the department shall notify the guardian with proper notice, using Notice of Decision Form 470-5613.

204.6(7) When the child has resided out of the guardian's home for 30 consecutive days, the department shall request a renegotiation of the Guardianship Subsidy Agreement with the guardian to reduce or suspend payments as agreed to by the guardian.

[ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.7(234) Termination of subsidy. A Guardianship Subsidy Agreement shall remain in effect until the subsidy is terminated based on one of the grounds listed in this rule. The subsidy shall terminate when any of the following occur, and a notice shall be sent which states the reason for the termination:

1. The child reaches the age of 18, unless the department determines that the subsidy may continue until the child reaches the age of 21 to facilitate the child's completion of high school or a high school equivalency diploma.

2. The child marries or enlists in the military.

3. The child no longer lives with the guardian, except for placement outside the home as limited by subrule 204.4(3).

4. The relationship ends due to the death of the child.

5. The terms of the Guardianship Subsidy Agreement are concluded.

6. The guardian requests that the guardianship payment cease.

7. The department has determined the guardian is not providing financial support to the child.

8. The guardian fails to abide by the terms of the Guardianship Subsidy Agreement.

9. The guardianship case is terminated by court order.

10. The department funds for subsidized guardianship are no longer available.

[ARC 8914B, IAB 6/30/10, effective 8/4/10; ARC 4167C, IAB 12/5/18, effective 2/1/19; ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.8(234) Reinstatement of subsidy. Reinstatement of the subsidy shall be made when the subsidy was terminated at the guardian's request and the guardian has requested reinstatement.

[ARC 4167C, IAB 12/5/18, effective 2/1/19; ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.9(234) Appeals. The guardian may appeal adverse determination pursuant to 441—Chapter 7.

[ARC 5680C, IAB 6/16/21, effective 8/1/21]

441—204.10(234) Medical assistance. Children eligible for subsidy are entitled to medical assistance as defined in 441—Chapter 75. When an Iowa child receives medical assistance from another state, Iowa shall discontinue paying any medical costs the month following the move unless additional time is necessary for a timely notice of decision to be provided to the guardian.

The funding source for medical assistance is based on the following criteria:

1. Children from Iowa residing in Iowa shall be covered by Iowa's medical assistance.

2. Children from Iowa residing in another state shall receive medical assistance from the state of residence if eligible. Iowa shall provide medical assistance for children not eligible in their state of residence. Medical assistance available in the family's state of residence may vary from Iowa's medical assistance.

3. Children from another state residing in Iowa shall continue to be covered by the other state's medical assistance unless the state has adopted the adoption assistance interstate compact and a contract between Iowa and the other state exists.

[ARC 5680C, IAB 6/16/21, effective 8/1/21]

These rules are intended to implement Iowa Code section 234.6 and 2006 Iowa Acts, House File 2734, section 17, subsection 10.

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481—6.1(10A,17A,ExecOrd11) Applicability. This chapter outlines a uniform process for the granting of waivers from rules adopted by the department. The intent of this chapter is to allow persons to seek exceptions to the application of rules issued by the department.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.2(10A,17A,ExecOrd11) Definitions.

“Attached units” means units attached to the department and includes the employment appeal board, child advocacy board, racing and gaming commission, and state public defender’s office.

“Department” means the department of inspections and appeals authorized by Iowa Code chapter 10A, which is comprised of the administrative division, administrative hearings division, audits division, health facilities division, inspections division and investigations division. Pursuant to Iowa Code section 7E.2(5), five attached units are included in the department.

“Director” means the director of the department of inspections and appeals or the director’s designee.

“Director/board” means the director, board, commission or state public defender depending on which one has the decision-making authority pursuant to Iowa Code chapter 10A or 7E.

“Person” means an individual, corporation, limited liability company, government or governmental subdivision or association, or any legal entity.

[ARC 5670C, IAB 6/2/21, effective 7/21/21; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.3(10A,17A,ExecOrd11) Interpretive rules. This chapter shall not apply to rules that merely define the meaning of a statute or other provision of law or precedent if the department does not possess delegated authority to bind the courts to any extent with its definition.

481—6.4(10A,17A,ExecOrd11) Compliance with statute. The department shall not grant a petition for waiver from a rule unless a statute or other provision of law has delegated authority to the department sufficient to justify that action and the waiver is consistent with the statute or other provision of law. No waiver may be granted from a requirement that is imposed by statute, unless the statute itself specifically authorizes that action. Any waiver must be consistent with statute.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.5(10A,17A,ExecOrd11) Criteria for waiver. At the sole discretion of the director/board, the director/board may issue an order, in response to a completed petition, granting a waiver from a rule adopted by the department, in whole or in part, as applied to the circumstances of a specified person or a specific and narrowly drawn class of persons if the director/board finds based on clear and convincing evidence that:

1. The application of the rule to the petitioner would pose an undue hardship on the person or class of persons for whom the waiver is requested;
2. The waiver from the requirements of a rule in the specific case would not prejudice the substantial legal rights of any person;
3. The provisions of a rule subject to a petition for a waiver are not specifically mandated by statute or another provision of law; and
4. Substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.6(10A,17A,ExecOrd11) Filing of petition. A petition for a waiver must be submitted in writing to the Department of Inspections and Appeals, Office of the Director, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319. If the petition relates to a pending contested case, the petition shall also be filed in the contested case proceeding.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.7(10A,17A,ExecOrd11) Content of petition. A petition for waiver shall include the following information where applicable and known to the requester:

1. The name, address, and telephone number of the entity or person for whom a waiver is being requested and the case number of any related contested case.
2. A description and citation of the specific rule from which a waiver is requested.
3. The specific waiver requested, including the precise scope and operative period that the waiver will extend.
4. The relevant facts that the petitioner believes would justify a waiver. This statement shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition and a statement of reasons that the petitioner believes will justify a waiver.
5. A history of any prior contacts between the department and the petitioner relating to the regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department that would be affected by the proposed waiver, including a description of each regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department, any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department within the last five years.
6. Any information known to the requester regarding the department's treatment of similar cases.
7. The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question or which might be affected by the granting of a waiver.
8. The name, address, and telephone number of any person or entity that would be adversely affected by the granting of a petition.
9. The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver.
10. Signed releases of information authorizing persons with knowledge regarding the request to furnish the department with information relevant to the waiver.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.8(10A,17A,ExecOrd11) Additional information. Prior to issuing an order granting or denying a waiver, the department may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the department may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the department or department's designee.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.9(10A,17A,ExecOrd11) Notice. The department shall acknowledge a petition upon receipt. The department shall ensure that notice of the pendency of the petition and a concise summary of its contents have been provided to all persons to whom notice is required by any provision of law within 30 days of the receipt of the petition. In addition, the department may give notice to other persons. To accomplish this notice provision, the department may require the petitioner to serve the notice on all persons to whom notice is required by any provision of law and provide a written statement to the department attesting that notice has been provided.

481—6.10(10A,17A,ExecOrd11) Hearing procedures. The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply to any petition for a waiver of rule filed within a contested case and shall otherwise apply to agency proceedings for a waiver only when the department so provides by rule or order or is required to do so by statute.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.11(10A,17A,ExecOrd11) Ruling. An order granting or denying a waiver shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains,

a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and operative period of the waiver if one is issued.

6.11(1) Director/board discretion. The decision on whether the circumstances justify the granting of a waiver shall be made at the discretion of the director upon consideration of all relevant factors, except for the below-listed programs, for which the applicable board, commission or state public defender shall make the decision, upon consideration of all relevant factors:

- a. Employment appeal board, 486—Chapter 1.
- b. Child advocacy board, 489—Chapter 1.
- c. Racing and gaming commission, 491—Chapter 1.
- d. State public defender's office, 493—Chapter 1.

6.11(2) Burden of persuasion. The petitioner has the burden of persuasion when a petition is filed for a waiver from a department rule. The standard of proof is clear and convincing evidence.

6.11(3) Special waiver rules not precluded. This chapter shall not preclude the department from granting waivers in other contexts or on the basis of other standards if a statute authorizes the department to do so and the department deems it appropriate to do so.

6.11(4) Administrative deadlines. When the rule from which a waiver is sought establishes administrative deadlines, the director/board shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all persons similarly situated.

6.11(5) Conditions. The director/board may condition the granting of the waiver on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means and in compliance with the following provisions:

- a. Each petition for a waiver shall be evaluated by the department based on the unique, individual circumstances set out in the petition;
- b. A waiver, if granted, shall be drafted by the department so as to provide the narrowest exception possible to the provisions of the rule;
- c. The department may place on a waiver a condition that the department finds desirable to protect the public health, safety, and welfare;
- d. A waiver shall not be permanent, unless the petitioner can show that a temporary waiver would be impracticable; and
- e. If a temporary waiver is granted, there is no automatic right to renewal. At the sole discretion of the department, a waiver may be renewed if the department finds that all of the factors set out in rule 481—6.5(10A,17A,ExecOrd11) remain valid.

6.11(6) Time for ruling. The director/board shall grant or deny a petition for a waiver as soon as practicable but, in any event, shall do so within 120 days of its receipt, unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the director/board has the discretion to wait until the contested case is resolved before entering an order on the petition for waiver.

6.11(7) When deemed denied. Failure of the director/board to grant or deny a petition within the required time period shall be deemed a denial of that petition by the director/board.

6.11(8) Service of order. Within seven days of its issuance, any order issued under this chapter shall be transmitted to the petitioner or the person to whom the order pertains and to any other person entitled to such notice by any provision of law.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.12(10A,17A,ExecOrd11) Public availability.

6.12(1) Subject to the provisions of Iowa Code section 17A.3(1)“e,” the department shall maintain a record of all orders granting or denying waivers under this chapter. All final rulings in response to requests for waivers shall be indexed and available to members of the public at the director's office.

6.12(2) Within 60 days of granting or denying a waiver, the department must make a submission on the Internet site established pursuant to Iowa Code section 17A.9A for the submission of waiver information.

- a. The submission shall:
 - (1) Identify the rules for which a waiver has been granted or denied;

- (2) Identify the number of times a waiver was granted or denied for each rule;
- (3) Include a citation to the statutory provisions implemented by these rules; and
- (4) Include a general summary of the reasons justifying the department’s actions.

b. To the extent practicable, the department shall include information detailing the extent to which the granting of a waiver has established a precedent for additional waivers and the extent to which the granting of a waiver has affected the general applicability of the rule itself.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.13(10A,17A,ExecOrd11) Voiding or cancellation. A waiver is void if the material facts upon which the request is based are not true or if material facts have been withheld. The director/board may at any time cancel a waiver upon appropriate notice and hearing if the director/board finds that the facts as stated in the request are not true, material facts have been withheld, the alternative means of compliance provided in the waiver have failed to achieve the objectives of the statute, or the requester has failed to comply with the conditions of the order.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.14(10A,17A,ExecOrd11) Violations. Violation of conditions in the waiver approval is the equivalent of violation of the particular rule for which the waiver is granted and is subject to the same remedies or penalties.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.15(10A,17A,ExecOrd11) Defense. After the director/board issues an order granting a waiver, the order is a defense within its terms and the specific facts indicated therein for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.16(10A,17A,ExecOrd11) Appeals. Any request for an appeal from a decision granting or denying a waiver shall be in accordance with the procedures provided in Iowa Code chapter 17A and rules adopted by the department. An appeal shall be taken within 30 days of the issuance of the ruling in response to the request unless a contrary time is provided by rule or statute.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—6.17(10A,17A,ExecOrd11) Sample petition for waiver.

BEFORE THE DEPARTMENT OF INSPECTIONS AND APPEALS	
Petition by (insert the name of petitioner) for the waiver of (insert rule citation) relating to (insert the subject matter).	}
PETITION FOR WAIVER	

Include the following information in the petition for waiver where applicable and known:

1. Provide the petitioner’s (the person that is asking for the waiver) name, address and telephone number.
2. Describe and cite the specific rule from which a waiver is requested.
3. Describe the specific waiver requested. Include the exact scope and time period that the waiver will extend.
4. Explain the important facts that the petitioner believes justify the waiver. Include in your explanation (a) why application of the rule would pose an undue hardship to the petitioner; (b) why granting the waiver would not prejudice the substantial legal rights of any person; (c) state whether the provisions of a rule subject to this petition are specifically mandated by statute or another provision of law; and (d) state whether public health, safety and welfare will be affected if the requested waiver is granted.
5. Provide history of prior contacts between the department and the petitioner relating to the regulated activity, license, audit, investigation, inspection or representation that would be affected by the waiver. In that history, include a description of each affected regulated activity, license, appeal,

hearing, audit, investigation, inspection, representation or other assigned function of the department, any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department within the last five years.

6. Provide information known to the petitioner regarding the department’s treatment of similar cases.

7. Provide the name, address and telephone number of any public agency or political subdivision which also regulates the activity in question or which might be affected by the granting of a waiver.

8. Provide the name, address and telephone number of any person or entity that would be adversely affected or disadvantaged by the granting of the waiver.

9. Provide signed releases of information authorizing persons with knowledge regarding the request to furnish the department with information relevant to the waiver.

I hereby attest to the accuracy and truthfulness of the above information.

Petitioner’s signature

Date

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

These rules are intended to implement Iowa Code section 17A.9A and Executive Order Number 11.

[Filed 4/12/01, Notice 1/24/01—published 5/2/01, effective 6/6/01]

[Filed ARC 5670C (Notice ARC 5551C, IAB 4/7/21), IAB 6/2/21, effective 7/21/21]

[Filed ARC 5719C (Notice ARC 5560C, IAB 4/21/21), IAB 6/16/21, effective 7/21/21]

CHAPTER 41
PSYCHIATRIC MEDICAL INSTITUTIONS FOR CHILDREN (PMIC)

481—41.1(135H) Definitions.

“Nurse practitioner” means a registered professional nurse who is currently licensed to practice in the state, who meets state requirements and is currently licensed to practice nursing under the nursing board[655] rules in the Iowa Administrative Code.

“Physician” means a person licensed to practice medicine and surgery, osteopathic medicine and surgery or osteopathy under Iowa Code chapter 148, 150 or 150A.

“Physician assistant” means a person licensed to practice under Iowa Code chapter 148C.

“Psychiatric services” means services provided under the direction of a physician which address mental, emotional, medical or behavioral problems.

“Resident” means a person who is less than 21 years of age and has been admitted by a physician to a psychiatric medical institution for children.

481—41.2(135H) Application for license. In order to obtain an initial license for a PMIC, the applicant must comply with Iowa Code chapter 135H and the rules in this chapter. Each applicant must submit the following documents to the department:

1. A completed Psychiatric Medical Institutions for Children application;
2. A copy of a department of human services license as a comprehensive residential care facility issued pursuant to Iowa Code section 237.3(2)“a,” or a copy of a license granted by the department of public health pursuant to Iowa Code section 125.13, as a facility which provides substance abuse treatment;

3. A floor plan of each floor of the facility on 8½” by 11” paper showing:

Room areas in proportion,

Room dimensions,

Numbers for all rooms including bathrooms,

A designation of use for each room, and

Window and door locations;

4. A photograph of the front and side elevation of the facility;

5. The PMIC license fee; and

6. Evidence of:

Accreditation by the joint commission on accreditation of health care organizations (JCAHO);

Department of public health certificate of need;

Department of human services determination of approval; and

Three years under the direction of an agency which has operated a facility:

- Licensed under Iowa Code section 237.3(2)“a,” or

• Providing services exclusively to children or adolescents and the facility meets or exceeds the requirements for licensure under Iowa Code section 237.3(2)“a.”

This rule is intended to implement Iowa Code sections 135H.4 and 135H.5.

481—41.3(135H) Renewal application or change of ownership. In order to renew a license or change ownership of the psychiatric medical institution for children, the applicant must submit to the department:

1. A completed application form 30 days before the renewal date or before the date of the ownership change;

2. The PMIC license fee; and

3. A copy of any revisions to the department of human services application for a comprehensive care residential facility license.

41.3(1) Denial, suspension or revocation of a license. The department may deny, suspend or revoke a PMIC license for any of the following reasons:

- a. The applicant or licensee failed to comply with the rules in this chapter;

- b. A resident is a victim of cruelty or neglect because of the acts or omissions of the licensee;

- c. The licensee permitted, aided or abetted in the commission of an illegal act in the institution; or
- d. The applicant or licensee attempted to obtain or retain a license by fraudulent means, misrepresentation, or by submitting false information.

The department will issue notice of denial, suspension or revocation by certified mail or by personal service.

41.3(2) Appeal process. When a license is denied, revoked or suspended, a hearing may be requested pursuant to 481—subrule 50.5(2) and shall be conducted pursuant to rule 481—50.6(10A). During the appeal process, the status of a license shall remain as it was on the date the hearing was requested. The status shall not change until a final decision is rendered by the department.

This rule is intended to implement Iowa Code sections 135H.8 and 135H.9.

481—41.4(135H) Licenses for distinct parts. Separate licenses may be issued for clearly identifiable parts of a health care facility as defined in Iowa Code section 135C.1 or a hospital as defined in Iowa Code section 135B.1. A distinct part must contain contiguous rooms in a separate wing or building or be on a separate floor of the facility. Distinct parts shall provide care and services of separate categories. The following requirements shall be met for licensing a distinct part:

41.4(1) The distinct part shall serve only children who require the category of care and services immediately available within that part.

41.4(2) The distinct part shall meet all the standards, rules and regulations which pertain to the category for which a license is sought.

41.4(3) The distinct part must be operationally and financially feasible.

41.4(4) A separate personal care staff with qualifications appropriate to the care and services offered must be regularly assigned and working in the distinct part under responsible management.

41.4(5) Separately licensed distinct parts may have some services such as management, building maintenance, laundry and dietary in common with each other.

481—41.5(135H) Waivers. Waivers from these rules may be granted by the director of the department:

1. When the need for a waiver has been established; and
2. When there is no danger to the health, safety, welfare or rights of any child.

The waiver will apply only to a specific PMIC.

Waivers shall be reviewed at the time of each licensure survey by the department to determine continuing need.

41.5(1) To request a waiver, the licensee must:

- a. Apply in writing on a form provided by the department;
- b. Cite the rule or rules from which a waiver is desired;
- c. State why compliance with the rule or rules cannot be accomplished;
- d. Explain how the waiver is consistent with the individual program plans; and
- e. Demonstrate that the requested waiver will not endanger the health, safety, welfare or rights of any child.

41.5(2) Upon receipt of a request for waiver, the director shall:

- a. Examine the rule from which the waiver is requested;
- b. Evaluate the requested waiver against the requirement of the rule to determine whether the request is necessary to meet the needs of the children; and
- c. Examine the effect of the requested waiver on the health, safety or welfare of the children.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—41.6(135H) Notice to the department.

41.6(1) The department shall be notified at the times stated when the following events are expected to occur:

- a. Thirty days before addition, alteration or new construction is begun in the PMIC or on the premises;
- b. Thirty days in advance of closure of the PMIC;

- c. Within two weeks of any change of administrator; and
- d. Within 30 days when a change in the category of license is sought.

41.6(2) Prior to the purchase, transfer, assignment or lease of a PMIC the licensee shall:

- a. Inform the department in writing of the pending sale, transfer, assignment or lease of the facility;
- b. Inform the department in writing of the name and address of the prospective purchaser, transferee, assignee or lessee at least 30 days before the sale, transfer, assignment or lease is complete;
- c. Submit written authorization to the department permitting the department to release information of whatever kind from department files concerning the licensee's PMIC to the named prospective purchaser, transferee, assignee or lessee.

481—41.7(135H) Inspection of complaints. The department shall conduct a preliminary review of all complaints filed against a PMIC. Unless a complaint is determined to be intended as harassment or to be without reasonable basis, the department shall inspect the PMIC within 20 working days of receipt of the complaint.

This rule is intended to implement Iowa Code section 135H.12.

481—41.8(135H) General requirement. Inpatient psychiatric services for recipients under age 21 must be provided under the direction of a physician.

When a resident has received services immediately before reaching age 21, services must be complete before the earlier of the following:

1. The date the recipient no longer requires services; or
2. The date the recipient reaches age 22.

481—41.9(135H) Certification of need for services. All recipients of services shall have written certification which ensures the following:

1. Ambulatory care resources available in the community do not meet the treatment needs of the recipient;
2. Proper treatment of the recipient's psychiatric condition requires services on an inpatient basis under the direction of a physician; and
3. The services can reasonably be expected to improve the recipient's condition or prevent further regression so services will no longer be needed.

Certification of need shall be completed by the team described in subrules 41.13(2) and 41.13(3). Certification must be made at the time of admission by an independent team for Medicaid recipients. For emergency admissions, the certification must be made by the team described in 41.13(135H) within 14 days after admission. If an individual applies for Medicaid while in a PMIC, certification of need must be made by the team described in 41.13(135H) before a Medicaid agency authorizes payment.

481—41.10(135H) Active treatment. Inpatient psychiatric services must involve "active treatment," which means implementation of a professionally developed and supervised individual plan of care as described in rule 41.12(135H). The plan of care shall be:

1. Developed and implemented no later than 14 days after admission; and
2. Designed to achieve discharge from inpatient status at the earliest possible time.

481—41.11(135H) Individual plan of care. "Individual plan of care" means a written plan developed for each child. The plan of care shall be designed to improve the condition of each child to the extent that inpatient care is no longer necessary.

41.11(1) The plan of care must be based on a diagnostic evaluation that includes examination of the:

- a. Medical,
- b. Psychological,
- c. Social,
- d. Behavioral, and
- e. Developmental aspects of the child's situation.

The plan of care shall reflect the need for inpatient psychiatric care.

41.11(2) The plan of care shall be developed by the team of professionals specified in rule 41.13(135H) in consultation with the recipient, the parents, legal guardian or other person into whose care the child will be released after discharge. The plan of care shall include:

- a.* Diagnoses, symptoms, complaints and complications indicating the need for admission;
- b.* Treatment objectives;
- c.* An integrated program of therapies, activities and experiences designed to meet the objectives;
- d.* A description of the functional level of the individual;
- e.* Any orders for:
 - (1) Medications,
 - (2) Treatments,
 - (3) Restorative and rehabilitative services,
 - (4) Activities,
 - (5) Therapies,
 - (6) Social services,
 - (7) Diet, and
 - (8) Special procedures recommended for the health and safety of the patient; and
- f.* At an appropriate time, postdischarge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the recipient's family, school and community upon discharge.

41.11(3) The plan of care shall be reviewed every 30 days by the team referred to in rule 41.13(135H) to:

- a.* Determine that services being provided are or were required on an inpatient basis; and
- b.* Recommend changes in the plan as indicated by the recipient's overall adjustment as an inpatient.

This rule is intended to implement Iowa Code section 135H.3.

481—41.12(135H) Individual written plan of care. Before admission to a PMIC and before authorization for payment, the attending physician or staff physician must establish written plans for continuing care including review and modification of the plan of care.

481—41.13(135H) Plan of care team. The individual plan of care shall be developed by an interdisciplinary team of physicians and other personnel who are employed by the facility or provide services to patients.

41.13(1) Based on education and experience, the team must be capable of:

- a.* Assessing the recipient's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;
- b.* Assessing the potential resources of the recipient's family;
- c.* Setting treatment objectives; and
- d.* Prescribing therapeutic modalities to achieve the plan's objectives.

41.13(2) The team shall include at least one member who is experienced in child psychiatry or child psychology and must include, as a minimum, either:

- a.* A board-eligible or board-certified psychiatrist; or
- b.* A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or
- c.* A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnoses and treatment of mental diseases, and a psychologist who has a master's degree in clinical psychology or who has been certified by the state psychological association.

41.13(3) The team must also include one of the following:

- a.* A psychiatric social worker;
- b.* A registered nurse with specialized training or one year of experience in treating mentally ill individuals;

c. A licensed occupational therapist who has specialized training in treating mentally ill individuals; or

d. A psychologist who has a master's degree in clinical psychology or who has been certified by the state psychological association.

This rule is intended to implement Iowa Code section 135H.3.

481—41.14(135H) Required discharge. The licensee shall not refuse to discharge a child when directed by the physician, parent or legal guardian unless so directed by the court.

481—41.15(135H) Criminal behavior involving children. A person who has a record of a criminal conviction or a founded child abuse or dependent adult abuse shall not be licensed to operate, be employed by, or reside in a PMIC unless an evaluation of the crime or founded child or dependent adult abuse has been made by the department of human services which concludes that the crime or founded child or dependent adult abuse does not merit prohibition of employment.

41.15(1) A PMIC shall request that the department of human services (DHS) conduct a criminal and child abuse record check, when a person is being considered for licensure or for employment if the person will:

- a.* Have direct responsibility for a child;
- b.* Have access to a child when the child is alone; or
- c.* Reside in the facility.

41.15(2) A PMIC shall inform all new applicants for employment of the requirement for the criminal and child abuse record checks and the possibility of a dependent adult abuse record check. The PMIC shall obtain, from the applicant, a signed acknowledgment of the receipt of this information.

41.15(3) A PMIC shall include the following inquiry in an application for employment: "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime, in this state or any other state?"

41.15(4) DHS will inform the PMIC of the results of the criminal, child abuse, and dependent adult abuse record checks. If a record of a criminal conviction or founded child or dependent adult abuse exists, the PMIC will be informed on Form 470-2310, "Record Check Evaluation." The subject of the report shall complete that form and it shall be returned to DHS to request evaluation of the record to determine whether prohibition of the person's licensure, employment, or residence is warranted.

41.15(5) If the evaluation is not requested or if the DHS determines that the person has committed a crime or has a record of founded child abuse or dependent adult abuse which warrants prohibition of licensure, employment, or residence, the person shall not be licensed to operate, be employed by, or reside in a PMIC.

This rule is intended to implement Iowa Code section 135H.7.

481—41.16(22,135H) Confidential or open information. The department maintains files for psychiatric medical institutions for children. These files are organized by facility name and contain both open and confidential information.

41.16(1) Open information includes:

- a.* License application and status;
- b.* Waiver requests and responses;
- c.* Final findings of state license survey investigations;
- d.* Records of complaints;
- e.* Plans of correction submitted by the facility;
- f.* Medicaid status; and
- g.* Official notices of license sanctions.

41.16(2) Confidential information includes:

a. Inspection or investigation information which does not comprise a final finding. This information may be made public in a proceeding concerning the denial, suspension or revocation of a license, under Iowa Code section 135H.8;

- b. Names of all complainants; and
- c. Names of children in all facilities, identifying information and the address of anyone other than an owner.

This rule is intended to implement Iowa Code sections 22.11, 135H.11 and 135H.13.
[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—41.17(135H) Additional provisions concerning physical restraint. If a PMIC uses a physical restraint, the following provisions shall apply:

41.17(1) No employee shall use any prone restraints. For the purposes of this rule, “prone restraints” means those in which an individual is held face down on the floor. Employees who find themselves involved in the use of a prone restraint as the result of responding to an emergency must take immediate steps to end the prone restraint.

41.17(2) No employee shall use any restraint that obstructs the airway of any resident.

41.17(3) If an employee physically restrains a resident who uses sign language or an augmentative mode of communication as the resident’s primary mode of communication, the resident shall be permitted to have the resident’s hands free of restraint for brief periods, unless an employee determines that such freedom appears likely to result in harm to self or others.

This rule is intended to implement Iowa Code sections 135H.4 and 135H.5.
[ARC 8857B, IAB 6/16/10, effective 7/21/10]

This chapter is intended to implement Iowa Code chapters 17A, 22 and 135H.

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CHAPTER 50
HEALTH CARE FACILITIES ADMINISTRATION

481—50.1(10A) Inspections. The health facilities division inspects health care facilities, hospitals, and providers and suppliers of medical services in Iowa. Standards to obtain a license are explained in this chapter.

481—50.2(10A) Definitions.

“Administrator” means the person coordinating the administration of the division.

“Department” means the department of inspections and appeals.

“Director” means the director of inspections and appeals.

“Division” means the health facilities division.

481—50.3(135B,135C) Licensing. All hospitals and health care facilities shall be licensed by the department. Applications are available from the Health Facilities Division, Lucas State Office Building, Des Moines, Iowa 50319-0083. Completed applications are returned to the division with the fee.

50.3(1) Initial fees for hospitals are:

- a. Fifty beds or less, \$15;
- b. More than 50 and not more than 100 beds, \$25;
- c. Any greater number of beds, \$50.

A fee of \$10 is charged to renew a hospital license each year.

50.3(2) Initial and renewal fees for health care facilities are:

- a. Ten beds or less, \$20;
- b. More than 10 and not more than 25 beds, \$40;
- c. More than 26 and not more than 75 beds, \$60;
- d. More than 76 and not more than 150 beds, \$80;
- e. Any greater number of beds, \$100.

50.3(3) Standards used to determine whether a license is granted or retained are found in the rules of the department of inspections and appeals in the Iowa Administrative Code as follows:

- a. Hospitals, 481—Chapter 51;
- b. Hospices, 481—Chapter 53;
- c. Residential care facilities, 481—Chapters 57 and 60;
- d. Nursing facilities, 481—Chapters 58 and 61;
- e. Residential care facilities for persons with mental illness, 481—Chapters 60 and 62;
- f. Residential care facilities for the intellectually disabled, 481—Chapters 60 and 63;
- g. Intermediate care facilities for the intellectually disabled, 481—Chapter 64; and
- h. Intermediate care facilities for persons with mental illness, 481—Chapter 65.

50.3(4) Posting of license. The license shall be posted in each facility so the public can see it easily.
[ARC 0766C, IAB 5/29/13, effective 7/3/13]

481—50.4(135C) Fines and citations. A fine or citation will be issued and may be contested according to the rules in 481—Chapter 56.

481—50.5(135C) Denial, suspension or revocation.

50.5(1) A denial, suspension or revocation shall be effective 30 days after certified mailing or personal service of the notice.

50.5(2) A hearing may be requested and the request must be made in writing to the department within 30 days of the mailing or service.

481—50.6(10A) Formal hearing. All decisions of the division may be contested. Appeals and hearings are controlled by 481—Chapter 9, “Contested Cases.”

50.6(1) The proposed decision of the hearing officer becomes final ten days after it is mailed.

50.6(2) Any request for administrative review of a proposed decision must:

1. Be made in writing,
2. Be mailed by certified mail to the director, within ten days after the proposed decision was mailed to the aggrieved party,
3. State the reason(s) for the request.

A copy shall also be sent to the hearing officer at the Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

50.6(3) The decision of the director shall be based upon the record and becomes final agency action upon mailing by certified mail.

50.6(4) The fees of witnesses for attendance and travel shall be the same as the fees for witnesses before the district court and shall be paid by the party to the proceeding at whose request the subpoena is issued.

[ARC 3523C, IAB 12/20/17, effective 1/24/18]

481—50.7(10A,135C) Additional notification. The director or the director’s designee shall be notified within 24 hours, or the next business day, by the most expeditious means available (I,II,III):

50.7(1) Of any accident causing major injury.

a. “Major injury” shall be defined as any injury which:

- (1) Results in death; or
- (2) Requires admission to a higher level of care for treatment, other than for observation; or
- (3) Requires consultation with the attending physician, designee of the physician, or physician extender who determines, in writing on a form designated by the department, that an injury is a “major injury” based upon the circumstances of the accident, the previous functional ability of the resident, and the resident’s prognosis.

b. The following are not reportable accidents:

- (1) An ambulatory resident, as defined in rules 481—57.1(135C), 481—58.1(135C), and 481—63.1(135C), who falls when neither the facility nor its employees have culpability related to the fall, even if the resident sustains a major injury; or
- (2) Spontaneous fractures; or
- (3) Hairline fractures.

50.7(2) When damage to the facility is caused by a natural or other disaster.

50.7(3) When there is an act that causes major injury to a resident or when a facility has knowledge of a pattern of acts committed by the same resident on another resident that results in any physical injury. For the purposes of this subrule, “pattern” means two or more times within a 30-day period.

50.7(4) When a resident elopes from a facility. For the purposes of this subrule, “elopes” means when a resident who has impaired decision-making ability leaves the facility without the knowledge or authorization of staff.

50.7(5) When a resident attempts suicide, regardless of injury.

50.7(6) When a fire occurs in a facility and the fire requires the notification of emergency services, require full or partial evacuation of the facility, or causes physical injury to a resident.

50.7(7) When a defect or failure occurs in the fire sprinkler or fire alarm system for more than 4 hours in a 24-hour period. (This reporting requirement is in addition to the requirement to notify the state fire marshal.)

NOTE: Additional reporting requirements are created by other rules and statutes, including but not limited to Iowa Code chapter 235B and 2008 Iowa Acts, House File 2591, which require reporting of dependent adult abuse.

481—50.8(22,135B,135C) Records. The division collects and stores a variety of records in the course of licensing and inspecting health care facilities. Some information stored may be personally identifiable. None is retrievable by personal identifier with the exception of a business which uses an individual’s name in the title. All records stored by the health facilities division are kept in files under the name of a facility. Computer files are retrieved by facility name also.

50.8(1) The department maintains information about long-term care facilities in files which are organized by facility name, city, and county. No information is retrievable by personal identifier. Each long-term care facility record contains both open and confidential information.

a. Open information includes:

- (1) License application and status,
- (2) Waiver requests and responses,
- (3) Final findings of state and Medicaid survey investigations,
- (4) Records of complaints,
- (5) Reports from the fire marshal,
- (6) Plans of correction submitted by the facility,
- (7) Medicaid status,
- (8) Official notices of license and Medicaid sanctions.

b. Confidential information includes:

- (1) Survey or investigation information which does not comprise a final finding. Survey information which does not comprise a final finding may be made public in a proceeding concerning the citation of a facility, denial, suspension or revocation of a license, Iowa Code section 135C.19(1),
- (2) Names of all complainants, Iowa Code sections 135C.19(1) and 135C.37,
- (3) Names of patients in all facilities, identifying medical information and the address of anyone other than an owner, Section 1106 of the Social Security Act as amended, 42 CFR Part 401, Subpart B (October 1, 1986) and Iowa Code sections 22.9 and 135C.19(1).

50.8(2) The department maintains records about hospitals. The records are organized by facility name, city, and county. The records are not retrievable by personal identifier. The Joint Commission on the Accreditation of Healthcare Organizations is referred to as JCAHO, and the American Osteopathic Association is referred to as AOA in this rule. These records may contain both open and confidential information.

a. Open information includes:

- (1) License status,
- (2) Medicare certification status,
- (3) Medicare survey reports,
- (4) Plans of correction submitted by a hospital,
- (5) Official notices of involuntary provider termination or license sanctions,
- (6) For hospitals not certified by JCAHO or AOA, reports of the fire marshal,
- (7) Final survey findings of the JCAHO and the AOA with respect to compliance by a hospital with the requirements for licensure or accreditation.

b. Confidential information includes:

- (1) Names of patients and identifying medical information,
- (2) Identity of any complainant, and
- (3) The address of anyone other than the owner, Iowa Code section 135B.12 and Section 1106 of the Social Security Act, 42 CFR Part 401, Subpart B (October 1, 1986) and Iowa Code section 22.9.
- (4) Rescinded IAB 2/19/92, effective 3/25/92.
- (5) No information may be disclosed in a manner which will identify individuals or hospitals except in a proceeding concerning the question of license or the denial, suspension or revocation of a license, Iowa Code section 135B.12.

50.8(3) The department maintains files for all other Medicare-certified facilities. These files are organized by facility or agency name, city, and county. None is retrievable by personal identifier except when a business uses an individual's name in its title. These files contain both open and confidential information.

a. Open information includes:

- (1) Certification status,
- (2) Survey reports,
- (3) Plans of correction,
- (4) Official notices of involuntary provider termination,

(5) Proficiency test results for non-JCAHO or AOA accredited hospitals, Medicare laboratories and laboratories licensed under the clinical Laboratory Improvement Act.

b. Confidential information includes:

- (1) Name of any patient,
- (2) Medical information about any identifiable patient,
- (3) The identity of any complainant, and
- (4) The address of anyone other than an owner of the facility, Section 1106 of the Social Security Act, 43 CFR, Part 401, Subpart B (October 1, 1986), and Iowa Code section 22.9.

50.8(4) Rescinded IAB 3/31/04, effective 5/5/04.

50.8(5) Following a written request and payment of a fee in the amount determined by the department, one or more of the following lists may be obtained by the public.

a. Corporations which own more than one facility and the list of facilities owned by each corporation.

b. All the facilities in the state with the owner of the real estate property identified.

c. All corporations that lease facilities and the facilities they lease.

d. All corporations which manage facilities for other owners and the facilities they manage.

Requests are sent to Health Facilities Division, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—50.9(135C) Criminal, dependent adult abuse, and child abuse record checks.

50.9(1) *Definitions.* The following definitions apply for the purposes of this rule.

“Background check” or *“record check”* means criminal history, child abuse and dependent adult abuse record checks.

“Certified nurse aide training program” means a program approved in accordance with the rules for such programs adopted by the department of human services for the training of persons seeking to be a certified nurse aide for employment in a facility as defined by this rule or in a hospital as defined in Iowa Code section 135B.1.

“Comprehensive preliminary background check” means a criminal history check of all states in which the applicant has worked or resided over the seven-year period immediately prior to submitting an application for employment or participation in a certified nurse aide training program that is conducted by an approved third-party vendor.

“Direct services” means services provided through person-to-person contact. “Direct services” excludes services provided by individuals such as building contractors, repair workers, or others who are in a facility for a very limited purpose, are not in the facility on a regular basis, and who do not provide any treatment or services for residents, patients, tenants, or participants of the provider.

“Employed in a facility” or *“employment within a facility”* means all of the following if the provider is regulated by the state or receives any federal or state funding:

1. An employee of a health care facility licensed under Iowa Code chapter 135C if the employee provides direct or indirect services to residents;
2. An employee of a home health agency if the employee provides direct services to consumers;
3. An employee of a hospice if the employee provides direct services to consumers.

“Employee” means any individual who is paid either by the facility or any other entity (i.e., temporary agency, private duty, Medicare/Medicaid or independent contractors).

“Evaluation” means review by the department of human services to determine whether a founded child abuse, dependent adult abuse or criminal conviction warrants prohibition of the person’s employment in a facility; or whether a founded child abuse, dependent adult abuse or criminal conviction warrants prohibition of a student’s involvement in a clinical education component of the certified nurse aide training program involving children or dependent adults.

“Facility,” for purposes of this rule, means all of the following if the provider is regulated by the state or receives any federal or state funding:

1. A health care facility licensed under Iowa Code chapter 135C;

2. A home health agency;
3. A hospice.

“*Indirect services*” means services provided without person-to-person contact such as those provided by administration, dietary, laundry, and maintenance.

“*Student*” means a person applying for, enrolled in, or returning to a certified nurse aide training program.

50.9(2) *Explanation of “crime.”* For purposes of this rule, the term “crime” does not include offenses under Iowa Code chapter 321 classified as simple misdemeanor or equivalent simple misdemeanor offenses from another jurisdiction.

50.9(3) *Requirements for employer prior to employing an individual.* Prior to employment of a person in a facility, the facility shall complete the background check requirements set forth below.

a. Informing the prospective employee. A facility shall ask each person seeking employment by the facility, “Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime other than a simple misdemeanor offense relating to motor vehicles and laws of the road under Iowa Code chapter 321 or equivalent provisions, in this state or any other state?” In addition, the person shall be informed that a background check will be conducted. The person shall indicate, by signature, that the person has been informed that the background check will be conducted. (I, II, III)

b. Conducting a background check. The facility shall either request that the department of public safety perform a criminal history check and that the department of human services perform child and dependent adult abuse record checks of the person in this state, or access the single contact repository (SING) to perform the required background check. If the SING is used, the facility shall submit the person’s maiden name, if applicable, with the background check request. (I, II, III)

c. If a person being considered for employment has been convicted of a crime. If a person being considered for employment in a facility has been convicted of a crime under a law of any state, the facility shall request that the department of human services perform an evaluation to determine whether the crime warrants prohibition of the person’s employment in the facility. (I, II, III)

d. If a person being considered for employment has a record of founded child or dependent adult abuse. If a person being considered for employment in a facility has a record of founded child or dependent adult abuse under a law of any state, the facility shall request that the department of human services perform an evaluation to determine whether the founded child or dependent adult abuse warrants prohibition of the person’s employment in the facility. (I, II, III)

e. Employment pending evaluation. The facility may provisionally employ a person prior to completion of the required record check and evaluation by the department of human services, as applicable, subject to all of the following:

(1) The facility shall have accessed SING to perform the required record check and be awaiting results from SING or awaiting evaluation by the department of human services, as applicable;

(2) If applicable, the facility shall request an evaluation by the department of human services in accordance with paragraph 50.9(3) “c” or “d” within 30 days of receipt of the SING record check results;

(3) The facility shall have utilized an approved third-party vendor to perform a comprehensive preliminary background check;

(4) If the comprehensive preliminary background check determines that the person being considered for employment has been convicted of a crime, the crime does not constitute a felony as defined in Iowa Code section 701.7 and is not a crime specified pursuant to Iowa Code chapter 708, 708A, 709, 709A, 710, 710A, 711, or 712 or pursuant to Iowa Code section 726.3, 726.7, or 726.8;

(5) The comprehensive preliminary background check shall have determined that the person being considered for employment does not have a record of founded child abuse or dependent adult abuse, or, if the person being considered for employment does have a record of founded child abuse or dependent adult abuse, subrule 50.9(8) is applicable; and

(6) The provisional employment may continue until such time as the required record check through SING and evaluation by the department of human services, as applicable, are completed. (I, II, III)

50.9(4) *Validity of background check results.* The results of a background check conducted pursuant to this rule shall be valid for a period of 30 calendar days from the date the results of the background check are received by the facility. (I, II, III)

50.9(5) *Employment prohibition.* Except as provided in paragraph 50.9(3)“e,” a person who has committed a crime or has a record of founded child or dependent adult abuse shall not be employed in a facility unless an evaluation has been performed by the department of human services. (I, II, III)

50.9(6) *Transfer of an employee to another facility owned or operated by the same person.* If an employee transfers from one facility to another facility owned or operated by the same person, without a lapse in employment, the facility is not required to request additional criminal and child and dependent adult abuse record checks of that employee. (I, II, III)

50.9(7) *Transfer of ownership of a facility.* If the ownership of a facility is transferred, at the time of transfer the background check required by this rule shall be performed for each employee for whom there is no documentation that such background check has been performed. The facility may continue to employ such employee pending the performance of the background check and any related evaluation. (I, II, III)

50.9(8) *Change of employment—person with criminal or abuse record—exception to record check evaluation requirements.* A person with a criminal or abuse record who is or was employed by a facility and is hired by another facility shall be subject to the background check.

a. A reevaluation of the latest record check is not required, and the person may commence employment with the other facility if the following requirements are met:

(1) The department of human services previously performed an evaluation concerning the person’s criminal or abuse record and concluded the record did not warrant prohibition of the person’s employment;

(2) The latest background check does not indicate a crime was committed or founded abuse record was entered subsequent to the previous evaluation;

(3) The position with the subsequent employer is substantially the same or has the same job responsibilities as the position for which the previous evaluation was performed;

(4) Any restrictions placed on the person’s employment in the previous evaluation by the department of human services and still applicable shall remain applicable in the person’s subsequent employment; and

(5) The person subject to the background check has maintained a copy of the previous evaluation and provided it to the subsequent employer, or the previous employer provides the previous evaluation from the person’s personnel file pursuant to the person’s authorization. If a physical copy of the previous evaluation is not provided to the subsequent employer, a current record check evaluation shall be performed. (I, II, III)

b. For purposes of this subrule, a position is “substantially the same or has the same job responsibilities” if the position requires the same certification, licensure, or advanced training. For example, a licensed nurse has substantially the same or the same job responsibilities as a director of nursing; a certified nurse aide does not have substantially the same or the same job responsibilities as a licensed nurse.

c. The subsequent employer must maintain the previous evaluation in the employee’s personnel file for verification of the exception to the requirement for a record check evaluation. (I, II, III)

d. The subsequent employer may request a reevaluation of the background check and may employ the person while the reevaluation is being performed, even though an exemption under paragraph 50.9(8)“a” may be authorized.

50.9(9) *Employee notification of criminal conviction or founded abuse after employment.* If a person employed by a facility employer that is subject to this rule is convicted of a crime or has a record of founded child or dependent adult abuse entered in the abuse registry after the person’s employment application date, the person shall inform the employer of such information within 48 hours of the criminal conviction or entry of the record of founded child or dependent adult abuse.

a. The employer shall act to verify the information within seven calendar days of notification. “Verify,” for purposes of this subrule, means to access the single contact repository (SING) to perform a

background check, to request a criminal background check from the department of public safety, to request an abuse record check from the department of human services, to conduct an online search through the Iowa Courts Online website, or to contact the county clerk of court office and obtain a copy of relevant court documents.

b. If the information is verified, the facility shall follow the requirements of paragraphs 50.9(3) “*c*” and “*d.*” (I, II, III)

c. The employer may continue to employ the person pending the performance of an evaluation by the department of human services.

d. A person who is required by this subrule to inform the person’s employer of a conviction or entry of an abuse record and fails to do so within the required period commits a serious misdemeanor under Iowa Code section 135C.33.

e. The employer may notify the county attorney for the county where the employer is located of any violation or failure by an employee to notify the employer of a criminal conviction or entry of an abuse record within the period required under this subrule.

50.9(10) *Facility receipt of credible information that an employee has been convicted of a crime or has a record of founded abuse.* If the facility receives credible information, as determined by the facility, from someone other than the employee, that the employee has been convicted of a crime or a record of founded child or dependent adult abuse has been entered in the abuse registry after employment, and the employee has not informed the employer of the information within the time required by subrule 50.9(9), the facility shall take the following actions:

a. The facility shall act to verify credible information within seven calendar days of receipt. “Verify,” for purposes of this subrule, means to access the single contact repository (SING) to perform a background check, to request a criminal background check from the department of public safety, to request an abuse record check from the department of human services, to conduct an online search through the Iowa Courts Online website, or to contact the county clerk of court office and obtain a copy of relevant court documents.

b. If the information is verified, the facility shall follow the requirements of paragraphs 50.9(3) “*c*” and “*d.*” (I, II, III)

50.9(11) *Proof of background checks for temporary employment agencies and contractors.* Proof of background checks may be kept in the files maintained by temporary employment agencies and contractors. Facilities may require temporary employment agencies and contractors to provide a copy of the result of the background checks. Copies of such results shall be made available to the department upon request. (I, II, III)

50.9(12) *Certified nurse aide training program students.* Prior to a student’s beginning or returning to a certified nurse aide training program, the program shall either request that the department of public safety perform a criminal history check and that the department of human services perform child and dependent adult abuse record checks of the person in this state, or access the SING to perform the required background check.

a. *Prohibition of involvement in clinical education.* Except as provided in paragraph 50.9(1) “*b.*,” if a student has a criminal record or a record of founded child or dependent adult abuse, the student shall not be involved in a clinical education component of the certified nurse aide training program involving children or dependent adults unless an evaluation has been performed by the department of human services. The evaluation shall be performed upon request of the certified nurse aide training program.

b. *Involvement in clinical education component pending evaluation.* The training program may provisionally allow the student’s participation in the clinical education component of the certified nurse aide training program pending completion of the required record check and evaluation by the department of human services, as applicable, subject to all of the following:

(1) The training program shall have accessed SING to perform the required record check and be awaiting results from SING or awaiting evaluation by the department of human services, as applicable;

(2) If applicable, the training program shall request an evaluation by the department of human services in accordance with paragraph 50.9(12) “a” within 30 days of receipt of the SING record check results;

(3) The training program shall have utilized an approved third-party vendor to perform a comprehensive preliminary background check;

(4) If the comprehensive preliminary background check determines that the student being considered for participation has been convicted of a crime, the crime does not constitute a felony as defined in Iowa Code section 701.7 and is not a crime specified pursuant to Iowa Code chapter 708, 708A, 709, 709A, 710, 710A, 711, or 712 or pursuant to Iowa Code section 726.3, 726.7, or 726.8;

(5) The comprehensive preliminary background check shall have determined that the student does not have a record of founded child abuse or dependent adult abuse, or, if the student does have a record of founded child abuse or dependent adult abuse, subrule 50.9(8) is applicable; and

(6) The provisional participation may continue until such time as the required record check through SING and evaluation by the department of human services, as applicable, are completed.

c. Student notification of criminal conviction or founded abuse after performance of record checks and evaluation. If a student is convicted of a crime or has a record of founded child or dependent adult abuse entered in the abuse registry after the record checks and any evaluation have been performed, the student shall inform the certified nurse aide training program of such information within 48 hours of the criminal conviction or entry of the record of founded child or dependent adult abuse.

(1) The program shall act to verify the information within seven calendar days of notification. “Verify,” for purposes of this paragraph, means to access the single contact repository (SING) to perform a background check, to request a criminal background check from the department of public safety, to request an abuse record check from the department of human services, to conduct an online search through the Iowa Courts Online website, or to contact the county clerk of court office and obtain a copy of relevant court documents. If the information is verified, the program shall follow the requirements of paragraph 50.9(12) “a” to determine whether or not the student’s involvement in a clinical education component may continue.

(2) The program may allow the student involvement to continue pending the performance of an evaluation by the department of human services.

(3) A student who is required to inform the program of a conviction or entry of an abuse record and fails to do so within the required period commits a serious misdemeanor under Iowa Code section 135C.33.

(4) The program may notify the county attorney for the county where the program is located of any violation or failure by a student to notify the program of a criminal conviction or entry of an abuse record within the period required by this paragraph.

d. Program receipt of credible information that a student has been convicted of a crime or has a record of founded abuse. If a program receives credible information, as determined by the program, that a student has been convicted of a crime or a record of founded child or dependent adult abuse has been entered in the abuse registry after the record checks and any evaluation have been performed, from a person other than the student, and the student has not informed the program of such information within 48 hours, the program shall act to verify the credible information within seven calendar days of receipt of the credible information. “Verify,” for purposes of this paragraph, means to access the single contact repository (SING) to perform a background check, to request a criminal background check from the department of public safety, to request an abuse record check from the department of human services, to conduct an online search through the Iowa Courts Online website, or to contact the county clerk of court office and obtain a copy of relevant court documents. If the information is verified, the requirements of paragraph 50.9(12) “a” shall be applied to determine whether or not the student’s involvement in a clinical education component may continue.

e. Completion of a certified nurse aide training program conducted by the health care facility. If a certified nurse aide training program is conducted by the facility and a student of that program accepts and begins employment with the facility within 30 days of completing the program, the background check of the student performed prior to beginning the training program shall fulfill the criminal and

abuse background check requirements. The facility shall maintain the proof required in subrule 50.9(11). (I, II, III)

This rule is intended to implement Iowa Code sections 135C.14 and 135C.33.
[ARC 0903C, IAB 8/7/13, effective 9/11/13; ARC 1566C, IAB 8/6/14, effective 9/10/14; ARC 5421C, IAB 2/10/21, effective 3/17/21]

481—50.10(135C) Inspections, exit interviews, plans of correction, and revisits.

50.10(1) *Frequency of inspection.* The department shall inspect a licensed health care facility at least once within a 30-month period. Facilities participating in the Medicare or Medicaid programs may be inspected more frequently as a part of a joint state and federal inspection.

50.10(2) *Accessibility of records, the facility, and persons.* An inspector of the department may enter any licensed health care facility without a warrant and may examine all records pertaining to the care provided to residents of the facility. An inspector of the department may contact or interview any resident, employee, or any other person who might have knowledge about the operation of a health care facility. The inspector may duplicate records and take photographs as part of the inspection.

50.10(3) *Exit interviews.* The health care facility shall be provided an exit interview at the conclusion of an inspection, and the facility representative shall be informed of all issues and areas of concern related to the deficiencies.

a. Methods of conducting exit interview. The department may conduct the exit interview either in person or by telephone.

b. Second exit interviews. The department shall conduct a second exit interview if any additional areas of concern are identified.

50.10(4) *Submission of additional or rebuttal information.* The facility shall be provided two working days from the date of the exit interview to submit additional or rebuttal information to the department.

a. Receipt of additional information. Additional or rebuttal information must be received by the department within two working days in order to be considered.

b. Methods to submit additional information. The additional or rebuttal information may be submitted via email, facsimile, or overnight courier to the department.

c. Inform of the opportunity to submit additional or rebuttal information. During the inspection, the facility shall be informed of the opportunity to submit additional or rebuttal information and of the contact information for the department.

50.10(5) *Standards for determining whether a deficiency exists.* The department shall use a preponderance of the evidence standard when determining whether a regulatory deficiency exists. For purposes of this rule and rule 481—50.11(135C), “preponderance of the evidence standard” means that the evidence, considered and compared with the evidence opposed to it, produces the belief in a reasonable mind that the allegations or deficiency is more likely true than not true. This standard does not require that the inspector personally witnessed the alleged violation.

50.10(6) *Statement of deficiencies.* When one or more deficiencies are found, a statement of deficiencies detailing each deficiency shall be sent by the department to the health care facility within ten working days of the exit interview.

50.10(7) *Plan of correction.* Within ten calendar days following receipt of the statement of deficiencies, the health care facility shall submit a plan of correction to the department.

a. Contents of plan. The plan of correction shall contain the following information:

- (1) How the facility will correct the deficient practice;
- (2) How the facility will act to protect residents;
- (3) The measures the facility will take or the systems it will alter to ensure that the problem does not recur;
- (4) How the facility plans to monitor its performance to make sure that solutions are sustained; and
- (5) Date(s) when corrective action will be completed.

b. Review of plan. The department shall review the plan of correction within ten working days of receipt. The department may request additional information or revisions to the plan, which shall be provided as requested.

50.10(8) *Revisits.* If a facility licensed under this chapter is subject to or will be subject to denial of payment including payment for Medicare or medical assistance (Medicaid) under Iowa Code chapter 249A, or denial of payment for all new admissions pursuant to 42 CFR Section 488.417, and submits a plan of correction relating to the deficiencies or a response to a citation issued under 481—Chapter 56 and the department elects to conduct an on-site revisit inspection, the department shall commence the revisit inspection within the shortest time feasible of the date that the plan of correction is received or the date specified within the plan of correction alleging compliance, whichever is later.

50.10(9) *Appeals of statement of deficiencies.* The facility may appeal the statement of deficiencies by filing an appeal request with the department within 20 working days after receipt of the statement of deficiencies. The procedures defined in rule 481—50.6(10A) shall be followed for the appeal.

[ARC 8433B, IAB 12/30/09, effective 2/3/10; ARC 1566C, IAB 8/6/14, effective 9/10/14]

481—50.11(135C) Complaint and self-reported incident investigation procedure.

50.11(1) *Complaint.* The process for filing a complaint is as follows:

a. Any person with concerns regarding a facility may file a complaint with the Department of Inspections and Appeals, Complaint/Incident Bureau, Lucas State Office Building, Third Floor, 321 E. 12th Street, Des Moines, Iowa 50319-0083; by use of the complaint hotline, 1-877-686-0027; by facsimile sent to (515)281-7106; or through the website address dia-hfd.iowa.gov/DIA_HFD/Home.do.

b. When the nature of the complaint is outside the department's authority, the department shall forward the complaint or refer the complainant to the appropriate investigatory entity.

c. The complainant shall include as much of the following information as possible in the complaint: the complainant's name, address and telephone number; the complainant's relationship to the facility or resident; and the reason for the complaint.

d. The complainant's name shall be confidential information and shall not be released by the department.

e. The department shall act on anonymous complaints unless the department determines that the complaint is intended to harass the facility.

f. If the department, upon preliminary review, determines that the complaint is intended as harassment or is without a reasonable basis, the department may dismiss the complaint.

50.11(2) *Self-reported incident.* When the facility is required pursuant to rule 481—50.7(10A,135C) or other requirements to report an incident, the facility shall make the report to the department via:

a. The web-based reporting tool accessible from the following Internet site, dia-hfd.iowa.gov/DIA_HFD/Home.do, under the "Login" tab and then access "Add self report";

b. Mail by sending the self-report to the Department of Inspections and Appeals, Complaint/Incident Bureau, Lucas State Office Building, Third Floor, 321 E. 12th Street, Des Moines, Iowa 50319-0083;

c. The complaint/incident hotline, 1-877-686-0027; or

d. Facsimile sent to (515)281-7106.

50.11(3) *Time frames for investigation of complaint or self-reported incident.* The following guidelines shall be used for determining the time frame in which an on-site inspection of the facility shall be initiated:

a. Immediate jeopardy situation. Within 2 working days for a complaint or self-reported incident determined by the department to be an alleged immediate jeopardy situation. For purposes of this rule, "immediate jeopardy situation" means a situation in which the facility's alleged noncompliance with Iowa Code chapter 135C, or rules adopted pursuant thereto, has caused or is likely to cause, serious injury, harm, impairment, or death to a resident.

b. High-level nonimmediate jeopardy situation. Within 10 days for nursing facilities and within 20 working days for intermediate care facilities and residential care facilities for a complaint or self-reported incident determined by the department to be an alleged high-level nonimmediate jeopardy situation. For purposes of this rule, "high-level nonimmediate jeopardy situation" means the alleged noncompliance with Iowa Code chapter 135C, or rules adopted pursuant thereto, may have caused harm that negatively

impacts the resident's mental, physical, or psychosocial status and is of such consequence to the resident's well-being that a rapid response is warranted.

c. Other nonimmediate jeopardy situation. Within 45 calendar days for a complaint or self-reported incident determined by the department to be an alleged nonimmediate jeopardy situation, other than a high-level nonimmediate jeopardy situation. For purposes of this rule, "other nonimmediate jeopardy situation" means a situation that is not a high-level nonimmediate jeopardy situation where the alleged noncompliance with Iowa Code chapter 135C, or rules adopted pursuant thereto, may cause harm of limited consequence and does not significantly impair the individual's mental, physical, or psychosocial status or function.

d. No inspection of facility-reported incidents. The department may determine not to institute an inspection of a self-reported incident using criteria including, but not limited to, the following:

(1) There is no evident deficiency on the part of the facility, and the facility has taken appropriate measures to address the situation; or

(2) There is a potential deficiency but:

1. The facility has taken appropriate measures to address the situation;

2. The facility does not have a recent history of identified deficiency similar to or related to the incident being reported;

3. A complaint has not been filed regarding the incident being reported; and

4. The resulting injury does not cause a significant negative impact to the resident's quality of life.

50.11(4) Standard for determining whether a complaint or self-reported incident is substantiated. The department shall apply a preponderance of the evidence standard in determining whether a complaint or self-reported incident is substantiated.

50.11(5) Notification of program and complainant. The department shall notify the facility and, if known, the complainant of the findings of the complaint investigation. The department shall also notify the complainant, if known, if the department does not investigate a complaint, and the reasons for not investigating the complaint shall be included in the notification.

50.11(6) Process for complaint and self-reported incident. The department and facility shall follow the process outlined in rule 481—50.10(135C), as applicable, when conducting or responding to a complaint or self-reported incident investigation.

[ARC 8433B, IAB 12/30/09, effective 2/3/10]

481—50.12(135C) Requirements for service. At each inspection, the facility shall provide the most current contact information for the purpose of service of departmental notices. A statement of deficiencies or citation shall be served upon a facility using one of the following methods.

50.12(1) Electronic mail. If a facility has electronic mail, electronic mail shall be used for service of statements of deficiencies and citations. If electronic mail is used, the following shall be complied with:

a. The department shall send the electronic message return receipt requested. The response from the return receipt shall officially document receipt of the service and the date of receipt.

b. A facility shall allow the electronic return receipt to be returned to the department and shall not delay the sending of the return receipt.

c. If the department has not received the return receipt within three business days of sending the service via electronic mail, the department shall contact the facility to verify the receipt of the service.

50.12(2) Certified mail. If a facility does not have access to electronic mail, the service shall be sent via certified mail, return receipt requested.

50.12(3) Personal service. The department may choose to personally serve the notice upon the health care facility by delivering a copy of the statement of deficiencies or citation to the health care facility and presenting the copy to the facility.

[ARC 8433B, IAB 12/30/09, effective 2/3/10]

481—50.13(135C) Inspectors' conflicts of interest.

50.13(1) Conflicts. Any of the following circumstances disqualifies an inspector from inspecting a particular health care facility licensed under Iowa Code chapter 135C:

a. The inspector currently works or, within the past two years, has worked as an employee or employment agency staff at the health care facility, or as an officer, consultant, or agent for the health care facility to be inspected.

b. The inspector has any financial interest or any ownership interest in the facility. For purposes of this paragraph, indirect ownership, such as through a broad-based mutual fund, does not constitute a financial or ownership interest.

c. The inspector has an immediate family member who has a relationship with the facility as described in subrule 50.13(1), paragraphs “*a*” and “*b*.”

50.13(2) Immediate family member. For purposes of this rule, “immediate family member” means the same as set forth in 42 CFR 488.301, and includes a husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, or stepsibling; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; or grandparent or grandchild.

[ARC 8433B, IAB 12/30/09, effective 2/3/10]

These rules are intended to implement Iowa Code sections 22.11 and 135B.3 to 135B.7 and Iowa Code chapters 10A and 135C.

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CHAPTER 51 HOSPITALS

[Prior to 12/14/88, see Health Department[470] Ch 51]

[Prior to 8/8/90, see Public Health[641] Ch 51]

481—51.1(135B) Definitions. As used in this chapter, unless the context otherwise requires, the following definitions apply:

“Critical access hospital” means any hospital located in a rural area and certified by the Iowa department of public health as being a necessary provider of health care services to residents of the area. A “critical access hospital” makes available 24-hour emergency care, is a designated provider in a rural health network, and meets the criteria specified pursuant to 481—51.53(135B). If swing-bed approval has been granted, all 25 beds may be used interchangeably for acute or skilled nursing facility level of care services.

“Department” means the Iowa department of inspections and appeals.

“Governing board” means the board of trustees, the owner or the person or persons designated by the owner as the governing authority who shall have supreme authority in the hospital and be responsible for the management, control, and appointment of the medical staff.

“Governmental unit” means the state, or any county, municipality, or other political subdivision, or any department, division, board or other agency of any of the foregoing.

“Hospital” or *“general hospital”* means an institution, place, building, or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the diagnosis or treatment, over a period exceeding 24 hours, of two or more nonrelated individuals suffering from illness, injury, infirmity or deformity, or other physical or mental condition for which medical, surgical and obstetrical care services are provided. The term “hospital” does not include the following:

1. Any institution for well children, day nursery and child care center, foster boarding homes or houses, and homes for disabled children. However, such institutions that have a dual function, including nursing and medical care, and care of the sick are required to be licensed.
2. Homes, houses or institutions for aged persons which limit their functions to room and board and provide no medical or nursing care and house no bedridden person.
3. Dispensary or first-aid stations maintained for the care of employees, students, customers, and members of any commercial or industrial plant, educational institution, or convent.

“Long-term acute care hospital” means any hospital that has an average inpatient length of stay greater than 25 days, and that provides extended medical and rehabilitative care for patients who are clinically complex and who may suffer from multiple acute or chronic conditions. Services provided by a long-term acute care hospital include but are not limited to comprehensive rehabilitation, respiratory therapy, head trauma treatment, and pain management. A long-term acute care hospital shall meet the requirements for a general hospital including emergency services, except that obstetrical facilities are not required, and, if the long-term acute care hospital is located within a separately licensed hospital and does not provide its own emergency services, the long-term acute care hospital shall contract for emergency services with the host general hospital.

“Medical staff” means an organized body that is composed of individuals appointed by the hospital governing board, that operates under bylaws approved by the governing board and that is responsible for the quality of medical care provided to patients by the hospital. All members of the medical staff, one of whom shall be a licensed physician, shall be licensed to practice in the state of Iowa.

“Premises” means any or all designated portions of a building or structure, enclosures or places in the building, or real estate when the distinct and clearly identifiable parts provide separate care and services. The definition of “premises” shall not be construed to permit the existence of a separately licensed specialty hospital within the physical structure of a general hospital. A specialty hospital shall be defined pursuant to 42 CFR Section 411.351 and any amendments thereto, or pursuant to any regulations promulgated by the Secretary of Health and Human Services.

“*Specialized hospital*” means any hospital devoted primarily to the specialized care and treatment of persons with chronic or long-term illness, injury, or infirmity. The diagnosis, treatment or care shall be administered by or performed under the direction of persons especially qualified in the diagnosis and treatment of the particular illness, injury, or infirmity. A specialized hospital shall meet the requirements for a general hospital. “Specialized hospital” as defined in this rule does not include a specialty hospital defined pursuant to 42 CFR Section 411.351.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.2(135B) Classification, compliance and license.

51.2(1) Classification. For the purpose of administering the hospital licensing law, all institutions subject to licensure shall be classified as a critical access hospital, general hospital, long-term acute care hospital, or specialized hospital. The license issued by the department shall clearly identify the classification of the hospital.

51.2(2) Compliance requirements for each classification. A hospital shall comply with all of the general regulations for hospitals and shall comply with regulations pertaining to specialized services, if specialized services are provided in the hospital.

51.2(3) Separate license required. A separate license shall be required for each hospital even though more than one is operated under the same management. A separate license is not required for separate buildings of a hospital located on separate parcels of land, which are not adjoining but provide elements of the hospital’s full range of services for the diagnosis, care, and treatment of human illness, including convalescence and rehabilitation, and which are organized under a single owner or governing board with a single designated administrator and medical staff.

51.2(4) Posting of license. The license shall be conspicuously posted on the main premises of the hospital.

51.2(5) The department shall recognize, in lieu of its own licensure inspection, the comparable inspections and inspection findings of The Joint Commission (TJC), the American Osteopathic Association (AOA), DNV GL – Healthcare (DNV GL), or the Center for Improvement in Healthcare Quality (CIHQ) if the department is provided with copies of all requested materials relating to the inspection process. In cases of the initial licensure, the department may require its own inspection when needed in addition to comparable accreditations to allow the hospital to begin operations. The department may also initiate its own inspection when it is determined that the inspection findings of TJC, AOA, DNV GL, or CIHQ are insufficient to address concerns identified as possible licensure issues.

51.2(6) Hospitals not accredited by TJC, AOA, DNV GL, or CIHQ shall be inspected by the department utilizing the current Medicare conditions of participation found in Title XVIII of the federal Social Security Act and 42 CFR Part 482, Subparts A, B, C, D, and E, or 42 CFR Part 485, Subpart F. Licensed-only hospitals shall be inspected utilizing the requirements of this chapter. The department may promulgate additional standards. The department may recognize, in lieu of its own licensure inspection, the comparable inspection and inspection findings of a Medicare conditions of participation survey.

This rule is intended to implement Iowa Code chapter 135B.

[ARC 9253B, IAB 12/1/10, effective 1/5/11; ARC 1305C, IAB 2/5/14, effective 3/12/14; ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.3(135B) Quality improvement program.

51.3(1) There shall be an ongoing hospitalwide quality improvement program. This program is to be designed to improve, as needed, the quality of patient care by:

- a. Assessing clinical patient care;
- b. Assessing nonclinical and patient-related services within the hospital;
- c. Developing remedial action as needed; and
- d. Ongoing monitoring and evaluating of the progress of remedial action taken.

51.3(2) The governing body shall ensure there is an effective hospitalwide patient-oriented quality improvement program.

51.3(3) The quality improvement program shall involve active participation of physician members of the hospital's medical staff and other health care professionals, as appropriate. Evidence of this participation will include ongoing case review and assessment of other patient care problems which have been identified through the quality improvement process.

51.3(4) The quality improvement plan may include external, state, local, federal, and regional benchmarking activities designed to improve the quality of patient care. The quality improvement plan shall be written and may address the following:

- a. The program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities;
- b. The participation from all departments, services (including services provided both directly and under contract), and disciplines;
- c. An assessment of participation through a quality improvement committee meeting on an established periodic basis;
- d. The coordination of quality improvement activities;
- e. The communication, reporting and documentation of all quality improvement activities on a regular basis to the governing board, the medical staff, and the hospital administrator;
- f. An annual evaluation by the governing board of the effectiveness of the quality improvement program; and
- g. The accessibility and confidentiality of materials relating to, generated by or part of the quality improvement process.

This rule is intended to implement Iowa Code chapter 135B.
[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.4(135B) Long-term acute care hospital located within a general hospital.

51.4(1) If a long-term acute care hospital occupies the same building, premises or physical location of a general hospital, all treatment facilities and administrative offices for each hospital shall be clearly marked and separated from each other, and located within the licensed premises of each licensee.

- a. Treatment facilities shall be sufficient to meet the medical needs of the patients.
- b. Administrative offices shall include, but not be limited to, record rooms and personnel offices.
- c. There shall be clearly identifiable and distinguishable signs for each hospital.

51.4(2) If a long-term acute care hospital occupies the same building, premises or physical location of a general hospital, each hospital shall have its own entrance. The separate entrance shall have appropriate signs and shall be clearly identifiable as belonging to a particular hospital. Nothing shall prohibit a long-term acute care hospital that is occupying the same building, premises or physical location as a general hospital from utilizing the entrance, hallway, stairs, elevators or escalators of the general hospital to provide access to the long-term acute care hospital's separate entrance.

51.4(3) A long-term acute care hospital located within a general hospital shall have sufficient staff to meet the patients' needs. No nursing services staff of either the long-term acute care hospital or the host general hospital shall be simultaneously assigned patient duties in both licensed hospitals.

51.4(4) Each long-term acute care hospital located within a general hospital and the host general hospital shall have a separate and distinct governing board, which shall be in control of the respective hospital. No more than one board member shall serve in a common capacity on the governing board of each licensed hospital. For the purposes of this rule, control exists if an individual or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of an organization or institution.

51.4(5) A long-term acute care hospital located within a general hospital may contract with the host general hospital for the provision of services, including but not limited to pharmaceutical, radiological, laboratory, food and dietetic, surgical, anesthesia, emergency, housekeeping, laundry and environmental, or other services necessary to maintain a clean and safe physical environment. The contract shall be executed by the governing boards of the long-term acute care hospital and the host general hospital. All contracts shall clearly delineate the responsibilities of and services provided by the long-term acute care hospital and the host general hospital.

51.4(6) Any life safety code violation identified by the state fire marshal during an inspection of a licensee may be a life safety code violation for both the long-term acute care hospital and the general hospital.

481—51.5(135B) Medical staff.

51.5(1) A roster of medical staff members shall be kept.

51.5(2) All hospitals shall have one or more licensed physicians designated for emergency call service at all times.

51.5(3) A hospital shall not deny clinical privileges to physicians and surgeons, podiatrists, osteopaths or osteopathic surgeons, dentists, certified health service providers in psychology, physician assistants, advanced registered nurse practitioners or pharmacists licensed under Iowa Code chapter 147, 148, 148C, 149, 152, 153, or 155 or section 154B.7 solely by reason of the license held by the practitioner or solely by reasons of the school or institution in which the practitioner received health care education or postgraduate training if the health care education or postgraduate training was accredited by an organization recognized by the council on postsecondary accreditation or an accrediting group recognized by the United States Department of Education.

51.5(4) A hospital shall establish and implement written criteria for the granting of clinical privileges. The written criteria shall include, but not be limited to, consideration of the:

- a. Ability of the applicant to provide patient care services independently or appropriately in the hospital;
- b. License held by the applicant to practice;
- c. Training, experience, and competence of applicant;
- d. Relationship between the applicant's request for privileges and the hospital's current scope of patient care services;
- e. Applicant's ability to provide comprehensive, appropriate and cost-effective services.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.6(135B) Patient rights and responsibilities. The hospital governing board shall adopt a statement of principles relating to patient rights and responsibilities. In developing a statement of principles, the hospital may use reference statements of patient rights and responsibilities developed by the American Hospital Association, The Joint Commission (TJC), the American Osteopathic Association (AOA), DNV GL – Healthcare (DNV GL), the Center for Improvement in Healthcare Quality (CIHQ), and other appropriate sources.

51.6(1) The statement of principles shall be made available to patients of the hospital.

51.6(2) The statement of principles regarding patient rights shall, at a minimum, address:

- a. Access to treatment regardless of age, race, creed, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, gender identity or expression, diagnosis, or source of payment for care;
- b. Preservation of individual dignity and protection of personal privacy in receipt of care;
- c. Confidentiality of medical and other appropriate information;
- d. Assurance of reasonable safety within the hospital;
- e. Knowledge of the identity of the physician or other practitioner primarily responsible for the patient's care as well as identity and professional status of others providing services to the patient while in the hospital;
- f. Nature of patient's right to information regarding the patient's medical condition unless medically contraindicated, to consult with a specialist at the patient's request and expense, and to refuse treatment to the extent authorized by law;
- g. Access to and explanation of patient billings; and
- h. Process for patient pursuit of grievances.

51.6(3) The statement of principles regarding patient responsibilities shall, at a minimum, address:

- a. Need of patient to provide accurate and complete information regarding the patient's health status;

- b. Need of patient to follow recommended treatment plans;
- c. Requirement that patient abide by hospital rules and regulations affecting patient care and conduct and be considerate of the rights of other patients and hospital personnel; and
- d. Obligation to fulfill the patient's financial obligations as soon as possible following discharge.

This rule is intended to implement Iowa Code chapter 135B.

[ARC 9253B, IAB 12/1/10, effective 1/5/11; ARC 1305C, IAB 2/5/14, effective 3/12/14; ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.7(135B) Abuse.

51.7(1) Definitions.

“Abuse” means the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain or mental anguish. Neglect is a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

“Child abuse” means the same as provided for in Iowa Code section 232.68.

“Dependent adult abuse” means the same as provided for in Iowa Code section 235E.1.

“Domestic abuse,” as defined in Iowa Code section 236.2, means the commission of assault under any of the following circumstances:

1. The assault is between family or household members who resided together at the time of the assault;
2. The assault is between separated spouses or persons divorced from each other and not residing together at the time of the assault;
3. The assault is between persons who are parents of the same minor child, regardless of whether they have been married or have lived together at any time; or
4. The assault is between persons who have been family or household members residing together within the past year and are not residing together at the time of the assault.

“Elder abuse” means the same as provided for in Iowa Code section 235F.1.

“Family or household members,” as defined in Iowa Code section 236.2, are spouses, persons cohabiting, parents, or other persons related by consanguinity or affinity, except children under the age of 18.

51.7(2) Abuse prohibited. Each patient shall receive kind and considerate care at all times and shall be free from all forms of abuse or harassment.

a. Restraints shall be applied only when they are necessary to prevent injury to the patient or to others and shall be used only when alternative measures are not sufficient to accomplish their purposes.

b. There must be a written order signed by the attending physician approving the use of restraints either at the time they are applied or as soon thereafter as possible.

c. Careful consideration shall be given to the methods by which the restraints can be speedily removed in case of fire or other emergency.

51.7(3) Hospital response to domestic abuse. Each hospital shall establish and implement protocols with respect to victims of domestic abuse.

a. The policies and procedures shall at a minimum provide for:

- (1) An interview with the victim in a place that ensures privacy;
- (2) Confidentiality of the person's treatment and information;
- (3) Sharing of information regarding the domestic abuse hotline and programs; and
- (4) Education of appropriate emergency department staff to assist in the identification of victims of domestic abuse.

b. The treatment records of victims of domestic abuse shall include:

- (1) An assessment of the extent of abuse to the victim specifically describing the location and extent of the injury and reported pain;
- (2) Evidence that the victim was informed of the telephone numbers for the domestic abuse hotline and domestic abuse programs, and the victim's response;
- (3) A record of the treatment and intervention by health care provider personnel;

(4) A record of the need for follow-up care and specification of the follow-up care to be given (e.g., X-rays, surgery, consultation, similar care); and

(5) The victim's statement of how the injury occurred.

51.7(4) Hospital response to elder abuse. Each hospital shall establish and implement protocols with respect to victims of elder abuse.

a. The policies and procedures shall at a minimum provide for:

(1) An interview with the victim in a place that ensures privacy;

(2) Confidentiality of the person's treatment and information; and

(3) Education of appropriate emergency department staff to assist in the identification of victims of elder abuse.

b. The treatment records of victims of elder abuse shall include:

(1) An assessment of the extent of abuse to the victim specifically describing the location and extent of the injury and reported pain;

(2) A record of the treatment and intervention by health care provider personnel;

(3) A record of the need for follow-up care and specification of the follow-up care to be given (e.g., X-rays, surgery, consultation, similar care); and

(4) The victim's statement of how the injury occurred.

51.7(5) Mandatory reporting of child abuse and dependent adult abuse. Each hospital shall ensure that written policies and procedures cover all requirements for the mandatory reporting of abuse pursuant to the Iowa Code. Each hospital shall provide that the treatment records of victims of child abuse or dependent adult abuse include a statement that the department of human services' protective services was contacted.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.8(135B) Organ, tissue and eye procurement. Each hospital licensed in accordance with Iowa Code chapter 135B shall have in place written policies and protocols for organ, tissue and eye donation. Hospitals shall be familiar with the revised uniform anatomical gift Act, Iowa Code chapter 142C, and shall develop policies and protocols for consent to organ, tissue and eye donation by either the patient or an appropriate person to consent on the patient's behalf consistent with that Act's provisions. Hospitals shall ensure that the specific organ, tissue and eye procurement requirements are met, as provided in 42 CFR 482.45 or 42 CFR 485.643.

This rule is intended to implement Iowa Code section 135B.7.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.9(135B) Nursing services.

51.9(1) The hospital shall have an organized nursing service which shall provide complete and efficient nursing care to each patient. The authority, responsibility and function of each nurse shall be clearly defined.

51.9(2) Registered nurses shall utilize the nursing process in the practice of nursing, consistent with accepted and prevailing practice. The nursing process is ongoing and includes:

a. Nursing assessments about the health status of an individual or group.

b. Formulation of a nursing diagnosis based on analysis of the data from the nursing assessment.

c. Planning of nursing care, which includes determining goals and priorities for actions that are based on the nursing diagnosis.

d. Nursing interventions implementing the plan of care.

e. Evaluation of the individual's or group's status in relation to established goals and the plan of care.

51.9(3) Licensed practical nurse(s) shall participate in the nursing process as described in subrule 51.9(2) consistent with accepted practice by assisting the registered nurse or physician.

51.9(4) All nurses employed in a hospital who practice nursing as a registered nurse or licensed practical nurse shall hold an active Iowa license or hold an active license in another state and be recognized for licensure in this state pursuant to the nurse licensure compact in Iowa Code section 152E.1.

51.9(5) There shall be a director of nursing service with administrative and executive competency who shall hold an active Iowa license or hold an active license in another state and be recognized for licensure in this state pursuant to the nurse licensure compact in Iowa Code section 152E.1.

51.9(6) Nursing management shall have had preparation courses and experience in accordance with hospital policy commensurate with the responsibility of the specific assignment.

51.9(7) All unlicensed personnel performing patient-care service shall be under the supervision of a registered nurse. The duties of unlicensed personnel shall be defined in writing by the hospital, and unlicensed personnel shall be instructed in all duties assigned to them.

51.9(8) The nursing service shall have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care essential for the proper treatment, well-being, and recovery of the patient.

51.9(9) Written policies and procedures shall be established for the administrative and technical guidance of the personnel in the hospital. Each employee shall be familiar with these policies and procedures.

51.9(10) Each hospital shall have a minimum of one registered nurse on duty at all times.
[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.10(135B) Water supply. Rescinded IAB 12/22/93, effective 1/26/94.

481—51.11(135B) Sewage disposal. Rescinded IAB 12/22/93, effective 1/26/94.

481—51.12(135B) Records and reports.

51.12(1) Medical records. Accurate and complete medical records shall be maintained for all patients and signed by the appropriate provider. These records shall be filed and stored in an accessible manner and in accordance with the statute of limitations as specified in Iowa Code chapter 614.

51.12(2) Hospital records.

- a. *Admission records.* A register of all admissions to the hospital shall be maintained.
- b. *Death records.* A record of all deaths in the hospital shall be kept, including all information required on a standard death certificate as specified in Iowa Code chapter 144.
- c. *Birth records.* A record of all births in the hospital shall be kept, including all information required on a standard birth certificate as specified in Iowa Code chapter 144.
- d. *Controlled substance records.* Controlled substance records shall be maintained in accordance with state and federal laws, rules and regulations.

51.12(3) Electronic records. In addition to the access provided in 481—subrule 50.10(2), an authorized representative of the department shall be provided unrestricted access to electronic records pertaining to the care provided to the patients of the hospital.

a. If access to an electronic record is requested by the authorized representative of the department, the hospital may provide a tutorial on how to use its particular electronic system or may designate an individual who will, when requested, access the system, respond to any questions or assist the authorized representative as needed in accessing electronic information in a timely fashion.

b. The hospital shall provide a terminal where the authorized representative may access records.

c. If the hospital is unable to provide direct print capability to the authorized representative, the hospital shall make available a printout of any record or part of a record on request in a time frame that does not intentionally prevent or interfere with the department's survey or investigation.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.13(135B) Sterilizing equipment. Rescinded IAB 12/22/93, effective 1/26/94; see 481—51.50(135B).

481—51.14(135B) Pharmaceutical service.

51.14(1) General requirements. Hospital pharmaceutical services shall be licensed in accordance with Iowa board of pharmacy rules in 657—Chapters 7, 8, 9, 10, 11, 20, 21, 22 and 40.

51.14(2) Medication administration. All drugs and biologicals must be administered by, or under the supervision of, nursing or other trained personnel in accordance with hospital policies and procedures. The person assigned the responsibility of medication administration must complete the entire procedure by personally preparing the dose from a multiple-dose container or using a prepackaged unit dose, personally administering it to the patient, and observing the act of the medication being taken.

51.14(3) Medication orders. All verbal orders must be authenticated by signature or other secure electronic method by the prescribing practitioner within a period not to exceed 30 days following a patient's discharge.

When verbal or electronic mechanisms are used to transmit medication orders, they must be accepted only by personnel that are authorized to do so by hospital policies and procedures in a manner consistent with federal and state law.

51.14(4) Standing orders. Standing orders for drugs may be used for specified patients when authorized by the prescribing practitioner. These standing orders shall be in accordance with policies and procedures established by the appropriate committee within each hospital. At a minimum, the standing orders shall:

- a. Specify the clinical situations under which the drug is to be administered;
- b. Specify the types of medical conditions of the patients for whom the standing orders are intended;
- c. Be reviewed and revised by the medical staff and the hospital's nursing and pharmacy leadership on a regular basis as specified by hospital policies and procedures;
- d. Be specific as to the drug, dosage, route, and frequency of administration; and
- e. Be dated, authorized by signature or other secure electronic method by the prescribing practitioner within a period not to exceed 30 days following a patient's discharge, and included in the patient's medical record.

51.14(5) Self-administration of medications. Patients shall only be permitted to self-administer medications when specifically ordered by the prescribing practitioner and the prescribing practitioner has determined this practice is safe for the specific patient. The hospital shall develop policies and procedures regarding storage and documentation of the administration of drugs.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.15(135B) Orders other than medication. All verbal orders must be authenticated by the ordering practitioner within a period not to exceed 30 days following a patient's discharge. When verbal or electronic mechanisms are used to transmit orders, the orders must be accepted only by personnel who are authorized to accept them by hospital policies and procedures in a manner consistent with federal and state law.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.16(135B) Radiological services.

51.16(1) The hospital must maintain, or have available, radiological services to meet the needs of the patients.

51.16(2) All radiological services including diagnostic, fluoroscopy, mammography, therapeutic, and nuclear medicine furnished by the hospital or its agent shall be furnished in compliance with 641—Chapters 38 to 42.

481—51.17(135B) Laundry. Rescinded IAB 12/22/93, effective 1/26/94; see 481—51.50(135B).

481—51.18(135B) Laboratory service.

51.18(1) The hospital must maintain, or have available, adequate laboratory and pathology services and facilities to meet the needs of its patients. The medical staff shall determine which laboratory tests are necessary to be performed on site to meet the needs of the patients.

51.18(2) Emergency laboratory services must be available 24 hours a day.

51.18(3) The hospital must ensure that all laboratory services provided to its patients are performed in a laboratory certified and operating in accordance with the Code of Federal Regulations in 42 CFR Part 493.

[ARC 1751C, IAB 12/10/14, effective 1/14/15]

481—51.19 Reserved.

481—51.20(135B) Food and nutrition services.

51.20(1) *Food and nutrition service definition.* “Food service” means providing safe, satisfying, and nutritionally adequate food for patients through the provision of appropriate staff, space, equipment, and supplies. “Nutrition service” means providing assessment and education to ensure that the nutritional needs of the patients are met.

51.20(2) *General requirements.*

a. All food shall be handled, prepared, served, and stored in compliance with the requirements of the Food Code adopted under provisions of Iowa Code section 137F.2.

b. The food service shall provide food of the quality and quantity to meet the patient’s needs in accordance with the qualified health practitioner’s orders and, to the extent medically possible, to meet the current Recommended Dietary Allowances, adopted by the Food and Nutrition Board of the National Research Council, National Academy of Sciences, and the following:

(1) Not less than three meals shall be served daily unless contraindicated.

(2) Not more than 14 hours shall elapse between the evening meal and breakfast of the following day.

(3) Nourishment between meals shall be available to all patients unless contraindicated by the qualified health care practitioner.

(4) Patient food preferences shall be respected as much as possible, and substitutes shall be offered through use of appropriate food groups.

(5) When food is provided by a contract food service, all applicable requirements set forth herein shall be met. The hospital shall maintain adequate space, equipment, and staple food supplies to provide patient food service in emergencies.

c. Policies and procedures shall be developed and maintained.

d. A current diet manual approved by the dietitian and the medical staff shall be used as the basis for diet orders and for planning therapeutic diets. The diet manual shall be reviewed, revised and updated at least every five years. Copies of the diet manual shall be readily available to all medical, nursing, and food service personnel.

e. Therapeutic diets shall be provided as ordered by the qualified health care practitioner, including a registered, licensed dietitian, and shall be planned, prepared, and served with supervision or consultation from the registered, licensed dietitian. Persons responsible for therapeutic diets shall have sufficient knowledge of food to make appropriate substitutions when necessary.

f. The patient’s likes, dislikes, food allergies, and other pertinent information shall be included with the patient’s diet information.

g. Menus.

(1) Menus for regular and therapeutic diets shall be nutritionally appropriate, meet the needs of patients, and be available.

(2) If meals served vary from the planned menu, the change shall be noted in writing as part of the available menu. A copy of the menu as served shall be kept on file for at least 30 days.

(3) Menus should be planned with consideration for cultural and religious background and food habits of patients.

(4) Standardized recipes with nutritional analysis adjusted to number of portions shall be maintained and used in food preparation.

h. Food shall be prepared by methods that conserve nutritive value, flavor, and appearance. Food shall be served attractively at appropriate and safe temperatures and in a form to meet individual needs.

i. Nutritional care.

(1) Nutrition screening shall be conducted by qualified hospital staff to determine the patient's need for a comprehensive nutrition assessment by the licensed dietitian.

(2) Nutritional care shall be integrated in the patient care plan, as appropriate, based upon the patient's diagnosis and length of stay.

(3) The licensed dietitian shall record in the patient's medical record any observations and information pertinent to medical nutrition therapy.

(4) Pertinent dietary records shall be included in the patient's transfer discharge record to ensure continuity of nutritional care.

(5) Upon discharge, nutrition counseling and education shall be provided to the patient and family as ordered by the qualified health care practitioner, requested by the patient or deemed appropriate by the licensed dietitian.

j. In-service training, in accordance with hospital policies, shall be provided for all food and nutrition service personnel. A record of subject areas covered, date and duration of each session, and attendance lists shall be maintained. In-service records shall be kept for a minimum of one year.

k. On the nursing units, a separate patient food storage area shall be maintained that ensures proper temperature control.

51.20(3) Food and nutrition service staff.

a. A licensed dietitian shall be employed on a full-time, part-time or consulting basis. Part-time or consultant services shall be provided on the premises at appropriate times on a regularly scheduled basis. These services shall be of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, patient counseling, guidance to the supervisor and staff of the food and nutrition service, approval of all menus, and participation in the development or revision of departmental policies and procedures and in planning and conducting in-service education programs.

b. If a licensed dietitian is not employed full-time, then one must be employed on a part-time or consultation basis with an additional full-time person who has completed a 250-hour dietary manager course and who shall be employed to be responsible for the operation of the food service.

c. Sufficient food service personnel shall be employed, oriented, trained, and their working hours scheduled to provide for the nutritional needs of the patients and to maintain the food service areas. If food service employees are assigned duties in other service areas, those duties shall not interfere with the sanitation, safety, or time required for food service work assignments.

51.20(4) Food service equipment and supplies. Equipment necessary for preparation and maintenance of menus, records, and references shall be provided. At least one week's supply of staple foods and a reasonable supply of perishable foods shall be maintained on the premises. Supplies shall be appropriate to meet the requirements of the menu.

[ARC 9252B, IAB 12/1/10, effective 1/5/11; ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.21 Reserved.

481—51.22(135B) Equipment for patient care. Hospital equipment shall be selected, maintained and utilized in accordance with the manufacturer's specifications and the needs of the patients.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.23 Reserved.

481—51.24(135B) Infection control. There shall be proper policies and procedures for the prevention and control of communicable diseases. The hospital shall provide for compliance with the current rules for the control of communicable disease as provided by the Iowa department of public health and current Centers for Disease Control and Prevention (CDC) guidelines for isolation precautions.

51.24(1) Segregation. There shall be proper arrangement of areas, rooms and patients' beds to provide for the prevention of cross-infections and the control of communicable diseases.

a. There shall be proper procedures for the cleansing of rooms and surgeries, immediately following the care of a communicable case.

b. Segregation of communicable cases shall include policies for staff, providing for proper isolation technique in order to prevent cross-infection.

51.24(2) Visitors. The hospital shall establish proper policies and procedures for the control of visitors to all services in the hospital.

51.24(3) Health assessments. Health assessments for all contracted or employed personnel who provide direct services shall be required at the commencement of employment and thereafter at least every four years.

a. “Direct services” means services provided through person-to-person contact. “Direct services” excludes services provided by individuals such as building contractors, repair workers, or others who are in the hospital for a very limited purpose, who are not in the hospital on a regular basis, and who do not provide any treatment or services for the patients of the hospital.

b. The health assessment may be performed by the person’s primary care provider.

c. The health assessment shall include, at a minimum, vital signs and an assessment for infectious or communicable diseases.

d. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59.

51.24(4) Notification. Prior to removal of a deceased resident/patient from a facility, the funeral director or person responsible for transporting the body shall be notified by the facility staff of any special precautions that were followed by the facility having to do with the mode of transmission of a known or suspected communicable disease.

This rule is intended to implement Iowa Code section 135B.7.

[ARC 0484C, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.25 Reserved.

481—51.26(135B) Surgical services. All hospitals providing surgical services shall be properly organized and equipped to provide for the safe and aseptic treatment of surgical patients.

51.26(1) Written policies and procedures shall be implemented governing surgical services that are consistent with the needs of the patient and the resources of the hospital.

a. Policies and procedures shall be developed in consultation with and the approval of the hospital’s medical staff. At a minimum, the policies and procedures shall provide for:

(1) Surgical services under the direction of a qualified doctor of medicine or osteopathy.

(2) Delineation of the privileges and qualifications of individuals authorized to provide surgical services as set forth in the hospital’s medical staff bylaws and in accordance with subrule 51.5(4). The surgical service must maintain a roster of these individuals specifying the surgical privileges of each. Surgical privileges shall be reviewed and updated at least once every two years.

(3) Immediate availability of at least one registered nurse for the operating room suites to respond to emergencies.

(4) The qualifications and job descriptions of nursing personnel, surgical technicians, and other support personnel and continuing education required.

(5) Appropriate staffing for surgical services including physician and anesthesia coverage and other support personnel.

(6) Availability of ancillary services for surgical patients including, but not limited to: blood banking, laboratory, radiology, and anesthesia.

(7) Infection control and disease prevention, including aseptic surveillance and practice, identification of infected and noninfected cases, sterilization and disinfection procedures, and ongoing monitoring of infections and infection rates.

(8) Housekeeping requirements.

(9) Safety practices.

(10) Ongoing quality assessment, performance improvement, and process improvement.

(11) Provisions for the pathological examination of tissue specimens either directly or through contractual arrangements.

(12) Appropriate preoperative teaching and discharge planning.

b. Hospitals may consider the most recent edition of the following publications in the development of policies and procedures: “Statement of Principles,” American College of Surgeons; and “Standards and Recommended Practices,” Association of Operating Room Nurses.

51.26(2) Policies and procedures may be adjusted as appropriate to reflect the provision of surgical services in inpatient, outpatient or one-day surgical settings.

51.26(3) There must be an appropriate history and physical workup documented and a properly executed consent form in the chart of each patient prior to surgery, except in the event of an emergency.

51.26(4) A full operative report must be written or dictated within 24 hours following surgery and signed by the individual conducting the surgery.

51.26(5) Equipment available in the operating room, recovery room, outpatient surgical areas, and for postsurgical care, must be consistent with the needs of the patient.

51.26(6) The surgical facilities shall be constructed in accordance with 481—51.50(135B).
[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.27 Reserved.

481—51.28(135B) Anesthesia services.

51.28(1) There shall be written policies and procedures governing anesthesia services which are consistent with the needs and resources of the hospital.

a. Policies and procedures shall be developed in consultation with and with the approval of the hospital’s medical staff.

b. At a minimum, the policies and procedures shall provide:

(1) Anesthesia services shall be provided under the direction of a qualified doctor of medicine or osteopathy.

(2) Delineation of the qualifications of individuals authorized to administer anesthesia as set out in the hospital’s medical staff bylaws or medical staff rules and regulations.

(3) For preanesthesia evaluation, appraisal of a patient’s current condition, preparation of an intraoperative anesthesia record, and discharge criteria for patients.

(4) For equipment functioning and safety, including ensuring that a qualified medical doctor, osteopathic physician and surgeon or anesthetist checks, prior to the administration of anesthesia, the readiness, availability, cleanliness, and working condition of all equipment to be used in the administration of anesthetic agents.

(5) For minimizing electrical hazards in all anesthetizing areas.

(6) Quality assurance which shall at least include infection control procedures; integration of anesthesia services into various areas of the hospital; and ongoing monitoring, review, and evaluation of anesthesia services, processes, and procedures.

51.28(2) Policies and procedures may be adjusted as appropriate to reflect provision of anesthesia services in inpatient or outpatient settings.

This rule is intended to implement Iowa Code section 135B.7.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.29 Reserved.

481—51.30(135B) Emergency services.

51.30(1) All hospitals shall provide for emergency service which offers reasonable care within the medical capabilities of the facility in determining whether an emergency exists, renders care appropriate to the facility and at a minimum renders lifesaving first aid and makes appropriate referral to a facility that is capable of providing needed services.

51.30(2) The hospital shall have written policies and procedures specifying the scope and conduct of patient care to be provided in the emergency service. The policies shall:

a. Specify the mechanism for providing physician coverage at all times.

b. Provide for training required of all personnel providing patient care in the emergency service.

c. Require that a medical record be kept on every patient given treatment in the emergency service and establish the medical record documentation. The documentation should include, at a minimum, appropriate information regarding the medical screening provided, except where the person refuses, then notation of patient refusal; physician documentation of the presence or absence of an emergency medical condition or active labor; physician documentation of transfer or discharge, stating the basis for transfer or discharge; and where transfer occurs, identity of the facility of transfer, acceptance of the patient by the facility of transfer, and means of transfer of the patient.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.31 Reserved.

481—51.32(135B) Obstetric and neonatal services.

51.32(1) All hospitals providing obstetrical care shall be properly organized and equipped to provide accommodations for mothers and newborn infants. The supervision of the maternity area shall be under the direction of a qualified registered nurse.

51.32(2) Written policies and procedures shall be implemented governing obstetric and neonatal services that are consistent with the needs of the patient and resources of the hospital.

a. Policies and procedures shall be developed in consultation with and with the approval of the hospital's medical staff. At a minimum, the policies and procedures shall provide for:

(1) Obstetric and neonatal services under the direction of a qualified doctor of medicine or osteopathy.

(2) Delineation of the privileges and qualifications of individuals authorized to provide obstetrical/gynecological service as set out in the hospital's medical staff bylaws.

(3) The qualifications of nursing personnel and continuing education required.

(4) Adequate staffing for obstetrical and newborn services.

(5) Location and arrangement of obstetric and newborn services.

(6) Infection control and disease prevention.

(7) Ongoing quality assessment.

b. Hospitals may consider the most recent edition of the following publications in the development of policies and procedures: 641—Chapter 150, Iowa Regionalized System of Perinatal Health Care, Iowa Administrative Code, and Guidelines for Perinatal Care, American Academy of Pediatrics, American College of Obstetrics and Gynecology.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.33 Reserved.

481—51.34(135B) Pediatric services.

51.34(1) All hospitals providing pediatric care shall be properly organized and equipped to provide appropriate accommodations for children. The supervision of the pediatric area shall be under the direction of a qualified registered nurse.

51.34(2) Written policies and procedures shall be implemented governing pediatric services that are consistent with the needs of the child and resources of the hospital.

a. Policies and procedures shall be developed in consultation with and the approval of the hospital's medical staff. At a minimum, the policies and procedures shall provide for:

(1) Pediatric services under the medical direction of a qualified doctor of medicine or osteopathy.

(2) Delineation of the privileges and qualifications of individuals authorized to provide pediatric services as set out in the hospital's medical staff bylaws.

(3) The qualifications of nursing personnel and continuing education required, including care in the event of emergency situations.

(4) Adequate staffing and equipment for pediatric services including ancillary services. Staff participating in the care of pediatric patients shall have education appropriate for the care of pediatric patients.

(5) Ancillary services for pediatric patients shall be available and include, but not be limited to, pharmaceutical care, laboratory services, respiratory therapy, physical therapy and speech therapy.

(6) Ongoing quality assessment.

(7) Written protocol for transfer of pediatric patients in the event the hospital does not have capability to provide care for these patients.

b. Hospitals may consider the most recent editions of the following publications in the development of policies and procedures: the American Academy of Pediatrics' Policy Reference Guide and policy statements which are published on a monthly basis in "Pediatrics" and the "Pediatric & Neonatal Dosage Handbook," American Pharmacists Association.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.35 Reserved.

481—51.36(135B) Psychiatric services.

51.36(1) Any hospital operating as a psychiatric hospital or operating a psychiatric unit shall:

a. Be a hospital or unit primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of persons with psychiatric illnesses/disorders;

b. Meet the general and specialized rules of this chapter pertaining to general hospitals. If medical and surgical diagnostic and treatment services are not available within the institution, the institution shall have an agreement with an outside source of these services to ensure they are immediately available;

c. Have policies and procedures for informing patients of their rights and responsibilities and for ensuring the availability of a patient advocate; and

d. Have sufficient numbers of qualified professionals and support staff to evaluate patients, formulate written individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

51.36(2) Personnel.

a. Director of inpatient psychiatric services. The director of inpatient psychiatric services shall be a doctor of medicine or osteopathy qualified to meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry. The number and qualifications of doctors of medicine, doctors of osteopathy or advanced registered nurse practitioners certified in psychiatric or mental health nursing on staff must be adequate to provide essential psychiatric and medical services.

b. Director of psychiatric nursing services. The director of psychiatric nursing services shall:

(1) Be a registered nurse who has a master's degree in psychiatric or mental health nursing;

(2) Be an advanced registered nurse practitioner certified in psychiatric or mental health nursing;

or

(3) Be qualified by education and two years' experience in the care of persons with mental disorders.

c. Psychological services. Psychological services shall be provided or available which are in compliance with Iowa Code chapter 154B.

d. Social services. Social services shall provide, or have available by contract, at least one staff member who has:

(1) A master's degree from an accredited school of social work; or

(2) A bachelor's degree in social work with two years' experience in the care of persons with mental disorders.

e. Therapeutic services. Therapeutic activities shall be provided by qualified therapists. The activities shall be appropriate to the needs and interests of the patients.

51.36(3) Individual written plan of care. An individual written plan of care shall be developed by an interdisciplinary team of a physician and other personnel who are employed by, or who provide service under contract to patients in the facility. The plan of care shall:

- a. Be based on a diagnostic and psychiatric evaluation that includes examination of the medical, psychological, social, behavioral, and developmental aspects of the patient. The initial diagnostic and psychiatric evaluation shall be completed within 60 hours of admission;
- b. Be developed by an interdisciplinary team in consultation with the patient, the patient's legal guardian, and others who are currently providing services or who will provide care upon discharge;
- c. State treatment objectives through measurable and obtainable outcomes;
- d. Prescribe an integrated program of therapies, activities, and experiences designed to meet those objectives;
- e. Include an appropriate postdischarge plan with coordination of services to provide continuity of care following discharge; and
- f. Be reviewed as needed by the interdisciplinary team for the continued appropriateness of the plan and for a determination of needed changes.

[ARC 2472C, IAB 3/30/16, effective 5/4/16]

481—51.37 Reserved.

481—51.38(135B) Long-term care service.

51.38(1) Long-term care service definition. Long-term care service means any building or distinct part of a building utilized by the hospital for the provision of a service (except as provided by 51.38(2) below) that falls within the definition of a health care facility as specified in Iowa Code chapter 135C and Iowa Code section 135C.1(12), nursing facility, as it would be applied were it not operating as part of a hospital licensed under Iowa Code chapter 135B.

51.38(2) Long-term care service general requirements. The general requirements for the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority for the category of health care facility involved. Exceptions to those rules requiring distinct parts to be established may be waived where it is found to be in the best interest of the long-term care resident and of no detriment to the patients in the hospital.

Requests for waivers to other rules for which equivalent health, safety and welfare provisions are provided may be made in accordance with the appropriate health care facility rules. In any case where a distinct part has been established for long-term residents or where the department has given approval for the intermingling of such residents with acute care patients, the same provisions and rules promulgated under Iowa Code chapter 135C shall be applicable. These rules include, but are not limited to, the same restrictions, obligations, programs of care, personal and rehabilitative services and all of the conveniences and considerations which the residents would normally have received in a licensed health care facility.

51.38(3) Long-term care service staff. The staffing requirements for the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority for the category of health care facility involved. Where a hospital operates a freestanding nursing care facility, it shall be under the administrative authority of a licensed nursing home administrator who will be responsible to the hospital's administrator. Where a hospital operates a distinct part long-term care unit under the auspices of the hospital license, a licensed nursing home administrator is not required.

51.38(4) Long-term care service equipment and supplies. The equipment and supplies required for the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority for the category of health care facility involved.

51.38(5) Long-term care service space. The space requirements for the various areas and resident rooms of the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority for the category of health care facility involved.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—51.39(135B) Penalty and enforcement. See Iowa Code sections 135B.14 to 135B.16.

481—51.40(135B) Validity of rules. Rescinded ARC 2472C, IAB 3/30/16, effective 5/4/16.

481—51.41(135B) Criminal, dependent adult abuse, and child abuse record checks.

51.41(1) Definitions. The following definitions apply for the purposes of this rule.

“*Background check*” or “*record check*” means criminal history, child abuse and dependent adult abuse record checks.

“*Comprehensive preliminary background check*” means a criminal history check of all states in which the applicant has worked or resided over the seven-year period immediately prior to submitting an application for employment that is conducted by an approved third-party vendor.

“*Direct services*” means services provided through person-to-person contact. “Direct services” excludes services provided by individuals such as building contractors, repair workers, or others who are in a hospital for a very limited purpose, who are not in the hospital on a regular basis, and who do not provide any treatment or services for the patients of the hospital.

“*Employee*” means any individual who is paid either by the hospital or any other entity (i.e., temporary agency, private duty, Medicare/Medicaid or independent contractors) to provide direct or indirect services to patients of a hospital.

“*Evaluation*” means review by the department of human services to determine whether a founded child abuse, dependent adult abuse or criminal conviction warrants the person’s being prohibited from employment in a hospital.

“*Indirect services*” means services provided without person-to-person contact such as those provided by administration, dietary, laundry, and maintenance.

51.41(2) Requirements for employer prior to employing an individual. Prior to employment of a person in a hospital, the hospital shall complete the background check requirements set forth below.

a. *Informing the prospective employee.* A hospital shall ask each person seeking employment by the hospital, “Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime in this state or any other state?” The person shall also be informed that a background check will be conducted. The person shall indicate, by signature, that the person has been informed that the background check will be conducted.

b. *Conducting a background check.* The hospital shall either request that the department of public safety perform a criminal history check and that the department of human services perform child and dependent adult abuse record checks of the person in this state, or access the single contact repository (SING) to perform the required background check. If the SING is used, the hospital shall submit the person’s maiden name, if applicable, with the background check request.

c. *If a person considered for employment has been convicted of a crime.* If a person being considered for employment in a hospital has been convicted of a crime under a law of any state, the hospital shall request that the department of human services perform an evaluation to determine whether the crime warrants prohibition of the person’s employment in the hospital.

d. *If a person considered for employment has a record of founded child abuse or dependent adult abuse.* If a person being considered for employment in a hospital has a record of founded child or dependent adult abuse under a law of any state, the hospital shall request that the department of human services perform an evaluation to determine whether the founded child or dependent adult abuse warrants prohibition of employment in the hospital.

e. *Employment pending evaluation.* The hospital may provisionally employ a person prior to completion of the required record check and evaluation by the department of human services, as applicable, subject to all of the following:

(1) The hospital shall have accessed SING to perform the required record check and be awaiting results from SING or awaiting evaluation by the department of human services, as applicable;

(2) If applicable, the hospital shall request an evaluation by the department of human services in accordance with paragraph 51.41(2)“b” or “c” within 30 days of receipt of the SING record check results;

(3) The hospital shall have utilized an approved third-party vendor to perform a comprehensive preliminary background check;

(4) If the comprehensive preliminary background check determines that the person being considered for employment has been convicted of a crime, the crime does not constitute a felony as

defined in Iowa Code section 701.7 and is not a crime specified pursuant to Iowa Code chapter 708, 708A, 709, 709A, 710, 710A, 711, or 712 or pursuant to Iowa Code section 726.3, 726.7, or 726.8;

(5) The comprehensive preliminary background check shall have determined that the person being considered for employment does not have a record of founded child abuse or dependent adult abuse, or, if the person being considered for employment does have a record of founded child abuse or dependent adult abuse, subrule 51.41(6) is applicable; and

(6) The provisional employment may continue until such time as the required record check through SING and evaluation by the department of human services, as applicable, are completed.

f. Validity of background check results. The results of a background check conducted pursuant to this rule shall be valid for a period of 30 calendar days from the date the results of the background check are received by the hospital.

51.41(3) *Employment prohibition.* Except as provided in paragraph 51.41(2) “e,” a person who has committed a crime or has a record of founded child or dependent adult abuse shall not be employed in a hospital unless an evaluation has been performed by the department of human services.

51.41(4) *Transfer of an employee to another hospital owned or operated by the same person.* If an employee transfers from one hospital to another hospital owned or operated by the same person, without a lapse in employment, the hospital is not required to request additional criminal and child and dependent adult abuse record checks of that employee.

51.41(5) *Transfer of ownership of a hospital.* If the ownership of a hospital is transferred, at the time of transfer the background check required by this rule shall be performed for each employee for whom there is no documentation that such background check has been performed. The hospital may continue to employ such employee pending the performance of the background check and any related evaluation.

51.41(6) *Change of employment—person with criminal or abuse record—exception to record check evaluation requirements.* A person with a criminal or abuse record who is or was employed by a certified hospital and is hired by another certified hospital shall be subject to the background check.

a. A reevaluation of the latest record check is not required, and the person may commence employment with the other hospital if the following requirements are met:

(1) The department of human services previously performed an evaluation concerning the person’s criminal or abuse record and concluded the record did not warrant prohibition of the person’s employment;

(2) The latest background check does not indicate a crime was committed or founded abuse record was entered subsequent to the prior evaluation;

(3) The position with the subsequent employer is substantially the same or has the same job responsibilities as the position for which the previous evaluation was performed;

(4) Any restrictions placed on the person’s employment in the previous evaluation by the department of human services and still applicable shall remain applicable in the person’s subsequent employment; and

(5) The person subject to the background check has maintained a copy of the previous evaluation and provided it to the subsequent employer, or the previous employer provides the previous evaluation from the person’s personnel file pursuant to the person’s authorization. If a physical copy of the previous evaluation is not provided to the subsequent employer, a current record check evaluation shall be performed.

b. For purposes of this subrule, a position is “substantially the same or has the same job responsibilities” if the position requires the same certification, licensure, or advanced training. For example, a licensed nurse has substantially the same or the same job responsibilities as a director of nursing; a certified nurse aide does not have substantially the same or the same job responsibilities as a licensed nurse.

c. The subsequent employer must maintain the previous evaluation in the employee’s personnel file for verification of the exception to the requirement for a record check evaluation.

d. The subsequent employer may request a reevaluation of the background check and may employ the person while the reevaluation is being performed, even though an exemption under paragraph 51.41(6) “a” may be authorized.

51.41(7) *Employee notification of criminal convictions or founded abuse after employment.* If a person employed by an employer that is subject to this rule is convicted of a crime or has a record of founded child or dependent adult abuse entered in the abuse registry after the person's employment application date, the person shall inform the employer of such information within 48 hours of the criminal conviction or entry of the record of founded child or dependent adult abuse.

a. The employer shall act to verify the information within seven calendar days of notification. "Verify," for purposes of this subrule, means to access the single contact repository (SING) to perform a background check, to request a criminal background check from the department of public safety, to request an abuse record check from the department of human services, to conduct an online search through the Iowa Courts Online website, or to contact the county clerk of court office and obtain a copy of relevant court documents.

b. If the information is verified, the hospital shall follow the requirements of paragraphs 51.41(2) "c" and "d."

c. The employer may continue to employ the person pending the performance of an evaluation by the department of human services.

d. A person who is required by this subrule to inform the person's employer of a conviction or entry of an abuse record and fails to do so within the required period commits a serious misdemeanor under Iowa Code section 135C.33.

e. The employer may notify the county attorney for the county where the employer is located of any violation or failure by an employee to notify the employer of a criminal conviction or entry of an abuse record within the period required under this subrule.

51.41(8) *Hospital receipt of credible information that an employee has been convicted of a crime or founded for abuse.* If the hospital receives credible information, as determined by the hospital, from someone other than the employee, that the employee has been convicted of a crime or a record of founded child or dependent adult abuse has been entered in the abuse registry after employment, and the employee has not informed the employer of the information within the time required by subrule 51.41(7), the hospital shall take the following actions:

a. The hospital shall act to verify credible information within seven calendar days of receipt. "Verify," for purposes of this subrule, means to access the single contact repository (SING) to perform a background check, to request a criminal background check from the department of public safety, to request an abuse record check from the department of human services, to conduct an online search through the Iowa Courts Online website, or to contact the county clerk of court office and obtain a copy of relevant court documents.

b. If the information is verified, the hospital shall follow the requirements of paragraphs 51.41(2) "c" and "d."

51.41(9) *Proof of background checks for temporary employment agencies and contractors.* Proof of background checks may be kept in the files maintained by temporary employment agencies and contractors. Facilities may require temporary employment agencies and contractors to provide a copy of the result of the background checks. Copies of such results shall be made available to the department upon request.

This rule is intended to implement Iowa Code sections 135B.7 and 135B.34 and 2020 Iowa Acts, Senate File 2299.

[ARC 0963C, IAB 8/21/13, effective 9/25/13; ARC 1304C, IAB 2/5/14, effective 3/12/14; ARC 1751C, IAB 12/10/14, effective 1/14/15; ARC 2472C, IAB 3/30/16, effective 5/4/16; ARC 5421C, IAB 2/10/21, effective 3/17/21]

481—51.42 to 51.49 Reserved.

481—51.50(135B) Minimum standards for construction.

51.50(1) *Minimum standards.* Hospitals and off-site premises licensed under this chapter shall be built in accordance with the following construction standards.

a. Construction shall be in accordance with the standards set forth in the Guidelines for Design and Construction of Hospitals, 2018 edition, published by the Facility Guidelines Institute.

b. Existing hospitals and off-site premises built in compliance with prior editions of the hospital construction guidelines will be deemed in compliance with subsequent regulations, with the exception of any new structural renovations, additions, functional alterations, or changes in utilization to existing facilities, which shall meet the standards specified in this subrule.

c. The design and construction of a hospital or off-site premises shall be in conformance with the provisions of 661—Chapter 205.

d. In jurisdictions without a local building code enforcement program, the construction shall be in conformance with the state building code, as authorized by Iowa Code section 103A.7, in effect at the time of plan submittal for review and approval. In jurisdictions with a local building code enforcement program, local building code enforcement must include both the adoption and enforcement of a local building code through plan reviews and inspections.

e. In any case in which an applicable requirement of 661—Chapter 205 is inconsistent with an applicable requirement of the state building code, the hospital or off-site premises shall be deemed to be in compliance with the state building code requirement if the requirement of 661—Chapter 205 is met.

51.50(2) *Submission of construction documents.*

a. Submissions of architectural technical documents, engineering documents, and plans and specifications to the building code commissioner are the responsibility of the owner of the building or facility, although the actual submission may be completed by an authorized agent of the owner or the responsible design professional.

b. Submissions shall comply with the provisions of rule 661—300.4(103A).

c. The responsible design professional shall certify that the building plans meet the requirements specified in subrule 51.50(1), unless a waiver has been granted pursuant to subrule 51.50(3).

51.50(3) *Waivers.* The director of the department may grant waivers to building and construction guidelines as contained in the Guidelines for Design and Construction of Hospitals, 2018 edition. The hospital or off-site premises must submit a waiver request in writing to the director. The request must demonstrate how patient safety and the quality of care offered will not be compromised by the waiver. The facility must demonstrate its ability to completely fulfill all other requirements of the service. The director shall make a written determination of the request. In determining whether a waiver request shall be granted, the director shall give consideration to the following conditions and to any other conditions the director deems relevant:

a. The design and planning for the specific property shall offer improved or compensating features which provide equivalent desirability and utility;

b. Alternate or special construction methods, techniques, and mechanical equipment shall offer equivalent durability; utility; safety; structural strength and rigidity; sanitation; odor control; protection from corrosion, decay and insect attack; and quality of workmanship;

c. The health, safety or welfare of any patient shall not be endangered;

d. The waiver shall be limited to the specific project under consideration and shall not be construed as establishing a precedent for similar acceptance in other cases;

e. Occupancy and function of the building shall be considered; and

f. The type of licensing shall be considered.

[ARC 9251B, IAB 12/1/10, effective 1/5/11; ARC 0135C, IAB 5/30/12, effective 7/4/12; ARC 2157C, IAB 9/30/15, effective 11/4/15; ARC 4070C, IAB 10/10/18, effective 11/14/18; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—51.51(135B) Minimum standards for construction after July 8, 1998, and prior to May 22, 2002. Rescinded IAB 12/1/10, effective 1/5/11.

481—51.52(135B) Minimum standards for construction after May 22, 2002. Rescinded IAB 12/1/10, effective 1/5/11.

481—51.53(135B) Critical access hospitals. Critical access hospitals shall meet the following criteria:

51.53(1) The hospital shall be no less than 35 miles from another hospital or no less than 15 miles over secondary roads or shall be designated by the department of public health as a necessary provider of health care prior to January 1, 2006.

51.53(2) The hospital shall be a public or nonprofit hospital and shall be located in a county in a rural area. Rural counties do not include Black Hawk, Johnson, Linn, Polk, Pottawattamie, Scott and Woodbury Counties. All other counties are considered to be in rural areas for purposes of this subrule.

51.53(3) The hospital shall provide 24-hour emergency care services as described in 481 IAC 51.30(135B).

51.53(4) The hospital shall maintain no more than 25 acute care inpatient beds. However, if the hospital provides inpatient psychiatric services in a distinct part unit or inpatient rehabilitation services in a distinct part unit, no more than 10 beds shall be maintained in the distinct part unit. The beds in the distinct part unit are excluded from the 25 inpatient-bed count limit specified in 42 CFR 485.620(a).

51.53(5) The hospital shall meet the Medicare conditions of participation as a critical access hospital as described in 42 CFR Part 485, Subpart F.

51.53(6) The hospital shall continue to comply with all general hospital license requirements as defined in 481 IAC 51.

51.53(7) The department shall recognize, in lieu of its own inspection, the comparable inspections and inspections findings of The Joint Commission (TJC), the American Osteopathic Association (AOA), DNV GL – Healthcare (DNV GL), or the Center for Improvement in Healthcare Quality (CIHQ) if the department is provided with copies of all requested materials relating to the inspections and the inspection process.

[ARC 9253B, IAB 12/1/10, effective 1/5/11; ARC 1305C, IAB 2/5/14, effective 3/12/14; ARC 2472C, IAB 3/30/16, effective 5/4/16]

These rules are intended to implement Iowa Code chapter 135B.

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[◇] Two or more ARCs

¹ Hospital Protocol for Donor Requests as it appeared in IAC 641—Chapter 180 prior to 4/4/90.

² January 16, 2013, effective date of 51.24(3) [ARC 0484C] delayed 70 days by the Administrative Rules Review Committee at its meeting held January 8, 2013.

CHAPTER 57
RESIDENTIAL CARE FACILITIES
[Prior to 7/15/87, Health Department[470] Ch 57]

481—57.1(135C) Definitions. The following definitions apply to this chapter and to 481—Chapter 62. The definitions set out in Iowa Code section 135C.1 shall be considered to be incorporated verbatim in these rules.

“Accommodation” means the provision of lodging, including sleeping, dining, and living areas.

“Activities of daily living” means the following self-care tasks: bathing, dressing, grooming, eating, transferring, toileting and ambulation.

“Administrator” means a person approved by the department who administers, manages, supervises, and is in general administrative charge of a residential care facility, whether or not such person has an ownership interest in the facility, and whether or not the functions and duties are shared with one or more other persons.

“Ambulatory” means the condition of a person who immediately and without the aid of another person is physically and mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

“Basement” means that part of a building where the finish floor is more than 30 inches below the finish grade of the building.

“Board” means the regular provision of meals.

“Change of ownership” means the purchase, transfer, assignment, or lease of a licensed residential care facility.

“Communicable disease” means a disease caused by the presence within a person’s body of a virus or microbial agent which may be transmitted either directly or indirectly to other persons.

“Department” means the department of inspections and appeals.

“Distinct part” means a clearly identifiable area or section containing contiguous rooms within a health care facility.

“Interdisciplinary team” means the group of persons who develop a single, integrated, individual program plan to meet a resident’s needs for services. The interdisciplinary team consists of, at a minimum, the resident, the resident’s legal guardian if applicable, the resident’s advocate if desired by the resident, a referral agency representative, other appropriate staff members, other providers of services, and other persons relevant to the resident’s needs.

“Legal representative” means the resident’s guardian or conservator if one has been appointed or the resident’s power of attorney.

“Mechanical restraint” means restriction by the use of a mechanical device of a resident’s mobility or ability to use the hands, arms or legs.

“Medication” means any drug, including over-the-counter substances, ordered and administered under the direction of the primary care provider.

“Nonambulatory” means the condition of a person who immediately and without the aid of another person is not physically or mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

“Personal care” means assistance with the activities of daily living which the recipient can perform only with difficulty. Examples are help in getting in and out of bed, assistance with personal hygiene and bathing, help with dressing and eating, and supervision over medications which can be self-administered.

“Physical restraint” means direct physical contact on the part of a staff person to control a resident’s physical activity for the resident’s own protection or for the protection of others.

“Primary care provider” means any of the following who provide primary care and meet licensure standards:

1. A physician who is a family or general practitioner or an internist.
2. An advanced registered nurse practitioner.
3. A physician assistant.

“Program of care” means all services being provided for a resident in a health care facility.

“*Prone restraint*” means a restraint in which a resident is in a face-down position against the floor or another surface.

“*Rate*” means the daily fee that is charged for all residents equally and that includes the cost of all minimum services required in these rules and regulations.

“*Records*” includes electronic records.

“*Responsible party*” means the person who signs or cosigns the residency agreement required in rule 481—57.15(135C) or the resident’s legal representative. In the event that a resident has neither a legal representative nor a person who signed or cosigned the resident’s residency agreement, the term “responsible party” shall include the resident’s sponsoring agency, e.g., the department of human services, the U.S. Department of Veterans Affairs, a religious group, fraternal organization, or foundation that assumes responsibility and advocates for its client patients and pays for their health care.

“*Restraints*” means the measures taken to control a resident’s physical activity for the resident’s own protection or for the protection of others.

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 3737C, IAB 4/11/18, effective 5/16/18; ARC 3738C, IAB 4/11/18, effective 5/16/18]

481—57.2(135C,17A) Waiver. A waiver from these rules may be granted by the director of the department in accordance with 481—Chapter 6. A request for waiver will be granted or denied by the director within 120 calendar days of receipt.

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—57.3(135C) Application for licensure.

57.3(1) Application and licensing—new facility or change of ownership. In order to obtain an initial residential care facility license for a facility not currently licensed as a residential care facility or for a residential care facility when a change of ownership is contemplated, the applicant must:

- a. Make application at least 30 days prior to the proposed opening date of the facility. Application shall be made on forms provided by the department.
- b. Meet all of the rules, regulations, and standards contained in 481—Chapters 50, 57 and 60. Exceptions noted in 481—subrule 60.3(2) shall not apply.
- c. Submit a letter of intent and a written résumé of care. The résumé of care shall meet the requirements of subrule 57.3(2).
- d. Submit a floor plan of each floor of the residential care facility. The floor plan of each floor shall be drawn on 8½" × 11" paper, show room areas in proportion, room dimensions, window and door locations, designation of the use of each room, and the room numbers for all rooms, including bathrooms.
- e. Submit a photograph of the front and side of the residential care facility.
- f. Submit the statutory fee for a residential care facility license.
- g. Comply with all other local statutes and ordinances in existence at the time of licensure.
- h. Submit a certificate signed by the state or local fire inspection authority as to compliance with fire safety rules and regulations.

57.3(2) Résumé of care. The résumé of care shall describe the following:

- a. Purpose of the facility;
- b. Criteria for admission to the facility;
- c. Ownership of the facility;
- d. Composition and responsibilities of the governing board;
- e. Qualifications and responsibilities of the administrator;
- f. Medical services provided to residents, to include the availability of emergency medical services in the area and the designation of a primary care provider to be responsible for residents in an emergency;
- g. Dental services provided to residents and available in the area;
- h. Nursing services provided to residents, if applicable;
- i. Personal services provided to residents, including supervision of or assistance with activities of daily living;
- j. Activity program;

- k.* Dietary services, including qualifications of the person in charge, consultation service (if applicable) and meal service;
- l.* Other services available as applicable, including social services, physical therapy, occupational therapy, and recreational therapy;
- m.* Housekeeping;
- n.* Laundry;
- o.* Physical plant; and
- p.* Staffing provided to meet residents' needs.

57.3(3) *Renewal application.* In order to obtain a renewal of the residential care facility license, the applicant must submit the following:

- a.* The completed application form 30 days prior to the annual license renewal date of the residential care facility license;
- b.* The statutory license fee for a residential care facility;
- c.* An approved current certificate signed by the state or local fire inspection authority as to compliance with fire safety rules and regulations;
- d.* Changes to the résumé of care, if any; and
- e.* Changes to the current residency agreement, if any.

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.4(135C) Issuance of license. Licenses are issued to the person, entity or governmental unit with responsibility for the operation of the facility and for compliance with all applicable statutes, rules and regulations.

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.5(135C) Licenses for distinct parts.

57.5(1) Separate licenses may be issued for distinct parts of a health care facility which are clearly identifiable, contain contiguous rooms, and provide separate categories of care and services.

57.5(2) The following requirements shall be met for separate licensing of a distinct part:

- a.* The distinct part shall serve only residents who require the category of care and services immediately available to them within that part. (III)
- b.* The distinct part shall meet all the standards, rules, and regulations pertaining to the category for which a license is being sought.
- c.* The distinct part must be operationally and financially feasible.
- d.* Personal care staff with qualifications appropriate to the care and services being rendered must be regularly assigned and working in the distinct part under responsible management. (III)
- e.* Separately licensed distinct parts may have certain services such as management, building maintenance, laundry and dietary in common with each other.

This rule is intended to implement Iowa Code sections 135C.6(2) and 135C.14.

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.6(135C) Special classifications.

57.6(1) *Memory care.*

a. Designation and application. A residential care facility may choose to care for residents who require memory care in a distinct part of the facility or designate the entire residential care facility as one that provides memory care. Residents in the memory care unit or facility shall meet the level of care requirements for a residential care facility. “Memory care” in a residential care facility means the care of persons with early Alzheimer’s-type dementia or other disorders causing dementia. (I, II, III)

(1) Application for approval to provide this category of care shall be submitted by the licensee on a form provided by the department. (III)

(2) Plans to modify the physical environment shall be submitted to the department for review based on the requirements of 481—Chapter 60. (III)

(3) If the unit or facility is to be a locked unit or facility, all locking devices shall meet the Life Safety Code and any requirements of the state fire marshal. If the unit or facility is to be unlocked, a system of security monitoring is required. (I, II, III)

b. Résumé of care. A résumé of care shall be submitted to the department for approval at least 30 days before a separate memory care unit or facility is opened. For facilities with a memory care unit, this résumé of care is in addition to the résumé of care required by subrule 57.3(2). A new résumé of care shall be submitted when services are substantially changed. The résumé of care shall:

- (1) Describe the population to be served;
- (2) State the philosophy and objectives;
- (3) List criteria for transfer to and from the memory care unit or facility;
- (4) Include a copy of the floor plan;
- (5) List the titles of policies and procedures developed for the unit or facility;
- (6) Propose a staffing pattern;
- (7) Set out a plan for specialized staff training;
- (8) State visitor, volunteer, and safety policies;
- (9) Describe programs for activities, social services and families; and
- (10) Describe the interdisciplinary team and the role of each team member.

c. Policies and procedures. Separate written policies and procedures shall be implemented in the memory care unit or facility and shall address the following:

(1) Criteria for admission and the preadmission evaluation process. The policy shall require a statement from the primary care provider approving the placement before a resident may be moved into a memory care unit or facility. (II, III)

(2) Safety, including a description of the actions required of staff in the event of a fire, natural disaster, emergency medical event or catastrophic event. Safety procedures shall also explain steps to be taken when a resident is discovered to be missing from the unit or facility and when hazardous cleaning materials or potentially dangerous mechanical equipment is being used in the unit or facility and explain the manner in which the effectiveness of the security system will be monitored. (II, III)

(3) Staffing requirements, including the minimum number, types and qualifications of staff in the unit or facility in accordance with resident needs. (II, III)

(4) Visitation policies, including suggested times for visitation and ensuring the residents' rights to free access to visitors unless visits are contraindicated by the interdisciplinary team. (II, III)

(5) The process and criteria which will be used to monitor and to respond to risks specific to the residents, including but not limited to drug use, restraint use, infections, incidents and acute behavioral events. (II, III)

d. Assessment prior to transfer or admission. Prior to the transfer or admission of a resident applicant to the memory care unit or facility, a complete assessment of the resident applicant's physical, mental, social and behavioral status shall be completed to determine whether the applicant meets admission criteria. This assessment shall be completed by facility staff and shall become part of the resident's permanent record upon admission. (II, III)

e. Staff training. All staff working in a memory care unit or facility shall have training appropriate to the needs of the residents. (I, II, III)

(1) Upon assignment to the unit or facility, all staff working in the unit or facility shall be oriented to the needs of residents requiring memory care. Staff members shall have at least six hours of special training appropriate to their job descriptions within 30 days of assignment to the unit or facility. (I, II, III)

(2) Training shall include the following topics: (II, III)

1. An explanation of Alzheimer's disease and related disorders, including symptoms, behavior and disease progression;
2. Skills for communicating with persons with dementia;
3. Skills for communicating with family and friends of persons with dementia;
4. An explanation of family issues such as role reversal, grief and loss, guilt, relinquishing the caregiving role, and family dynamics;

5. The importance of planned and spontaneous activities;
6. Skills in providing assistance with activities of daily living;
7. Skills in working with challenging residents;
8. Techniques for cueing, simplifying, and redirecting;
9. Staff support and stress reduction;
10. Medication management and nonpharmacological interventions.

(3) Nursing staff, certified medication aides, medication managers, social services personnel, housekeeping and activity personnel shall have a minimum of six hours of in-service training annually. This training shall be related to the needs of memory care residents. The six-hour initial training required in subparagraph 57.6(1) “e”(1) shall count toward the required annual in-service training. (II, III)

f. Staffing. There shall be at least one staff person on a memory care unit at all times. (I, II, III)

g. Others living in the memory care unit. A resident not requiring memory care services may live in the memory care unit if the resident’s spouse requiring memory care services lives in the unit or if no other beds are available in the facility and the resident or the resident’s legal representative consents in writing to the placement. (II, III)

h. Revocation, suspension or denial. The memory care unit license or facility license may be revoked, suspended or denied pursuant to Iowa Code chapter 135C and 481—Chapter 50.

57.6(2) Residential care facility for persons with an intellectual disability (RCF/ID).

a. Definition. For purposes of this rule, the following term shall have the meaning indicated.

“*Qualified intellectual disability professional*” means a psychologist, physician, registered nurse, educator, social worker, physical or occupational therapist, speech therapist or audiologist who meets the educational requirements for the profession, as required in the state of Iowa, and has one year’s experience working with persons with an intellectual disability.

b. Designation and application. A residential care facility may choose to care for persons with an intellectual disability in a distinct part of the facility or designate the entire residential care facility as a residential care facility for persons with an intellectual disability. Residents shall meet the level of care requirements for a residential care facility. (I, II, III)

(1) Application for approval to provide this category of care shall be submitted by the licensee on a form provided by the department. (III)

(2) Plans to modify the physical environment shall be submitted to the department for review based on the requirements of 481—Chapter 60. (III)

c. Résumé of care. A résumé of care shall be submitted to the department for approval at least 30 days before a residential care facility for persons with an intellectual disability is opened. A new résumé of care shall be submitted when services are substantially changed. The résumé of care shall:

- (1) Describe the population to be served;
- (2) Include a copy of the floor plan;
- (3) List the titles of policies and procedures developed for the unit or facility;
- (4) Set out a plan for specialized staff training;
- (5) State visitor, volunteer, and safety policies;
- (6) Describe programs for activities, social services and families; and
- (7) Describe the interdisciplinary team and the role of each team member.

d. Policies and procedures. Separate written policies and procedures shall be implemented in the residential care facility for persons with an intellectual disability and shall address the following:

(1) Criteria for admission and the preadmission evaluation process. The policy shall require a statement from the primary care provider approving the placement before a resident may be moved into a residential care facility for persons with an intellectual disability. The policy shall require a primary diagnosis of an intellectual disability for admission. (II, III)

(2) Safety, including a description of the actions required of staff in the event of a fire, natural disaster, emergency medical event or catastrophic event. (II, III)

(3) Staffing requirements, including the minimum number, types and qualifications of staff in the facility in accordance with resident needs. (II, III)

(4) Visitation policies, including suggested times for visitation and ensuring the residents' rights to free access to visitors unless visits are contraindicated by the interdisciplinary team. (II, III)

(5) The process and criteria which will be used to monitor and to respond to risks specific to the residents, including but not limited to drug use, restraint use, infections, incidents and acute behavioral events. (II, III)

e. Assessment prior to transfer or admission. Prior to the transfer or admission of a resident applicant to the facility, a complete assessment of the resident applicant's physical, mental, social and behavioral status shall be completed to determine whether the applicant meets admission criteria. This assessment shall be completed by facility staff and shall become part of the resident's permanent record upon admission. (II, III)

f. Administrator qualifications. In addition to meeting the requirements of subrule 57.10(1), the administrator of a residential care facility for persons with an intellectual disability shall have at least one year's documented experience in direct care or supervision of persons with an intellectual disability. An individual employed as an administrator on May 16, 2018, will be deemed to meet the requirements of this subrule.

g. In-service educational programming. The in-service educational programming required by paragraph 57.10(2)"c" shall include educational programming specific to serving persons with an intellectual disability.

h. Revocation, suspension or denial. The facility license may be revoked, suspended or denied pursuant to Iowa Code chapter 135C and 481—Chapter 50.

This rule is intended to implement Iowa Code sections 135C.2(3)"b" and 135C.14.
[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 3737C, IAB 4/11/18, effective 5/16/18]

481—57.7(135C) General requirements.

57.7(1) The license shall be displayed in the facility in a conspicuous place which is accessible to the public. (III)

57.7(2) The license shall be valid only in the possession of the licensee to whom it is issued.

57.7(3) The posted license shall accurately reflect the current status of the residential care facility. (III)

57.7(4) The license shall expire one year after the date of issuance or as indicated on the license.

57.7(5) The licensee shall:

a. Assume the responsibility for the overall operation of the residential care facility. (I, II, III)

b. Be responsible for compliance with all applicable laws and with the rules of the department. (I, II, III)

c. Provide an organized continuous 24-hour program of care commensurate with the needs of the residents. (I, II, III)

57.7(6) Each citation or a copy of each citation issued by the department for a class I or class II violation shall be prominently posted by the facility in plain view of the residents, visitors, and persons inquiring about placement in the facility. The citation or copy of the citation shall remain posted until the violation is corrected to the satisfaction of the department. (I, II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.8(135C) Certified volunteer long-term care ombudsman program. A certified volunteer long-term care ombudsman appointed in accordance with Iowa Code section 231.45 shall operate within the scope of the rules for volunteer ombudsmen promulgated by the office of the long-term care ombudsman and the Iowa department on aging.

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.9(135C) Required notifications to the department. The department shall be notified:

57.9(1) Thirty days before any proposed change in the residential care facility's functional operation or addition or deletion of required services; (III)

57.9(2) Thirty days before the beginning of the renovation, addition, functional alteration, change of space utilization, or conversion in the residential care facility or on the premises; (III)

57.9(3) Thirty days before closure of the residential care facility; (III)

57.9(4) Within two weeks of any change in administrator; (III)

57.9(5) Ninety days before a change in the category of license; (III)

57.9(6) Thirty days before a change of ownership, the licensee shall:

a. Inform the department of the pending change of ownership; (III)

b. Inform the department of the name and address of the prospective purchaser, transferee, assignee, or lessee; (III)

c. Submit a written authorization to the department permitting the department to release all information of whatever kind from the department's files concerning the licensee's residential care facility to the named prospective purchaser, transferee, assignee, or lessee. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.10(135C) Administrator. Each residential care facility shall have one person in charge, duly approved by the department or acting in a provisional capacity in accordance with these rules. (III)

57.10(1) *Qualifications of an administrator.*

a. The administrator shall be at least 21 years of age and shall have a high school diploma or equivalent. (III) In addition, this person shall meet at least one of the following conditions:

(1) Have a two-year degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field and have a minimum of two years' experience in the field; or (III)

(2) Have a four-year degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field and have a minimum of one year experience in the field; or (III)

(3) Have a master's degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field and have a minimum of one year experience in the field; or (III)

(4) Be a licensed nursing home administrator; or (III)

(5) Have completed a one-year educational training program approved by the department for residential care facility administrators; or (III)

(6) Have passed the National Association of Long Term Care Administrator Boards (NAB) RC/AL administrator licensure examination; or

(7) Have two years of direct care experience and at least six months of administrative experience in a residential care facility. (III)

b. An individual employed as an administrator on January 14, 2015, will be deemed to meet the requirements of this subrule.

57.10(2) *Duties of an administrator.* The administrator shall:

a. Select and direct competent personnel who provide services for the residential care program. (III)

b. Arrange for the heads of nursing, social services, dietary and activities to attend a minimum of ten contact hours of educational programs per year to increase skills and knowledge needed for their positions. The ten hours is in addition to the in-service requirements in paragraph 57.10(2) "c." (III)

c. Provide in-service educational programming for all employees with direct resident contact and maintain records of programs and participants. (III) In-service educational programming offered during each calendar year shall include, at minimum, the following topics: (I, II, III)

(1) Infection control.

(2) Emergency preparedness (fire, tornado, flood, 911, etc.).

(3) Meal time procedures/dietary.

(4) Resident activities.

(5) Mental illness/behavior modification/crisis intervention.

(6) Resident safety/supervision.

(7) Resident rights.

(8) Medication education, to include administration, storage and drug interactions.

(9) Resident service plans/programming/goals.

57.10(3) Administrator serving at more than one residential care facility. The administrator may be responsible for no more than 150 beds in total if the administrator is an administrator of more than one facility. (II)

a. An administrator of more than one facility shall designate in writing an administrative staff person in each facility who shall be responsible for directing programs in the facility.

b. The administrative staff person designated by the administrator shall:

(1) Have at least one year of experience in a supervisory or direct care position in a residential care facility or in a facility for the intellectually disabled, mentally ill or developmentally disabled; (II, III)

(2) Be knowledgeable of the operation of the facility; (II, III)

(3) Have access to records concerned with the operation of the facility; (II, III)

(4) Be capable of carrying out administrative duties and of assuming administrative responsibilities; (II, III)

(5) Be at least 21 years of age; (III)

(6) Be empowered to act on behalf of the licensee concerning the health, safety and welfare of the residents; and (II, III)

(7) Have training in emergency response, including how to respond to residents' sudden illnesses. (II, III)

c. If an administrator serves more than one facility, the administrator must designate in writing regular and specific times during which the administrator will be available to consult with staff and residents to provide direction and supervision of resident care and services. (II, III)

57.10(4) Provisional administrator. A provisional administrator may be appointed on a temporary basis by the residential care facility licensee to assume the administrative responsibilities for a residential care facility for a period not to exceed one year when the facility has lost its administrator and has not been able to replace the administrator, provided that the department has been notified and approved the provisional administrator prior to the date of the provisional administrator's appointment. (III) The provisional administrator must meet the requirements of paragraph 57.10(3) "b."

57.10(5) Temporary absence of administrator.

a. In the temporary absence of the administrator, a responsible person shall be designated in writing to the department to be in charge of the facility. (III) The person designated shall:

(1) Be knowledgeable of the operation of the facility; (III)

(2) Have access to records concerned with the operation of the facility; (III)

(3) Be capable of carrying out administrative duties and of assuming administrative responsibilities; (III)

(4) Be at least 21 years of age; (III)

(5) Be empowered to act on behalf of the licensee during the administrator's absence concerning the health, safety, and welfare of the residents; (III)

(6) Have training in emergency response, including how to respond to residents' sudden illnesses. (II, III)

b. If the administrator is absent for more than six weeks, a provisional administrator must be appointed pursuant to subrule 57.10(4).

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.11(135C) Personnel.

57.11(1) Alcohol and drug use prohibited. No person under the influence of intoxicating drugs or alcoholic beverages shall be permitted to provide services in a residential care facility. (I, II)

57.11(2) Job description. There shall be a written job description developed for each category of worker. The job description shall include the job title, responsibilities and qualifications. (III)

57.11(3) Employee criminal record checks, child abuse checks and dependent adult abuse checks and employment of individuals who have committed a crime or have a founded abuse. The facility shall comply with the requirements found in Iowa Code section 135C.33 as amended by 2014 Iowa Acts, chapter 1040, and rule 481—50.9(135C) related to completion of criminal record checks, child abuse

checks, and dependent adult abuse checks and to employment of individuals who have committed a crime or have a founded abuse. (I, II, III)

57.11(4) *Personnel record.* A personnel record shall be kept for each employee and shall include but not be limited to the following information about the employee: name and address, social security number, date of birth, date of employment, position, experience and education, references, results of criminal record checks, child abuse checks and dependent adult abuse checks, and date of discharge or resignation. (III)

57.11(5) *Supervision and staffing.*

- a. The facility shall provide sufficient staff to meet the needs of the residents served. (I, II, III)
- b. Personnel in a residential care facility shall provide 24-hour coverage for residential care services. Personnel shall be awake at all times while on duty. (I, II, III)
- c. Direct care staff shall be present in the facility unless all residents are involved in activities away from the facility. (I, II, III)
- d. Staff shall be aware of and provide supervision levels based on the present needs of the residents in the staff's care. The facility shall document the supervision of residents who require more than general supervision, as defined by facility policy. (I, II, III)

e. The facility shall maintain an accurate record of actual hours worked by employees. (III)

57.11(6) *Physical examination and screening.* Employees shall have a physical examination no longer than 12 months prior to beginning employment and every four years thereafter. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59. (I, II, III)

57.11(7) *Orders for medications and treatments.* Orders for medications and treatments shall be correctly implemented by qualified personnel. (I, II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 2273C, IAB 12/9/15, effective 1/13/16]

481—57.12(135C) *General policies.* The licensee shall establish and implement written policies and procedures as set forth in this rule. The policies and procedures shall be available for review by the department, other agencies designated by Iowa Code section 135C.16(3), staff, residents, residents' families or legal representatives, and the public and shall be reviewed by the licensee annually. (II)

57.12(1) *Facility operation.* The licensee shall establish written policies for the operation of the facility, including, but not limited to the following: (III)

- a. Personnel; (III)
- b. Admission; (III)
- c. Evaluation services; (II, III)
- d. Programming and individual program plans; (II, III)
- e. Registered sex offender management; (II, III)
- f. Crisis intervention; (II, III)
- g. Discharge or transfer; (III)
- h. Medication management, including self-administration of medications and chemical restraints; (III)
- i. Resident property; (II, III)
- j. Resident finances; (II, III)
- k. Records; (III)
- l. Health and safety; (II, III)
- m. Nutrition; (III)
- n. Physical facilities and maintenance; (III)
- o. Resident rights; (II, III)
- p. Investigation and reporting of alleged dependent adult abuse; (II, III)
- q. Investigation and reporting of accidents or incidents; (II, III)
- r. Transportation of residents; (II, III)
- s. Resident supervision; (II, III)
- t. Smoking; (III)
- u. Visitors; (III)

- v. Disaster/emergency planning; (III) and
- w. Infection control. (III)

57.12(2) *Personnel policies.* Written personnel policies shall include the hours of work and attendance at educational programs. (III)

57.12(3) *Infection control.* The facility shall have a written and implemented infection control program, which shall include policies and procedures based on guidelines issued by the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. The infection control program shall address the following:

- a. Techniques for hand washing; (I, II, III)
- b. Techniques for handling of blood, body fluids, and body wastes; (I, II, III)
- c. Dressings, soaks or packs; (I, II, III)
- d. Infection identification; (I, II, III)
- e. Resident care procedures to be used when there is an infection present; (I, II, III)
- f. Sanitation techniques for resident care equipment; (I, II, III)
- g. Techniques for sanitary use and reuse of feeding syringes and single-resident use and reuse of urine collection bags; (I, II, III) and
- h. Techniques for use and disposal of needles, syringes, and other sharp instruments. (I, II, III)

57.12(4) *Resident care techniques.* The facility shall have written and implemented procedures to be followed if a resident needs any of the following treatment or devices:

- a. Intravenous or central line catheter; (I, II, III)
- b. Urinary catheter; (I, II, III)
- c. Respiratory suction, oxygen or humidification; (I, II, III)
- d. Decubitus care; (I, II, III)
- e. Tracheostomy; (I, II, III)
- f. Nasogastric or gastrostomy tubes; (I, II, III)
- g. Sanitary use and reuse of feeding syringes and single-resident use and reuse of urine collection bags. (I, II, III)

57.12(5) *Emergency care.* The facility shall establish written policies for the provision of emergency medical care to residents and employees in case of sudden illness or accident. The policies shall include a list of those individuals to be contacted in case of an emergency. (I, II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.13(135C) Admission, transfer and discharge.

57.13(1) *General admission policies.*

a. Residents shall be admitted to a residential care facility only on a written order signed by a primary care provider, specifying the level of care, and certifying that the individual being admitted requires no more than personal care and supervision and does not require routine nursing care. (II, III)

b. No residential care facility shall admit or retain a resident who is in need of greater services than the facility can provide. (I, II, III)

c. No residential care facility shall admit more residents than the number of beds for which the facility is licensed. (II, III)

d. A residential care facility is not required to admit an individual through court order, referral or other means without the express prior approval of the administrator. (III)

e. The admission of a resident shall not grant the residential care facility the authority or responsibility to manage the personal affairs of the resident except as may be necessary for the safety of the resident and the safe and orderly management of the residential care facility as required by these rules. (III)

f. Individuals under the age of 18 shall not be admitted to a residential care facility without prior written approval by the department. A distinct part of a residential care facility, segregated from the adult section, may be established based on a résumé of care that is submitted by the licensee or applicant and is commensurate with the needs of the residents of the residential care facility and that has received the department's review and approval. (III)

g. No health care facility and no owner, administrator, employee or representative thereof shall act as guardian, trustee, or conservator for any resident's property unless such resident is related within the third degree of consanguinity to the person acting as guardian. (III)

57.13(2) Discharge or transfer.

a. Notification shall be made to the legal representative, primary care provider, and sponsoring agency, if any, prior to the transfer or discharge of any resident. (III)

b. The licensee shall not refuse to discharge or transfer a resident when the primary care provider, family, resident, or legal representative requests such transfer or discharge. (II, III)

c. Advance notification will be made to the receiving facility prior to the transfer of any resident. (III)

d. When a resident is transferred or discharged, the appropriate record will accompany the resident to ensure continuity of care. "Appropriate record" includes the resident's face sheet, service plan, most recent orders of the primary care provider and any notifications of upcoming scheduled appointments. (II, III)

e. When a resident is transferred or discharged, the resident's unused prescriptions shall be sent with the resident or with a legal representative only upon the written order of a primary care provider. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.14(135C) Involuntary discharge or transfer.

57.14(1) Involuntary discharge or transfer permitted. A facility may involuntarily discharge or transfer a resident for only one of the following reasons:

a. Medical reasons;

b. The resident's welfare or that of other residents;

c. Repeated refusal by the resident to participate in the resident's service plan;

d. Due to action pursuant to Iowa Code chapter 229; or

e. Nonpayment for the resident's stay, as described in the residency agreement for the resident's stay.

57.14(2) Medical reasons. Medical reasons for transfer or discharge shall be based on the resident's needs and shall be determined and documented in the resident's record by the primary care provider. Transfer or discharge may be required in order to provide a different level of care to the resident. (II)

57.14(3) Welfare of a resident. Welfare of a resident or that of other residents refers to a resident's social, emotional, or physical well-being. A resident may be transferred or discharged because the resident's behavior poses a continuing threat to the resident (e.g., suicidal) or to the well-being of other residents or staff (e.g., the resident's behavior is incompatible with other residents' needs and rights). Written documentation that the resident's continued presence in the facility would adversely affect the resident's own welfare or that of other residents shall be made by the administrator or designee and shall include specific information to support this determination. (II)

57.14(4) Notice. Involuntary transfer or discharge of a resident from a facility shall be preceded by a written notice to the resident and the responsible party. (II, III)

a. The notice shall contain all of the following information:

(1) The stated reason for the proposed transfer or discharge. (II)

(2) The effective date of the proposed transfer or discharge. (II)

(3) A statement, in not less than 12-point type, that reads as follows:

You have a right to appeal the facility's decision to transfer or discharge you. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within seven days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department and you will not be transferred prior to a final decision. In emergency circumstances, extension of the 14-day requirement may be permitted upon request to the department's designee. If you lose the hearing, you will not be transferred before the expiration of (1) 30 days following receipt of the original notice of the discharge or transfer, or (2) 5 days following final decision of such hearing, including exhaustion of all appeals, whichever occurs later. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. (II)

b. The notice shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department; the resident's responsible party; the resident's primary care provider; the person or agency responsible for the resident's placement, maintenance, and care in the facility; and the department on aging's long-term care ombudsman. The notice shall indicate that a copy has been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent. (II)

c. The notice required by paragraph 57.14(4) "a" shall be provided at least 30 days in advance of the proposed transfer or discharge unless one of the following occurs: (II)

(1) An emergency transfer or discharge is mandated by the resident's health care needs and is in accordance with the written orders and medical justification of the primary care provider. Emergency transfers or discharges may also be mandated in order to protect the health, safety, or well-being of other residents and staff from the resident being transferred. (II)

(2) The transfer or discharge is subsequently agreed to by the resident or the resident's responsible party, and notification is given to the responsible party, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility.

d. A hearing requested pursuant to this subrule shall be held in accordance with subrule 57.14(6). **57.14(5) *Emergency transfer or discharge.*** In the case of an emergency transfer or discharge, the resident must be given a written notice prior to or within 48 hours following transfer or discharge. (II, III)

a. A copy of this notice must be placed in the resident's file. The notice must contain all of the following information:

- (1) The stated reason for the transfer or discharge. (II)
- (2) The effective date of the transfer or discharge. (II)
- (3) A statement, in not less than 12-point type, that reads:

You have a right to appeal the facility's decision to transfer or discharge you on an emergency basis. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals within 7 days after receiving this notice. You have the right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department. You may be transferred or discharged before the hearing is held or before a final decision is rendered. If you win the hearing, you have the right to be transferred back into the facility. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. (II)

b. The notice shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department; the resident's responsible party; the resident's primary care provider; the person or agency responsible for the resident's placement, maintenance, and care in the facility; and the department on aging's long-term care ombudsman. The notice shall indicate that a copy has been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent. (II)

c. A hearing requested pursuant to this subrule shall be held in accordance with subrule 57.14(6).
57.14(6) Hearing.

a. Request for hearing.

(1) The resident must request a hearing within 7 days of receiving the written notice.

(2) The request must be made to the department, either in writing or verbally.

b. The hearing shall be held no later than 14 days after receipt of the request by the department unless the resident requests an extension due to emergency circumstances.

c. Except in the case of an emergency discharge or transfer, a request for a hearing shall stay a transfer or discharge pending a final decision, including the exhaustion of all appeals. (II)

d. The hearing shall be heard by a department of inspections and appeals administrative law judge pursuant to Iowa Code chapter 17A and 481—Chapter 9. The hearing shall be public unless the resident or the resident's legal representative requests in writing that the hearing be closed. In a determination as to whether a transfer or discharge is authorized, the burden of proof by a preponderance of evidence rests on the party requesting the transfer or discharge.

e. Notice of the date, time, and place of the hearing shall be sent by certified mail or delivered in person to the facility, the resident, the responsible party, and the office of the long-term care ombudsman not later than 5 full business days after receipt of the request. The notice shall also inform the facility and the resident or the responsible party that they have a right to appear at the hearing in person or be represented by an attorney or other individual. The appeal shall be dismissed if neither party is present or represented at the hearing. If only one party appears or is represented, the hearing shall proceed with one party present. A representative of the office of the long-term care ombudsman shall have the right to appear at the hearing.

f. The administrative law judge's written decision shall be mailed by certified mail to the licensee, resident, responsible party, and the office of the long-term care ombudsman within 10 working days after the hearing has been concluded.

57.14(7) Nonpayment. If nonpayment is the basis for involuntary transfer or discharge, the resident shall have the right to make full payment up to the date that the discharge or transfer is to be made and then shall have the right to remain in the facility. (II)

57.14(8) Discussion of involuntary transfer or discharge. Within 48 hours after notice of involuntary transfer or discharge has been received by the resident, the facility shall discuss the involuntary transfer or discharge with the resident, the resident's responsible party, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. (II)

a. The facility administrator or other appropriate facility representative serving as the administrator's designee shall provide an explanation and discussion of the reasons for the resident's involuntary transfer or discharge. (II)

b. The content of the explanation and discussion shall be summarized in writing, shall include the names of the individuals involved in the discussion, and shall be made part of the resident's record. (II)

c. The provisions of this subrule do not apply if the involuntary transfer or discharge has already occurred pursuant to subrule 57.14(5) and emergency notice is provided within 48 hours.

57.14(9) Transfer or discharge planning.

a. The facility shall develop a plan to provide for the orderly and safe transfer or discharge of each resident to be transferred or discharged. (II)

b. To minimize the possible adverse effects of the involuntary transfer, the resident shall receive counseling services by the sending facility before the involuntary transfer and by the receiving facility after the involuntary transfer. Counseling shall be documented in the resident's record. (II)

c. The counseling requirement in paragraph 57.14(9)“b” does not apply if the discharge has already occurred pursuant to subrule 57.14(5) and emergency notice is provided within 48 hours.

d. Counseling, if required, shall be provided by a licensed mental health professional as defined in Iowa Code section 228.1(6).

e. The receiving health care facility of a resident involuntarily transferred shall immediately formulate and implement a plan of care which takes into account possible adverse effects the transfer may cause. (II)

57.14(10) Transfer upon revocation of license or voluntary closure. Residents shall not have the right to a hearing to contest an involuntary discharge or transfer resulting from the revocation of the facility’s license by the department of inspections and appeals. In the case of the voluntary closure of a facility, a period of 30 days must be allowed for an orderly transfer of residents to other facilities.

57.14(11) Intrafacility transfer.

a. Residents shall not be arbitrarily relocated from room to room within a licensed health care facility. (I, II) Involuntary relocation may occur only in the following situations, which shall be documented in the resident’s record: (II)

(1) Incompatibility with or disturbing to other roommates.

(2) For the welfare of the resident or other residents of the facility.

(3) To allow a new admission to the facility that would otherwise not be possible due to separation of roommates by sex.

(4) In the case of a resident whose source of payment was previously private, but who now is eligible for Title XIX (Medicaid) assistance, the resident may be transferred from a private room to a semiprivate room or from one semiprivate room to another.

(5) Reasonable and necessary administrative decisions regarding the use and functioning of the building.

b. Unreasonable and unjustified reasons for changing a resident’s room without the concurrence of the resident or responsible party include:

(1) Change from private pay status to Title XIX, except as outlined in subparagraph 57.14(11)“a”(4). (II)

(2) As punishment or behavior modification, except as specified in subparagraph 57.14(11)“a”(1). (II)

(3) Discrimination on the basis of race or religion. (II)

c. If intrafacility relocation is necessary for reasons outlined in paragraph 57.14(11)“a,” the resident shall be notified at least 48 hours prior to the transfer and the reason therefor shall be explained. The responsible party shall be notified as soon as possible. The notification shall be documented in the resident’s record and signed by the resident or responsible party. (II, III)

d. If emergency relocation is required in order to protect the safety or health of the resident or other residents, the notification requirements may be waived. The conditions of the emergency shall be documented. The family or responsible party shall be notified immediately or as soon as possible of the condition that necessitates emergency relocation, and such notification shall be documented. (II, III)

e. A transfer to a part of a facility that has a different license must be handled the same way as a transfer to another facility, and not as an intrafacility transfer. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 3523C, IAB 12/20/17, effective 1/24/18]

481—57.15(135C) Residency agreement.

57.15(1) Each residency agreement shall:

a. State the base rate or scale per day or per month, the services included, and the method of payment. (III)

b. Contain a complete schedule of all offered services for which a fee may be charged in addition to the base rate. (III) Furthermore, the agreement shall:

(1) Stipulate that no further additional fees shall be charged for items not contained in the complete schedule of services; (III)

(2) State the method of payment for additional charges; (III)

(3) Contain an explanation of the method of assessment of such additional charges and an explanation of the method of periodic reassessment, if any, resulting in changing such additional charges; (III)

(4) State that additional fees may be charged to the resident for nonprescription drugs, other personal supplies, and services provided by a barber, beautician, and such. (III)

c. Contain an itemized list of services to be provided to the resident based on an assessment at the time of the resident's admission and in consultation with the administrator and including the specific fee the resident will be charged for each service and the method of payment. (III)

d. Include the total fee to be charged initially to the resident. (III)

e. State the conditions whereby the facility may make adjustments to its overall fees for resident care as a result of changing costs. (II, III) Furthermore, the agreement shall provide that the facility shall give:

(1) Written notification to the resident, or the responsible party when appropriate, of changes in the overall rates of both base and additional charges at least 30 days prior to the effective date of such changes; (II, III)

(2) Notification to the resident, or the responsible party when appropriate, of changes in additional charges, based on a change in the resident's condition. Notification must occur prior to the date such revised additional charges begin. If notification is given orally, subsequent written notification must also be given within a reasonable time, not to exceed one week, listing specifically the adjustments made. (II, III)

f. State the terms of agreement in regard to a refund of all advance payments in the event of the transfer, death, or voluntary or involuntary discharge of the resident. (II, III)

g. State the terms of agreement concerning the holding of and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons. The terms shall contain a provision that the bed will be held at the request of the resident or the resident's responsible party. (II, III)

(1) The facility shall ask the resident or responsible party whether the resident's bed should be held. This request shall be made before the resident leaves or within 48 hours after the resident leaves. The inquiry and the response shall be documented. (II, III)

(2) The facility shall inform the resident or responsible party that, when requested, the bed may be held beyond the number of days designated by the funding source, as long as payments are made in accordance with the agreement. (II, III)

h. State the conditions under which the involuntary discharge or transfer of a resident would be effected. (II, III)

i. Set forth any other matters deemed appropriate by the parties to the agreement. No agreement or any provision thereof shall be drawn or construed so as to relieve any health care facility of any requirement or obligation imposed upon it by this chapter or any standards or rules in force pursuant to this chapter. (II, III)

57.15(2) Each party to the residency agreement shall receive a copy of the signed agreement. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.16(135C) Medical examinations.

57.16(1) Each resident in a residential care facility shall have a designated primary care provider who may be contacted when needed. (II, III)

57.16(2) Each resident admitted to a residential care facility shall have a physical examination prior to admission. (II, III)

a. If the resident is admitted directly from a hospital, a copy of the hospital admission physical and discharge summary may be a part of the record in lieu of an additional physical examination. A record of the examination, signed by the primary care provider, shall be a part of the resident's record. (II, III)

b. The record of the admission physical examination and medical history shall portray the current medical status of the resident and shall include the resident's name, sex, age, medical history, physical

examination, diagnosis, statement of medical concerns, diet, and results of any diagnostic procedures. (II, III)

c. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59. (I, II, III)

57.16(3) The person in charge shall immediately notify the primary care provider of any accident, injury or adverse change in the resident's condition that has the potential for requiring physician intervention. (I, II, III)

57.16(4) Each resident shall be visited by or shall visit the resident's primary care provider at least once each year. The one-year period shall be measured from the date of admission and does not include the resident's preadmission physical. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.17(135C) Records.

57.17(1) *Resident record.* The licensee shall keep a permanent record on every resident admitted to the residential care facility, and all entries in the permanent record shall be current, dated, and signed. (III) The record shall include:

- a.* Name and previous address of resident; (III)
- b.* Birth date, sex, and marital status of resident; (III)
- c.* Church affiliation, if designated; (III)
- d.* Primary care provider's name, telephone number, and address; (III)
- e.* Dentist's name, telephone number, and address; (III)
- f.* Name, address, and telephone number of next of kin or legal representative; (III)
- g.* Name, address, and telephone number of person to be notified in case of emergency; (III)
- h.* Pharmacy name, telephone number, and address; (III)
- i.* Mortuary name, telephone number, and address, if designated; (III)
- j.* Physical examination and medical history; (III)
- k.* Primary care provider's orders for the resident's level of care, medication, treatments, and diet. The orders shall be in writing and signed by the primary care provider quarterly; (III)
- l.* A notation of visits to primary care provider and other professional services; (III)
- m.* Documentation regarding services provided by other providers, including but not limited to home health agencies, hospice, day treatment and those providing medical, mental health and Medicaid waiver services; (III)
- n.* Documentation of any adverse change in the resident's condition; (II, III)
- o.* A notation describing the resident's condition on admission, transfer and discharge; (III)
- p.* A copy of instructions given to the resident, legal representative or facility in the event of discharge or transfer; (III)
- q.* In the event of a resident's death, notations of the date and time of the resident's death, the circumstances of the resident's death, the disposition of the resident's body, and the date and time the resident's family and primary care provider were notified of the resident's death; and (III)
- r.* A notation of disposition of personal property and medications upon the resident's transfer, discharge or death. (III)

57.17(2) *Confidentiality of resident records.* Each resident shall be ensured confidential treatment of all information contained in the resident's records. The resident's written consent shall be required for the release of information to persons not otherwise authorized under law to receive the information. (II)

a. The facility shall limit access to any medical records to staff and professionals providing services to the resident. (II)

b. The facility shall limit access to the resident's personal records, e.g., financial records and social services records, to staff and professionals providing the service to the resident. Only those personnel concerned with the financial affairs of the resident may have access to the financial records. (II)

c. The resident, or the resident's responsible party, shall be entitled to examine all information contained in the resident's record and shall have the right to secure full copies of the record at reasonable cost upon request, unless the primary care provider determines that the disclosure of the record or

section thereof is contraindicated, in which case this information will be deleted prior to making the record available to the resident or responsible party. This determination and the reasons for it must be documented in the resident's record. (II)

d. This subrule is not meant to preclude access to resident records by representatives of state and federal regulatory agencies.

57.17(3) Incident record.

a. Each residential care facility shall maintain an incident record report and shall have available incident report forms. (II, III)

b. Report of incidents shall be in detail on an incident report form. (III)

c. The person in charge at the time of the incident shall oversee the preparation of and sign the incident report. The administrator or designee shall review, sign and date the incident report within 72 hours of the accident, incident or unusual occurrence. (II, III)

d. An incident report shall be completed for every accident or incident where there is apparent injury or where an injury of unknown origin may have occurred. (II)

e. An incident report shall be completed for every accident, incident or unusual occurrence within the facility or on the premises that affects a resident, visitor, or employee. (II, III)

f. A copy of the incident report shall be kept on file in the facility. (II, III)

57.17(4) Retention of records.

a. Records shall be retained in the facility for five years following the termination of services to a resident. (III)

b. Records shall be retained within the facility upon change of ownership. (III)

c. When the facility ceases to operate, a copy of the resident's record shall be released to the facility to which the resident is transferred. (III)

d. When the facility ceases to operate, records shall be maintained for five years in a clean, dry secured storage area. (III)

57.17(5) Electronic records. In addition to the access provided in 481—subrule 50.10(2), an authorized representative of the department shall be provided unrestricted access to electronic records pertaining to the care provided to the residents of the facility. (II, III)

a. If access to an electronic record is requested by the authorized representative of the department, the facility may provide a tutorial on how to use its particular electronic system or may designate an individual who will, when requested, access the system, respond to any questions or assist the authorized representative as needed in accessing electronic information in a timely fashion. (II, III)

b. The facility shall provide a terminal where the authorized representative may access records. (II, III)

c. If the facility is unable to provide direct print capability to the authorized representative, the facility shall make available a printout of any record or part of a record on request in a time frame that does not intentionally prevent or interfere with the department's survey or investigation. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.18(135C) Resident care and personal services.

57.18(1) A complete change of bed linen shall be provided at least once a week and more often if necessary. (III)

57.18(2) Residents shall receive sufficient supervision to promote personal cleanliness. (II, III)

57.18(3) Residents shall have clean clothing as needed. Clothing shall be appropriate to residents' activities and to the weather. (III)

57.18(4) Residents shall be encouraged to bathe at least twice a week. (II, III)

57.18(5) All nonambulatory residents shall be housed on the grade level floor unless the facility has a suitably sized elevator. (II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.19(135C) Drugs.

57.19(1) Drug storage.

a. Residents who have been certified in writing by their primary care provider as capable of taking their own medications may retain these medications in their bedroom, but locked storage must be provided, with staff and the resident having access. Monitoring of the storage, administration and documentation by the resident shall be carried out by a person who meets the requirements of subrule 57.19(3) and is responsible for administering medications. (II, III)

b. Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

- (1) Locked storage for drugs, solutions, and prescriptions shall be provided. (III)
- (2) A bathroom shall not be used for drug storage. (III)
- (3) The drug storage shall be kept locked when not in use. (III)
- (4) The drug storage key shall be secured and available only to those employees charged with the responsibility of administering medications. (II, III)
- (5) Schedule II drugs, as defined by Iowa Code chapter 124, shall be kept in a locked box within the locked drug storage. (II, III)
- (6) Medications requiring refrigeration shall be kept locked in a refrigerator and separated from food and other items. (II, III)
- (7) Drugs for external use shall be stored separately from drugs for internal use. (II, III)
- (8) All potent, poisonous, or caustic materials shall be stored separately from drugs, shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet, or storeroom, and shall be made accessible only to authorized persons. (I, II)
- (9) Inspection of drug storage shall be made by the administrator or designee and a registered pharmacist not less than once every three months. The inspection shall be verified by a report signed by the administrator and the pharmacist and filed with the administrator. The report shall include, but not be limited to, certification of the absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current primary care provider's order, and drugs improperly stored. (III)
- (10) Bulk supplies of prescription drugs for multiresident use shall not be kept in a residential care facility. (III)

57.19(2) Drug safeguards.

a. All prescribed medications shall be clearly labeled indicating the resident's full name, primary care provider's name, prescription number, name and strength of drug, dosage, directions for use, date of issue, and name and address and telephone number of pharmacy or primary care provider issuing the drug. Where unit dose is used, prescribed medications shall, at a minimum, indicate the resident's full name, primary care provider's name, name and strength of drug, and directions for use. Standard containers shall be utilized for dispensing drugs. (III)

b. Sample medications provided by the resident's primary care provider shall clearly identify to whom the medications belong. (III)

c. Medication containers having soiled, damaged, illegible, or makeshift labels shall be returned to the issuing pharmacist, pharmacy, or primary care provider for relabeling or disposal. (III)

d. The medication for each resident shall be kept or stored in the original containers unless the resident is participating in an individualized medication program. (II, III)

e. Unused prescription drugs shall be destroyed by the person in charge, in the presence of a witness, and with a notation made on the resident's record or shall be returned to the supplying pharmacist. (III)

f. Prescriptions shall be refilled only with the permission of the resident's primary care provider. (II, III)

g. No medications prescribed for one resident may be administered to or allowed in the possession of another resident. (I, II)

h. Instructions shall be requested from the Iowa board of pharmacy concerning disposal of unused Schedule II drugs prescribed for a resident who has died or for whom the Schedule II drug was discontinued. (III)

i. Discontinued medications shall be destroyed within a specified time by a responsible person, in the presence of a witness, and with a notation made to that effect or shall be returned to the pharmacist for destruction. Drugs listed under the Schedule II drugs shall be destroyed in accordance with the requirements established by the Iowa board of pharmacy. (II, III)

j. All medication orders which do not specifically indicate the number of doses to be administered or the length of time the drug is to be administered shall be stopped automatically after a given time period. The automatic-stop order may vary for different types of drugs. The resident's primary care provider, in conjunction with the pharmacist, shall institute these policies and provide procedures for review and endorsement. (II, III)

k. No resident shall be allowed to possess any medications unless the primary care provider has certified in writing on the resident's medical record that the resident is mentally and physically capable of doing so. (II)

l. No medications or prescription drugs shall be administered to a resident without a written order signed by the primary care provider. (II)

m. The facility shall establish a policy to govern the distribution of prescribed medications to residents who are on leave from the facility. (II, III)

(1) Medications may be issued to residents who will be on leave from a facility for less than 24 hours. Only those medications needed for the time period the resident will be on leave from the facility may be issued. Non-child-resistant containers may be used. Instructions shall be provided and include the date, the resident's name, the name of the facility, and the name of the medication, its strength, dose and time of administration. (II, III)

(2) Medication for residents on leave from a facility for longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy. (II, III)

(3) Medication for residents on leave from a facility may be issued only by facility personnel responsible for administering medication. (II, III)

57.19(3) Drug administration—authorized personnel.

a. A properly trained person shall be charged with the responsibility of administering medications as ordered by a primary care provider. (II, III)

b. The person shall have knowledge of the purpose of the drugs and their dangers and contraindications. (II, III)

c. The person shall be a licensed nurse or primary care provider or shall have successfully completed a department-approved medication aide course and passed a department-approved medication aide challenge examination administered by an area community college. (II, III)

d. Prior to taking a department-approved medication aide course, the person shall have a letter of recommendation for admission to the medication aide course from the employing facility. (III)

e. A person who is a nursing student or a graduate nurse may take the challenge examination in place of taking a medication aide course. The person shall do all of the following before taking the medication aide challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination; (III)

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination; (III)

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating that the person is competent in medication administration. (III)

f. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination. The requirements of paragraph 57.19(3) "d" do not apply to this person. (III)

g. In a freestanding residential care facility licensed for 15 or fewer beds, a person who has successfully completed a state-approved medication manager course may administer medications.

57.19(4) Drug administration.

a. Unless the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by personally preparing the dose, observing the actual act of swallowing the oral medication, and charting the medication. In facilities where the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by observing the actual act of swallowing the oral medication and by charting the medication. Medications shall be prepared on the same shift of the same day that they are administered unless the unit dose system is used. (II)

b. Injectable medications shall be administered as permitted by Iowa law by a registered nurse, licensed practical nurse, primary care provider or pharmacist. For purposes of this subrule, “injectable medications” does not include an epinephrine autoinjector, e.g., an EpiPen. (II, III)

c. A resident certified by the resident’s primary care provider as capable of injecting the resident’s own insulin may do so. Insulin may be administered pursuant to paragraph 57.19(4) “*b*” or as otherwise authorized by the resident’s primary care provider. (II, III) Authorization shall:

- (1) Be in writing,
- (2) Be maintained in the resident’s record,
- (3) Be renewed quarterly,
- (4) Include the name of the person authorized to administer the insulin,
- (5) Include documentation by the primary care provider that the authorized person is qualified to administer insulin to that resident. (II, III)

d. A resident may participate in the administration of the resident’s own medication if the primary care provider has certified in writing in the resident’s medical record that the resident is mentally and physically capable of participating and has explained in writing in the resident’s medical record what the resident’s participation may include.

e. An individual inventory record shall be maintained for each Schedule II drug prescribed for each resident, with an accurate count and authorized signatures at every shift. (II)

f. The facility may use a unit dose system.

g. Medication aides and medication managers may administer PRN medications without contacting a licensed nurse or primary care provider if all of the following apply: (I, II, III)

(1) A written order from the resident’s primary care provider specifies the purpose of the PRN medication and the frequency, dosage and strength of the PRN medication.

(2) The resident’s primary care provider provides in writing specific criteria for administering PRN medications.

(3) The pharmacist assesses the resident’s use of PRN medications when conducting the inspection of drug storage as required by subparagraph 57.19(1) “*b*”(9).

h. The pharmacist shall assess the use of PRN medications when conducting the inspection of drug storage as required by subparagraph 57.19(1) “*b*”(9). (II, III)

i. Medications administered by an employee of the facility shall be recorded on a medication record by the individual who administers the medication. (I, II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 2643C, IAB 8/3/16, effective 9/7/16; see Delay note at end of chapter]

481—57.20(135C) Dental services.

57.20(1) The residential care facility personnel shall assist residents in obtaining annual and emergency dental services and shall arrange transportation for such services. (III)

57.20(2) Dental services shall be performed only on the request of the resident, responsible party, legal representative, or primary care provider. The resident’s primary care provider shall be advised of the resident’s dental problems. (III)

57.20(3) All dental reports or progress notes shall be included in the resident record as available. The facility shall make reasonable efforts to obtain the records following the provision of services. (III)

57.20(4) Personal care staff shall assist the resident in carrying out the dentist’s recommendations. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.21(135C) Dietary.

57.21(1) Dietary staffing.

a. A minimum of one person directly responsible for food preparation shall successfully complete a course meeting the requirements for a food protection program included in the Food Code adopted pursuant to Iowa Code chapter 137F. Another course may be substituted if the course's curriculum includes substantially similar competencies to a course that meets the requirements of the Food Code and the provider of the course files with the department a statement indicating that the course provides substantially similar instruction as it relates to sanitation and safe food handling. (III)

b. If the person is in the process of completing the food protection program in paragraph 57.21(1) "a," the requirement relating to the completion of a state-approved food protection program shall be considered to have been met.

c. In addition to the requirement of paragraph 57.21(1) "a," personnel who are responsible for food preparation or service, or both food preparation and service, shall have an orientation on sanitation and safe food handling prior to handling food and shall have annual in-service training on food protection. (III)

57.21(2) Nutrition and menu planning.

a. Menus shall be planned and followed to meet the nutritional needs of residents in accordance with the primary care provider's orders. Diet orders should be reviewed as necessary, but at least quarterly, by the primary care provider. (II, III)

b. Menus shall be planned and served to include foods and amounts necessary to meet federal dietary guidelines. (II, III)

c. At least three meals or their equivalent shall be served daily, at regular hours. (II, III)

(1) There shall be no more than a 14-hour span between offering a substantial evening meal and breakfast. (II, III)

(2) Unless contraindicated, evening snacks shall be offered routinely to all residents. Special nourishments shall be available when ordered by the primary care provider. (II, III)

d. Menus shall include a variety of foods prepared in various ways. (III)

e. Menus shall be written at least one week in advance. The current menu shall be located in an accessible place for easy use by persons purchasing, preparing, and serving food. (III)

f. Records of menus as served shall be filed and maintained for 30 days and shall be available for review by departmental personnel. When substitutions are necessary or requested, they shall be of similar nutritive value and recorded on the menu or in a notebook. (III)

g. The facility shall provide an alternative choice at scheduled meal times. (III)

57.21(3) Dietary storage, food preparation, and service.

a. All food shall be handled, prepared, served and stored in compliance with the Food Code adopted pursuant to Iowa Code section 137F.2. (I, II, III)

b. Supplies of staple foods for a minimum of a one-week period and of perishable foods for a minimum of a two-day period shall be maintained on the premises. Minimum food portion requirements for a low-cost plan shall conform to information supplied by the bureau of nutrition and health promotion of the department of public health. (II, III)

c. Dishes shall be free of cracks, chips, and stains. (III)

d. If family-style service is used, all leftover prepared food that has been on the table shall be properly handled. (III)

57.21(4) Sanitation in food preparation area.

a. In facilities licensed for more than 15 beds, the kitchen shall not be used for serving meals to residents, food service personnel, or other staff. (III)

b. There shall be written procedures established for cleaning all work and serving areas in facilities with more than 15 beds. (III)

c. A schedule for duties to be performed daily shall be posted in each food area. (III)

d. All cooking equipment in facilities of 15 or more beds shall be provided with a properly sized exhaust system and hood to eliminate excess heat, moisture, and odors from the kitchen. (II, III)

e. The food service area shall be located so it will not be used as a passageway by residents, guests, or non-food service staff. (III)

f. There shall be no washing, ironing, sorting or folding of laundry in the food service area. Dirty linen shall not be carried through the food service area unless the linen is in sealed, leakproof containers. (III)

g. In facilities with more than 15 beds, a mechanical dishwasher is required. (III)

h. A three-compartment pot and pan sink with 110°F (43°C) to 115°F (46°C) water for washing, a compartment for rinsing with water at 170°F (76°C) to 180°F (82°C) for sanitizing with space for air drying, or a two-compartment sink with access to a mechanical dishwasher for sanitizing all utensils shall be provided. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.22(135C) Orientation and service plan.

57.22(1) Orientation. Within 24 hours of admission, each resident shall receive orientation to the facility. The orientation program shall be documented in the resident's file and shall include, but shall not be limited to, a review of the resident's rights, the daily schedule, house rules and the facility's evacuation plan. (II, III)

57.22(2) Initial service plan. Within 48 hours of admission, the administrator or the administrator's designee shall develop an initial service plan to address any immediate health and safety needs. The plan shall be based on information gathered from the resident, family, referring party, primary care provider, and other significant persons. The plan shall be followed until the service plan required in subrule 57.22(3) is complete. (I, II, III)

57.22(3) Service plan. Within 30 days of admission, the administrator or the administrator's designee, in conjunction with the resident, the resident's responsible party, the interdisciplinary team, and any organization that works with or serves the resident, shall develop a written, individualized, and integrated service plan for the resident. The service plan shall be developed and implemented to address the resident's priorities and assessed needs, such as activities of daily living, rehabilitation, activity, and social, behavioral, emotional, physical and mental health. (I, II, III)

a. The service plan shall include measurable goals and objectives and the specific service(s) to be provided to achieve the goals. Each goal shall include the date of initiation and anticipated duration of service(s). Any restriction of rights shall be included in the service plan. (I, II, III)

b. The service plan shall include the documentation procedure for each goal and objective. (II, III)

c. The service plan should be modified to add or delete goals and objectives as the resident's needs change. Communications related to service plan changes or changes in the resident's condition shall occur within five working days of the change and shall be conveyed to all individuals inside and outside the residential care facility who work with the resident, as well as to the resident's responsible party. (I, II, III)

d. The service plan shall be reviewed at least quarterly by relevant staff, the resident and appropriate others, such as the resident's family, case manager and responsible party. The review shall include a written report which addresses a summary of the resident's progress toward goals and objectives and the need for continued services. (I, II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.23(135C) Resident activities program.

57.23(1) Activities program. Each residential care facility shall provide an organized resident activities program for the group and for the individual resident which shall include suitable activities. The facility shall offer at least two organized evening group activities per week and two organized weekend group activities per month. (III)

a. The activities program shall be designed to meet the needs and interests of each resident and to assist residents in continuing normal activities within limitations set by the resident's primary care provider. This shall include helping residents continue in their individual interests or hobbies. (III)

b. The activities program shall include measureable goals for each resident. (III)

c. The activities program shall include both group and individual activities. (III)

d. Residents shall be encouraged, but not required, to participate in activities. (III)

57.23(2) Coordination of activities program.

a. Each residential care facility with 15 or fewer beds shall designate a person to oversee the activities program, develop goals and monitor progress. (III)

b. Each residential care facility with more than 15 beds shall employ a person to direct the activities program. (III)

c. Staffing for the activities program shall be provided on the minimum basis of 45 minutes per resident per week. (II, III)

d. The activities coordinator shall have completed the activities coordinator orientation course approved by the department within six months of employment or have comparable training and experience as approved by the department. (III)

e. There shall be a written plan for personnel coverage when the activities coordinator is absent during scheduled working hours. (III)

57.23(3) Duties of activities coordinator. The activities coordinator shall:

a. Have access to all residents' records. (III)

b. Coordinate all activities, including volunteer or auxiliary activities and religious services. (III)

c. Keep all necessary records including:

(1) Attendance records; (III)

(2) Individual resident progress notes, recorded at least every three months; (III)

(3) Monthly calendars, prepared in advance, updated as necessary and maintained for one year.

(III)

d. Coordinate the activities program with all other services in the facility. (III)

57.23(4) Supplies, equipment, and storage.

a. Each facility shall provide a variety of supplies and equipment of a nature calculated to fit the needs and interests of the residents. (III)

b. Storage shall be provided for recreational equipment and supplies. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.24(135C) Residents' rights.

57.24(1) Each facility shall ensure that policies and procedures are written and implemented which include, at a minimum, the provisions of this rule and which govern all areas of service provided by the facility. These policies and procedures shall be available to staff, residents, residents' families or legal representatives and the public and shall be reviewed annually. (II, III)

57.24(2) Policies and procedures shall include a method for submitting complaints and recommendations by residents or their responsible parties and for ensuring a response and disposition by the facility. (II, III) The written procedures shall:

a. Ensure the provision of assistance to residents as necessary to complete and submit complaints and recommendations; (II, III)

b. Ensure protection of the resident from any form of reprisal or intimidation; (II, III)

c. Include designation of an employee responsible for handling grievances and recommendations; (II, III)

d. Include a method of investigating and assessing the validity of a grievance or recommendation; (II, III) and

e. Include methods of recording grievances and actions taken. (II, III)

57.24(3) Policies and procedures shall include provisions governing access to, duplication of, and dissemination of information from the residents' records. (II, III)

57.24(4) Policies and procedures shall include a provision that each resident shall be fully informed of the resident's rights and responsibilities as a resident and of all rules governing resident conduct and responsibilities. This information must be provided upon the resident's admission, or in the case of residents already in the facility, upon the facility's adoption or amendment of residents' rights policies. (II, III)

a. The facility shall communicate to residents prior to or within five days after admission what residents may expect from the facility and its staff, and what is expected from residents. The

communication shall be in writing, e.g., in a separate handout or brochure describing the facility, and interpreted verbally, e.g., as part of a preadmission interview, resident counseling, or in individual or group orientation sessions following the resident's admission. (II, III)

b. Residents' rights and responsibilities shall be presented in language understandable to the resident. If the facility serves residents who are non-English-speaking or deaf or hard of hearing, steps shall be taken to translate the information into a foreign or sign language. In the case of blind residents, either Braille or a recording shall be provided. Residents shall be encouraged to ask questions about their rights and responsibilities and these questions shall be answered. (II, III)

c. A statement shall be signed by the resident, or the resident's responsible party, if applicable, indicating an understanding of these rights and responsibilities and shall be maintained in the resident's record. The statement shall be signed no later than five days after admission, and a copy of the signed statement shall be given to the resident or responsible party. (II, III)

d. In order to ensure that residents continue to be aware of these rights and responsibilities during their stay, a written copy shall be prominently posted in a location that is available to all residents. (II, III)

e. All residents shall be advised within 30 days following changes made in the statement of residents' rights and responsibilities. Appropriate means shall be utilized to inform non-English-speaking, deaf or hard-of-hearing, or blind residents of changes. (II, III)

57.24(5) Choice of primary care provider. Each resident shall be permitted free choice of a primary care provider, and pharmacy, if accessible. The facility may require the selected pharmacy to utilize a drug distribution system compatible with the system currently used by the facility. (II)

57.24(6) Each resident shall be afforded the opportunity to participate in the planning of the resident's total care and treatment, which may include, but shall not be limited to, medical care, nutritional needs, activities, and social work services. Each resident has the right to refuse treatment except as provided by Iowa Code chapter 229. In the case of a resident with impaired decision-making skills, the responsible party shall be afforded the opportunity to participate in the planning of the resident's total care and medical treatment and to be informed of the resident's medical condition. (II, III)

57.24(7) Each resident shall be encouraged and assisted throughout the resident's period of stay to exercise the resident's rights as a resident and as a citizen and may voice grievances and recommend changes in policies and services to administrative staff or to outside representatives of the resident's choice, free from interference, coercion, discrimination, or reprisal. (II)

57.24(8) The facility shall provide ongoing opportunities for residents to be aware of and to exercise their rights as residents. Residents shall be kept informed of changes in policies and services that are more restrictive, and their views shall be solicited prior to action. (II)

57.24(9) The facility shall post in a prominent area the text of Iowa Code section 135C.46 (Retaliation Prohibited) and the name, telephone number, and address of the long-term care ombudsman, the department, and the local law enforcement agency to provide residents a further course of redress. (II)

57.24(10) All rights and responsibilities of the resident devolve to the resident's responsible party or any legal surrogate designated in accordance with state law, to the extent permitted by state law. This subrule is not intended to limit the authority of any individual acting pursuant to Iowa Code chapter 144A. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 5711C, IAB 6/16/21, effective 7/21/21]

481—57.25(135C) Dignity preserved. The resident shall be treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and in care for personal needs. (I, II)

57.25(1) Staff shall display respect for residents when speaking with, caring for, or talking about them, as constant affirmation of their individuality and dignity as human beings. (I, II)

57.25(2) Schedules of daily activities shall allow maximum flexibility for residents to exercise choice about what they will do and when they will do it. Residents' individual preferences regarding

such things as menus, clothing, religious activities, friendships, activity programs, entertainment, sleeping and eating, also times to retire at night and arise in the morning shall be elicited and considered by the facility. (II)

57.25(3) Residents shall be examined and treated in a manner that maintains the privacy of their bodies. A closed door or a drawn curtain shall shield the resident from passersby. People not involved in the care of the residents shall not be present without the resident's consent while the resident is being examined or treated. (II)

57.25(4) Privacy of a resident's body also shall be maintained during toileting, bathing, and other activities of personal hygiene, except as needed for resident safety or assistance. (II)

57.25(5) Staff shall knock and be acknowledged before entering a resident's room unless the resident is not capable of a response. This shall not apply under emergency conditions. (II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.26(135C) Communications. Each resident may communicate, associate, and meet privately with persons of the resident's choice, unless to do so would infringe upon the rights of other residents, and may send and receive personal mail unopened. (II)

57.26(1) Subject to reasonable scheduling restrictions, visiting policies and procedures shall permit residents to receive visits from anyone they wish. Visiting hours shall be posted. (II)

57.26(2) Reasonable, regular visiting hours shall not be less than 12 hours per day and shall take into consideration the special circumstances of each visitor. A particular visitor(s) may be restricted by the facility for one of the following reasons:

- a. The resident refuses to see the visitor(s). (II)
- b. The resident's primary care provider documents specific reasons why such a visit would be harmful to the resident's health. (II)
- c. The visitor's behavior is unreasonably disruptive to the functioning of the facility. This judgment must be made by the administrator, and the reasons shall be documented and kept on file. (II)

57.26(3) Decisions to restrict a visitor are reviewed and reevaluated:

- a. Each time the medical orders are reviewed by the primary care provider;
- b. At least quarterly by the facility's staff; or
- c. At the resident's request. (II)

57.26(4) Space shall be provided for residents to receive visitors in reasonable comfort and privacy. (II)

57.26(5) Telephones shall be available and accessible for residents to make and receive calls with privacy. Residents who need help shall be assisted in using the telephone. (II)

57.26(6) Arrangements shall be made to provide assistance to residents who require help in reading or sending mail. (II)

57.26(7) Residents, including residents court-ordered to the facility, shall be permitted to leave the facility at reasonable times unless there are justifiable reasons established in writing by court order, the primary care provider, the interdisciplinary team, or facility administrator for refusing permission. (II)

57.26(8) Residents shall not have their personal lives regulated beyond reasonable adherence to meal schedules, bedtime hours, and other written policies which may be necessary for the orderly management of the facility and as required by these rules. However, residents shall be encouraged to participate in recreational programs. (II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.27(135C) Resident activities.

57.27(1) Each resident may participate in activities of social, religious, and community groups at the resident's discretion unless contraindicated for reasons documented by the primary care provider or interdisciplinary team as appropriate in the resident's record. (II)

57.27(2) Residents who wish to meet with or participate in activities of social, religious, or other community groups in or outside of the facility shall be informed, encouraged, and assisted to do so. (II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.28(135C) Resident property.

57.28(1) Residents shall be permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility. The facility shall offer the resident the opportunity to have personal property itemized and documented on an inventory sheet upon the resident's admission. The inventory sheet shall be kept in a safe location which is convenient to the resident and shall be updated at least annually. At discharge, residents may sign off on a list of the personal property they are taking with them. (II, III)

57.28(2) The facility shall provide for the safekeeping of personal effects, funds and other property of its residents. The facility may require that items of exceptional value or that would convey unreasonable responsibilities to the licensee be removed from the premises of the facility for safekeeping. (III)

57.28(3) Funds or properties received by the facility, belonging or due a resident, expendable for the resident's account, shall be trust funds. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.29(135C) Financial affairs—management. Each resident who has not been assigned a guardian or conservator by the court may manage the resident's own personal financial affairs. To the extent the facility assists in management, under written authorization by the resident, the management shall be carried out in accordance with Iowa Code section 135C.24. (II)

57.29(1) The facility shall maintain a written account of all residents' funds received by or deposited with the facility. (II)

57.29(2) An employee shall be designated in writing to be responsible for resident accounts. (II)

57.29(3) The facility shall keep on deposit personal funds over which the resident has control in accordance with Iowa Code section 135C.24. Should the resident request these funds, they shall be given to the resident on request with receipts maintained by the facility and a copy to the resident. In the case of a resident with impaired decision-making skills, the resident's legal representative shall designate a method of disbursing the resident's funds. (II)

57.29(4) If the facility makes financial transactions on a resident's behalf, the facility must document that it has prepared and sent an itemized accounting of disbursements and current balances at least quarterly. A copy of this statement shall be maintained in the resident's financial or business record. (II)

57.29(5) A resident's personal funds shall not be used without the written consent of the resident or the resident's legal representative. (I, II)

57.29(6) A resident's personal funds shall be returned to the resident when the funds have been used without the written consent of the resident or the resident's legal representative. The department may report findings that resident funds have been used without written consent to the department's investigations division or the local law enforcement agency, as appropriate. (II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.30(135C) Resident work. No resident may be required to perform services for the facility, except as provided by Iowa Code section 347B.5. (II)

57.30(1) Residents may not be used to provide a source of labor for the facility against their will. Approval by the primary care provider is required for all work programs. (I, II)

57.30(2) Residents who perform work for the facility must receive compensation unless the work is part of their approved training program. Persons on the resident census who perform work shall not be used to replace paid employees in fulfilling staffing requirements. (II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.31(135C) Family—shared rooms. Family members or spouses shall be permitted to share a room, if available, if requested by both parties, unless the primary care provider of one of the parties documents in the medical record specific reasons why such an agreement would have an adverse effect on the health of the resident. (II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.32(135C) Resident abuse prohibited. Each resident shall receive kind and considerate care at all times and shall be free from mental, physical, sexual, and verbal abuse, exploitation, neglect, and physical injury. (I, II)

57.32(1) Mental abuse includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation. (I, II)

57.32(2) Physical abuse includes, but is not limited to, corporal punishment and the use of restraints as punishment. (I, II)

57.32(3) Drugs such as tranquilizers shall only be used in accordance with orders of the primary care provider. (I, II)

57.32(4) Allegations of dependent adult abuse. Allegations of dependent adult abuse shall be reported and investigated pursuant to Iowa Code chapter 235E and 481—Chapter 52. (I, II, III)

57.32(5) Staff shall receive training relating to the identification and reporting of dependent adult abuse as required by Iowa Code section 235B.16. (I, II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 3737C, IAB 4/11/18, effective 5/16/18]

481—57.33(135C) Crisis intervention. If a facility utilizes physical restraints, the facility shall have written policies that define the uses of physical restraints, designate the administrator or designee as the person who may authorize their use, establish a mechanism for monitoring and controlling their use, and provide staff with proper training. (I, II, III)

57.33(1) Temporary physical restraint of residents shall be used only under the following conditions: (I, II)

a. An emergency to prevent injury to the resident or to others; or (I, II)

b. For crisis intervention, but shall not be used for punishment, for the convenience of staff or as a substitution for supervision or programming; (I, II) and

c. No staff person shall use any restraint that obstructs the airway of the resident. (I, II)

57.33(2) Authorization for the use of physical restraints must be prior to or immediately after application of the restraint. (I, II)

57.33(3) Prone restraint is prohibited. Staff persons who find themselves involved in the use of a prone restraint when responding to an emergency must take immediate steps to end the prone restraint. (I, II)

57.33(4) The rationale and authorization for the use of physical restraint and staff action and procedures carried out to protect the resident's rights and to ensure safety shall be clearly set forth in the resident's record by the responsible staff persons. (I, II)

57.33(5) The primary care provider, the interdisciplinary team and the resident's responsible party shall be notified of any restraints administered. (I, II, III)

57.33(6) The facility shall provide to the staff a department-approved training program by qualified professionals on physical restraint techniques. (I, II)

a. The facility shall keep a record of training for review by the department and shall include attendance. (II, III)

b. Only staff with documented training in physical restraint and techniques shall be authorized to assist with physical restraint of a resident. (I, II)

c. Under no circumstances shall a resident be allowed to actively or passively assist in the restraint of another resident. (I, II)

57.33(7) Residents shall not be kept behind locked doors. (I, II)

57.33(8) Mechanical restraint is prohibited. Staff persons who find themselves involved in the use of a mechanical restraint when responding to an emergency must take immediate steps to end the mechanical restraint. (I, II)

[ARC 1753C, IAB 12/10/14, effective 1/14/15; ARC 3738C, IAB 4/11/18, effective 5/16/18]

481—57.34(135C) Safety. The licensee of a residential care facility shall be responsible for the provision and maintenance of a safe environment for residents and personnel. (I, II, III)

57.34(1) *Fire safety.*

a. All residential care facilities shall meet the fire safety rules and regulations as promulgated by the state fire marshal. (I, II)

b. The size of the facility and needs of the residents shall be taken into consideration in evaluating safety precautions and practices.

57.34(2) *Safety duties of administrator.* The administrator shall have a written emergency plan to be followed in the event of fire, tornado, explosion, or other emergency. (III)

a. The plan shall be prominently posted in a common area of the building. (III)

b. In-service shall be provided to ensure that all employees are knowledgeable of the emergency plan. (II, III)

57.34(3) *Resident safety.*

a. Smoking shall be prohibited, except as allowed by Iowa Code chapter 142D, the smokefree air Act. (II, III)

b. Whenever full or empty tanks of oxygen are being used or stored, they shall be securely supported in an upright position. (II, III)

c. Residents shall receive adequate supervision to ensure against hazard from themselves, others, or elements in the environment. (I, II, III)

d. Storage areas for cleaning agents, bleaches, insecticides, or any other poisonous, dangerous, or flammable materials shall be locked. Residents permitted to access these materials shall be supervised by staff as identified in the resident's service plan. (I, II, III)

e. Sufficient numbers of noncombustible trash containers with covers shall be available. (III)

f. Residents' personal possessions that may constitute a hazard to residents or others shall be removed and stored. (III)

57.34(4) *First-aid kit.* A first-aid emergency kit shall be available on each floor in every facility. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.35(135C) Housekeeping.

57.35(1) Written procedures shall be established and implemented for daily and weekly cleaning schedules. (III)

57.35(2) Each resident room shall be cleaned on a routine schedule. (III)

57.35(3) All rooms, corridors, storage areas, linen closets, attics, and basements shall be kept in a clean, orderly condition, free of unserviceable furniture and equipment and accumulations of refuse. (II, III)

57.35(4) A hallway or corridor shall not be used for storage of equipment. (II, III)

57.35(5) All odors shall be kept under control by cleanliness and proper ventilation. (III)

57.35(6) Clothing worn by personnel shall be clean and washable. (III)

57.35(7) Housekeeping and maintenance personnel shall be provided with well-constructed and properly maintained equipment appropriate to the function for which it is to be used. (III)

57.35(8) All furniture, bedding, linens, and equipment shall be cleaned periodically and before use by another resident. (II, III)

57.35(9) Polishes used on floors shall provide a nonslip finish. (II, III)

57.35(10) Throw or scatter rugs shall have nonskid backing. (II, III)

57.35(11) Entrances, exits, steps, and outside walkways shall be kept free from ice, snow, and other hazards. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.36(135C) Maintenance.

57.36(1) Each facility shall establish a maintenance program to ensure the continued maintenance of the facility, to promote good housekeeping procedures, and to ensure sanitary practices throughout the facility. In facilities with more than 15 beds, the maintenance program shall be established in writing and available for review by the department. (II, III)

57.36(2) The building, grounds, and other buildings shall be maintained in a clean, orderly condition and in good repair. (II, III)

57.36(3) Window treatments and furniture shall be clean and in good repair. (II, III)

57.36(4) Cracks in plaster, peeling wallpaper or paint, and tears or splits in floor coverings shall be promptly repaired or replaced in a professional manner. (II, III)

57.36(5) The electrical systems, including appliances, cords, and switches, shall be maintained to guarantee safe functioning and comply with the National Electric Code. (II, III)

57.36(6) All plumbing fixtures shall function properly and comply with the state plumbing code. (II, III)

57.36(7) Yearly inspections of the heating and cooling systems shall be made to guarantee safe operation. (II, III)

57.36(8) The building, grounds, and other buildings shall be kept free of breeding areas for flies, other insects, and rodents. (II, III)

57.36(9) The facility shall be kept free of flies, other insects, and rodents. (II, III)

57.36(10) Janitor's closet.

a. Facilities shall be provided with storage for cleaning equipment and supplies. (III)

b. Mops, scrub pails, and other cleaning equipment used in the resident areas shall not be stored or used in the dietary area. (III)

c. In facilities licensed for more than 15 beds, a janitor's closet shall be provided. It shall be equipped with water for filling scrub pails and a janitor's sink for emptying scrub pails. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.37(135C) Laundry.

57.37(1) All soiled linens shall be collected and transported to the laundry room in closed, leakproof laundry bags or covered, impermeable containers. (III)

57.37(2) Except for related activities, the laundry room shall not be used for other purposes. (III)

57.37(3) Procedures shall be written for the proper handling of wet, soiled, and contaminated linens. (III)

57.37(4) Residents' personal laundry shall be marked with an identification if comingled with other residents' personal laundry. (III)

57.37(5) Bed linens, towels, and washcloths shall be clean and stain-free. (III)

57.37(6) If laundry is done in the facility, the following shall be provided:

a. A clean, dry, well-lit area to accommodate a washer and dryer of adequate size to serve the needs of the facility. (III)

b. In facilities with more than 15 beds, the laundry room shall be divided into separate areas, one for sorting soiled linen and one for sorting and folding clean linen. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.38(135C) Garbage and waste disposal.

57.38(1) All garbage shall be gathered, stored, and disposed of in a manner that will not permit transmission of disease, create a nuisance, or provide a breeding or feeding place for vermin or insects. (III)

57.38(2) All containers for refuse shall be watertight and rodent-proof and have tight-fitting covers. (III)

57.38(3) All unlined containers shall be thoroughly cleaned each time the containers are emptied. (III)

57.38(4) All waste shall be properly disposed of in compliance with local ordinances and state codes. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.39(135C) Supplies.

57.39(1) *Linen supplies.*

a. There shall be an adequate supply of linen so that each resident shall have at least three washcloths, hand towels, and bath towels per week. (III)

b. A complete change of bed linens shall be available in the linen storage area for each bed. (III)

c. Sufficient lightweight, clean, serviceable blankets shall be available. All blankets shall be laundered as often as necessary for cleanliness and freedom from odors. (III)

d. Each bed shall be provided with clean, washable bedspreads. There shall be a supply available when changes are necessary. (III)

e. Adequate storage shall be provided for linens, pillows, and bedding. (III)

57.39(2) *Supplies, equipment and storage.*

a. All equipment shall be properly cleaned and sanitized before use by another resident. (III)

b. Clean and sanitary storage shall be provided for equipment and supplies. (III)

c. Each facility shall provide a variety of supplies and equipment of a nature calculated to fit the needs and interests of the residents. (III)

d. Locked storage should be available for potentially dangerous items such as scissors, knives, and toxic materials. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.40(135C) Buildings, furnishings, and equipment.

57.40(1) *Buildings—general requirements.*

a. All windows shall be supplied with window treatments that are kept clean and in good repair. (III)

b. Whenever glass sliding doors or transparent panels are used, they shall be marked conspicuously. (III)

c. The facility shall meet the equivalent requirements of the appropriate group occupancy of the state building code. (III)

57.40(2) *Furnishings and equipment.*

a. All furnishings and equipment shall be durable, cleanable, and appropriate to their function. (III)

b. All resident areas shall be decorated, painted, and furnished to provide a homelike atmosphere. (III)

c. Upholstery materials shall be moisture- and soil-resistant as needed, except on furniture provided by the resident and the property of the resident. (III)

57.40(3) *Dining and living rooms.*

a. Every facility shall have a dining room and a living room easily accessible to all residents. (III)

b. Living rooms shall be maintained for the use of residents and their visitors and may be used for recreational activities. Living rooms shall be suitably furnished. (III)

c. Dining rooms shall be furnished with dining tables and chairs appropriate to the size and function of the facility. Dining rooms and furnishings shall be kept clean and sanitary. (III)

57.40(4) *Bedrooms.*

a. Each resident shall be provided with a standard, single, or twin bed, substantially constructed and in good repair. Rollaway beds, metal cots, or folding beds are not acceptable. (III)

b. Each bed shall be equipped with the following: casters or glides; clean springs in good repair; a clean, comfortable, well-constructed mattress approximately five inches thick and standard in size for the bed; and clean, comfortable pillows of average bed size. (III)

c. Each resident shall have a bedside table with a drawer to accommodate personal possessions. (III)

d. There shall be a comfortable chair, either a rocking chair or armchair, per resident bed. The resident's personal wishes shall be considered. (III)

e. There shall be drawer space for each resident's clothing. In a bedroom in which more than one resident resides, drawer space shall be assigned to each resident. (III)

f. Beds and other furnishings shall not obstruct free passage to and through doorways. (III)

g. Beds shall not be placed in such a manner that the side of the bed is against the radiator or in close proximity to it unless the radiator is covered so as to protect the resident from contact with it or from excessive heat. (III)

h. There shall be no more than four residents per room. (III)

57.40(5) Bath and toilet facilities.

a. All sinks shall have paper towel dispensers and an available supply of soap. (III)

b. Toilet paper shall be readily available to residents. (III)

57.40(6) Heating. A centralized heating system shall be maintained in good working order and capable of maintaining a comfortable temperature for residents of the facility. Portable units or space heaters are prohibited from being used in the facility except in an emergency. (II, III)

57.40(7) Water supply.

a. Private sources of water supply shall be tested annually and the report made available for review by the department upon request. (III)

b. A bacterially unsafe source of water supply shall be grounds for denial, suspension, or revocation of license. (III)

c. The department may require testing of private sources of water supply at its discretion in addition to the annual test. The facility shall supply reports of such tests as directed by the department. (III)

d. Hot and cold running water under pressure shall be available in the facility. (II, III)

e. Prior to construction of a new facility or new water source, private sources of water supply shall be surveyed and shall comply with the requirements of the department. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.41(135C) Family and employee accommodations.

57.41(1) In facilities where the total occupancy of family, employees, and residents is more than five, separate bathing and toilet facilities shall be required for the family or employees distinct from such areas provided for the residents. (III)

57.41(2) In all facilities, if the family or employees live within the facility, separate living quarters and recreation facilities shall be required for the family or employees distinct from such areas provided for the residents. (III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.42(135C) Animals. No animals shall be allowed to reside in the facility except with written approval of the department and under controlled conditions. (II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.43(135C) Another business or activity in a facility. A facility is allowed to have another business or activity in a health care facility or in the same physical structure of the facility, if the other business or activity is under the control of and is directly related to and incidental to the operation of the health care facility, or the business or activity is approved by the department and the state fire marshal. (I, II, III)

57.43(1) To obtain the approval of the department and the state fire marshal, the facility must submit to the department a written request for approval which identifies the service(s) to be offered by the business and addresses the factors outlined in paragraphs 57.43(2) “a” through “j.” (I, II, III)

57.43(2) The following factors will be considered by the department in determining whether a business or activity will interfere with the use of the facility by residents, interfere with services provided to residents, or be disturbing to residents:

a. Health and safety risks for residents;

b. Compatibility of the proposed business or activity with the facility program;

c. Noise created by the proposed business or activity;

d. Odors created by the proposed business or activity;

e. Use of entrances and exits for the business or activity in regard to safety and disturbance of residents and interference with delivery of services;

f. Use of the facility’s corridors or rooms as thoroughfares to the business or activity in regard to safety and disturbance of residents and interference with delivery of services;

g. Proposed staffing for the business or activity;

- h.* Sharing of services and staff between the proposed business or activity and the facility;
- i.* Facility layout and design; and
- j.* Parking area utilized by the business or activity.

57.43(3) Approval of the state fire marshal shall be obtained before approval of the department will be considered.

57.43(4) A business or activity conducted in a health care facility or in the same physical structure as a health care facility shall not reduce space, services or staff available to residents below minimums required in these rules and 481—Chapter 60. (I, II, III)
[ARC 1753C, IAB 12/10/14, effective 1/14/15]

481—57.44(135C) Respite care services. “Respite care services” means an organized program of temporary supportive care provided for 24 hours or more to a person in order to relieve the usual caregiver of the person from providing continual care to the person. “Respite care services” does not include crisis stabilization services provided pursuant to 2014 Iowa Acts, chapter 1044 (to be codified at Iowa Code section 225C.19A). “Respite care individual” means a person receiving respite care services. A residential care facility which chooses to provide respite care services must meet the following requirements related to respite services and must be licensed as a residential care facility. (II, III)

57.44(1) Length of stay. Respite care may be provided for no more than 30 consecutive days and for a total of no more than 60 days in a consecutive 12-month period. The 12-month period begins on the first day of the respite care individual’s stay at the facility. (II, III)

57.44(2) No separate license. A residential care facility which chooses to provide respite care services is not required to obtain a separate license or pay a license fee.

57.44(3) Involuntary termination of respite services. The facility may terminate the respite services for a respite care individual. Rule 481—57.14(135C) shall not apply. The facility shall make proper arrangements for the welfare of the respite care individual prior to involuntary termination of respite services, including notification of the respite care individual’s family or legal representative. (II, III)

57.44(4) Contract. Pursuant to rule 481—57.15(135C), the facility shall have a contract with each resident in the facility. When an individual is there for respite care services, the contract shall specify the time period during which the individual will be considered to be receiving respite care services. At the end of that period, the contract may be amended to extend that period of time. The contract shall specifically state that respite care services may be involuntarily terminated. The contract shall meet other requirements under rule 481—57.15(135C), except the requirements under subrule 57.15(7). (II, III)

57.44(5) Admission as a resident.

a. An individual being cared for under a respite care contract shall not be considered an admission to the facility.

b. A respite care individual shall be included in the facility’s census.

c. The facility shall not enter into multiple 30-day contracts with an individual being cared for under a respite care contract in order to lengthen the individual’s stay at the facility. (II, III)

d. If an individual being cared for under a respite care contract remains in the facility beyond 30 consecutive days and is eligible for admission, the department shall consider the individual a resident in the facility. The facility shall follow all requirements for the individual’s admission to the facility. (II, III)

57.44(6) Level of care. Respite care services shall not be provided by a health care facility to persons requiring a level of care which is higher than the level of care the facility is licensed to provide. (I, II, III)

57.44(7) Reporting requirements. The reporting requirements of rule 481—50.7(135C) shall apply to residents being cared for under a respite care contract. (I, II, III)

[ARC 1753C, IAB 12/10/14, effective 1/14/15]

These rules are intended to implement Iowa Code section 135C.14.

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◇ Two or more ARCs

¹ Effective date of 470—57.15(2)“a” and “b” delayed until the expiration of 45 calendar days into the 1987 session of the General Assembly pursuant to Iowa Code section 17A.8(9), IAB 6/4/86.

² See IAB, Inspections and Appeals Department.

³ Effective date of 481—57.12(2)“a,” last paragraph, delayed 70 days by the Administrative Rules Review Committee at its meeting held July 8, 1993.

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CHAPTER 58
NURSING FACILITIES

[Prior to 7/15/87, Health Department[470] Ch 58]

481—58.1(135C) Definitions. For the purpose of these rules, the following terms shall have the meaning indicated in this chapter. The definitions set out in Iowa Code section 135C.1 shall be considered to be incorporated verbatim in the rules. The use of the words “shall” and “must” indicates those standards are mandatory. The use of the words “should” and “could” indicates those standards are recommended.

“*Accommodation*” means the provision of lodging, including sleeping, dining, and living areas.

“*Administrator*” means a person licensed pursuant to Iowa Code chapter 147 who administers, manages, supervises, and is in general administrative charge of a nursing facility, whether or not such individual has an ownership interest in such facility, and whether or not the functions and duties are shared with one or more individuals.

“*Ambulatory*” means the condition of a person who immediately and without aid of another is physically or mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

“*Basement*” means that part of a building where the finish floor is more than 30 inches below the finish grade.

“*Board*” means the regular provision of meals.

“*Chairfast*” means capable of maintaining a sitting position but lacking the capacity of bearing own weight, even with the aid of a mechanical device or another individual.

“*Communicable disease*” means a disease caused by the presence of viruses or microbial agents within a person’s body, which agents may be transmitted either directly or indirectly to other persons.

“*Department*” means the state department of inspections and appeals.

“*Distinct part*” means a clearly identifiable area or section within a health care facility, consisting of at least a residential unit, wing, floor, or building containing contiguous rooms.

“*Medication*” means any drug including over-the-counter substances ordered and administered under the direction of the physician.

“*Nonambulatory*” means the condition of a person who immediately and without aid of another is not physically or mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

“*Nourishing snack*” is defined as a verbal offering of items, single or in combination, from the basic food groups. Adequacy of the “nourishing snack” will be determined both by resident interviews and by evaluation of the overall nutritional status of residents in the facility.

“*Person directed care environment*” means the provision of care and services provided in a facility that promotes decision making and choices by the resident, enhances the primary caregiver’s capacity to respond to each resident’s needs, and promotes a homelike environment. Examples of a person directed care environment include, but are not limited to, the Green House concept, the Eden alternative, service houses and neighborhoods.

“*Personal care*” means assistance with the activities of daily living which the recipient can perform only with difficulty. Examples are assistance in getting in and out of bed, assistance with personal hygiene and bathing, assistance with dressing, meal assistance, and supervision over medications which can be self-administered.

“*Potentially hazardous food*” means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinum, or in raw shell eggs, the growth of salmonella enteritidis. Potentially hazardous food includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic and oil mixtures that are not acidified or otherwise modified at a food processing plant in a way that results in mixtures that do not support growth of bacteria.

“*Primary care provider*” means any of the following who provide primary care and meet certification standards:

1. A physician who is a family or general practitioner or an internist.
2. An advanced registered nurse practitioner.
3. A physician assistant.

“Program of care” means all services being provided for a resident in a health care facility.

“Qualified intellectual disabilities professional” means a psychologist, physician, registered nurse, educator, social worker, physical or occupational therapist, speech therapist or audiologist who meets the educational requirements for the profession, as required in the state of Iowa, and having one year’s experience working with persons with an intellectual disability.

“Qualified nurse” means a registered nurse or a licensed practical nurse, as defined in Iowa Code chapter 152.

“Rate” means that daily fee charged for all residents equally and shall include the cost of all minimum services required in these rules and regulations.

“Responsible party” means the person who signs or cosigns the admission agreement required in 481—58.13(135C) or the resident’s guardian or conservator if one has been appointed. In the event that a resident does not have a guardian, conservator or other person signing the admission agreement, the term “responsible party” shall include the resident’s sponsoring agency, e.g., the department of human services, the U.S. Department of Veterans Affairs, religious groups, fraternal organizations, or foundations that assume responsibility and advocate for their client patients and pay for their health care.

“Restraints” means any chemical, manual method or physical or mechanical device, material, or equipment attached to the resident’s body that the individual cannot remove easily which restricts freedom of movement or normal access to one’s body.

“Substantial evening meal” is defined as an offering of three or more menu items at one time, one of which includes a high protein such as meat, fish, eggs or cheese. The meal would represent no less than 20 percent of the day’s total nutritional requirements.

[ARC 0766C, IAB 5/29/13, effective 7/3/13; ARC 1398C, IAB 4/2/14, effective 5/7/14; ARC 1752C, IAB 12/10/14, effective 1/14/15]

481—58.2(135C) Waivers. Waivers from these rules may be granted by the director of the department of inspections and appeals for good and sufficient reason when the need for a waiver has been established; no danger to the health, safety, or welfare of any resident results; alternate means are employed or compensating circumstances exist and the waiver will apply only to an individual nursing facility. Waivers will be reviewed at the discretion of the director of the department of inspections and appeals.

58.2(1) To request a waiver, the licensee must:

- a. Apply for a waiver in writing on a form provided by the department;
- b. Cite the rule or rules from which a waiver is desired;
- c. State why compliance with the rule or rules cannot be accomplished;
- d. Explain alternate arrangements or compensating circumstances which justify the waiver;
- e. Demonstrate that the requested waiver will not endanger the health, safety, or welfare of any resident.

58.2(2) Upon receipt of a request for a waiver, the director of inspections and appeals will:

- a. Examine the rule from which a waiver is requested to determine that the request is necessary and reasonable;
- b. If the request meets the above criteria, evaluate the alternate arrangements or compensating circumstances against the requirement of the rules;
- c. Examine the effect of the requested waiver on the health, safety, or welfare of the residents;
- d. Consult with the applicant if additional information is required.

58.2(3) Based upon these studies, approval of the waiver will be either granted or denied within 120 days of receipt.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—58.3(135C) Application for licensure.

58.3(1) Initial application and licensing. In order to obtain an initial nursing facility license, for a nursing facility which is currently licensed, the applicant must:

a. Meet all of the rules, regulations, and standards contained in 481—Chapters 58 and 61. Applicable exceptions found in rule 481—61.2(135C) shall apply based on the construction date of the facility.

b. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;

c. Make application at least 30 days prior to the change of ownership of the facility on forms provided by the department;

d. Submit a floor plan of each floor of the nursing facility, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which room will be put and window and door location;

e. Submit a photograph of the front and side elevation of the nursing facility;

f. Submit the statutory fee for a nursing facility license;

g. Meet the requirements of a nursing facility for which licensure application is made;

h. Comply with all other local statutes and ordinances in existence at the time of licensure;

i. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

58.3(2) In order to obtain an initial nursing facility license for a facility not currently licensed as a nursing facility, the applicant must:

a. Meet all of the rules, regulations, and standards contained in 481—Chapters 58 and 61. Exceptions noted in 481—subrule 61.1(2) shall not apply;

b. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;

c. Make application at least 30 days prior to the change of ownership of the facility on forms provided by the department;

d. Submit a floor plan of each floor of the nursing facility, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which room will be put and window and door locations;

e. Submit a photograph of the front and side elevation of the nursing facility;

f. Submit the statutory fee for a nursing facility license;

g. Comply with all other local statutes and ordinances in existence at the time of licensure;

h. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

58.3(3) *Renewal application.* In order to obtain a renewal of the nursing facility license, the applicant must:

a. Submit the completed application form 30 days prior to annual license renewal date of nursing facility license;

b. Submit the statutory license fee for a nursing facility with the application for renewal;

c. Have an approved current certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations;

d. Submit appropriate changes in the résumé to reflect any changes in the resident care program or other services.

58.3(4) Licenses are issued to the person or governmental unit which has responsibility for the operation of the facility and authority to comply with all applicable statutes, rules or regulations.

The person or governmental unit must be the owner of the facility or, if the facility is leased, the lessee.

481—58.4(135C) General requirements.

58.4(1) The license shall be displayed in a conspicuous place in the facility which is viewed by the public. (III)

58.4(2) The license shall be valid only in the possession of the licensee to whom it is issued.

58.4(3) The posted license shall accurately reflect the current status of the nursing facility. (III)

58.4(4) Licenses expire one year after the date of issuance or as indicated on the license.

58.4(5) No nursing facility shall be licensed for more beds than have been approved by the health facilities construction review committee.

58.4(6) Each citation or a copy of each citation issued by the department for a class I or class II violation shall be prominently posted by the facility in plain view of the residents, visitors, and persons inquiring about placement in the facility. The citation or copy of the citation shall remain posted until the violation is corrected to the satisfaction of the department. (III)

481—58.5(135C) Notifications required by the department. The department shall be notified:

58.5(1) Within 48 hours, by letter, of any reduction or loss of nursing or dietary staff lasting more than seven days which places the staffing ratio below that required for licensing. No additional residents shall be admitted until the minimum staffing requirements are achieved; (III)

58.5(2) Of any proposed change in the nursing facility's functional operation or addition or deletion of required services; (III)

58.5(3) Thirty days before addition, alteration, or new construction is begun in the nursing facility or on the premises; (III)

58.5(4) Thirty days in advance of closure of the nursing facility; (III)

58.5(5) Within two weeks of any change in administrator; (III)

58.5(6) When any change in the category of license is sought; (III)

58.5(7) Prior to the purchase, transfer, assignment, or lease of a nursing facility, the licensee shall:

- a. Inform the department of the pending sale, transfer, assignment, or lease of the facility; (III)
- b. Inform the department of the name and address of the prospective purchaser, transferee, assignee, or lessee at least 30 days before the sale, transfer, assignment, or lease is completed; (III)
- c. Submit a written authorization to the department permitting the department to release all information of whatever kind from the department's files concerning the licensee's nursing facility to the named prospective purchaser, transferee, assignee, or lessee. (III)

58.5(8) Pursuant to the authorization submitted to the department by the licensee prior to the purchase, transfer, assignment, or lease of a nursing facility, the department shall upon request send or give copies of all recent licensure surveys and of any other pertinent information relating to the facility's licensure status to the prospective purchaser, transferee, assignee, or lessee; costs for such copies shall be paid by the prospective purchaser.

481—58.6(135C) Witness fees. Rescinded IAB 3/30/94, effective 5/4/94. See 481—subrule 50.6(4).

481—58.7(135C) Licenses for distinct parts.

58.7(1) Separate licenses may be issued for distinct parts of a health care facility which are clearly identifiable, containing contiguous rooms in a separate wing or building or on a separate floor of the facility and which provide care and services of separate categories.

58.7(2) The following requirements shall be met for a separate licensing of a distinct part:

- a. The distinct part shall serve only residents who require the category of care and services immediately available to them within that part; (III)
- b. The distinct part shall meet all the standards, rules, and regulations pertaining to the category for which a license is being sought;
- c. A distinct part must be operationally and financially feasible;
- d. A separate staff with qualifications appropriate to the care and services being rendered must be regularly assigned and working in the distinct part under responsible management; (III)
- e. Separately licensed distinct parts may have certain services such as management, building maintenance, laundry, and dietary in common with each other.

481—58.8(135C) Administrator.

58.8(1) Each nursing facility shall have one person in charge, duly licensed as a nursing home administrator or acting in a provisional capacity. (III)

58.8(2) A licensed administrator may act as an administrator for not more than two nursing facilities.

- a. The distance between the two facilities shall be no greater than 50 miles. (II)
- b. The administrator shall spend the equivalent of three full eight-hour days per week in each facility. (II)
- c. The administrator may be responsible for no more than 150 beds in total if the administrator is an administrator of more than one facility. (II)

58.8(3) The licensee may be the licensed nursing home administrator providing the licensee meets the requirements as set forth in these regulations and devotes the required time to administrative duties. Residency in the facility does not in itself meet the requirement. (III)

58.8(4) A provisional administrator may be appointed on a temporary basis by the nursing facility licensee to assume the administrative duties when the facility, through no fault of its own, has lost its administrator and has been unable to replace the administrator.

- a. No facility licensed under Iowa Code chapter 135C shall be permitted to have a provisional administrator for more than 12 consecutive months.
- b. The facility shall notify the department in writing within ten business days of the administrator's appointment. The written notice shall include the estimated time frame for the appointment of the provisional administrator and the reason for the appointment of a provisional administrator. (III)
- c. The provisional administrator's appointment must be approved by the board of examiners for nursing home administrators. The approval shall be confirmed in writing to the department. (III)

58.8(5) In the absence of the administrator, a responsible person shall be designated in writing to the department to be in charge of the facility. The administrator shall not be absent from the facility for more than 3 months without approval of the department. (III)

The person designated shall:

- a. Be knowledgeable of the operation of the facility; (III)
- b. Have access to records concerned with the operation of the facility; (III)
- c. Be capable of carrying out administrative duties and of assuming administrative responsibilities; (III)
- d. Be at least 21 years of age; (III)
- e. Be empowered to act on behalf of the licensee during the administrator's absence concerning the health, safety, and welfare of the residents; (III)
- f. Have had training to carry out assignments and take care of emergencies and sudden illness of residents. (III)

58.8(6) A licensed administrator in charge of two facilities shall employ an individual designated as a full-time assistant administrator for each facility. (III)

58.8(7) An administrator of only one facility shall be considered as a full-time employee. Full-time employment is defined as 40 hours per week. (III)

[ARC 1398C, IAB 4/2/14, effective 5/7/14; ARC 2020C, IAB 6/10/15, effective 7/15/15]

481—58.9(135C) Administration.

58.9(1) The licensee shall:

- a. Assume the responsibility for the overall operation of the nursing facility; (III)
- b. Be responsible for compliance with all applicable laws and with the rules of the department; (III)
- c. Establish written policies, which shall be available for review, for the operation of the nursing facility. (III)

58.9(2) The administrator shall:

- a. Be responsible for the selection and direction of competent personnel to provide services for the resident care program; (III)
- b. Be responsible for the arrangement for all department heads to annually attend a minimum of ten contact hours of educational programs to increase skills and knowledge needed for the position; (III)
- c. Be responsible for a monthly in-service educational program for all employees and to maintain records of programs and participants; (III)
- d. Make available the nursing facility payroll records for departmental review as needed; (III)

e. Be required to maintain a staffing pattern of all departments. These records must be maintained for six months and are to be made available for departmental review. (III)

481—58.10(135C) General policies.

58.10(1) There shall be written personnel policies in facilities of more than 15 beds to include hours of work, and attendance at educational programs. (III)

58.10(2) There shall be a written job description developed for each category of worker. The job description shall include title of job, job summary, qualifications (formal education and experience), skills needed, physical requirements, and responsibilities. (III)

58.10(3) There shall be written personnel policies for each facility. Personnel policies shall include the following requirements:

- a. Employees shall have a physical examination before employment. (I, II, III)
- b. Employees shall have a physical examination at least every four years. (I, II, III)
- c. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59. (I, II, III)

58.10(4) Health certificates for all employees shall be available for review. (III)

58.10(5) Rescinded IAB 10/19/88, effective 11/23/88.

58.10(6) There shall be written policies for emergency medical care for employees and residents in case of sudden illness or accident which includes the individual to be contacted in case of emergency. (III)

58.10(7) The facility shall have a written agreement with a hospital for the timely admission of a resident who, in the opinion of the attending physician, requires hospitalization. (III)

58.10(8) Infection control program. Each facility shall have a written and implemented infection control and exposure control program with policies and procedures based on the guidelines issued by the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (I, II, III) CDC guidelines are available at www.cdc.gov/ncidod/dhqp/index.html.

58.10(9) Infection control committee. Each facility shall establish an infection control committee of representative professional staff responsible for overall infection control in the facility. (III)

a. The committee shall annually review and revise the infection control policies and procedures to monitor effectiveness and suggest improvement. (III)

b. The committee shall meet at least quarterly, submit reports to the administrator, and maintain minutes in sufficient detail to document its proceedings and actions. (III)

c. The committee shall monitor the health aspect and the environment of the facility. (III)

58.10(10) There shall be written policies for resident care programs and services as outlined in these rules. (III)

58.10(11) Prior to the removal of a deceased resident/patient from a facility, the funeral director or person responsible for transporting the body shall be notified by the facility staff of any special precautions that were followed by the facility having to do with the mode of transmission of a known or suspected communicable disease. (III)

[ARC 0663C, IAB 4/3/13, effective 5/8/13]

481—58.11(135C) Personnel.

58.11(1) General qualifications.

a. No person with a current record of habitual alcohol intoxication or addiction to the use of drugs shall serve in a managerial role of a nursing facility. (II)

b. No person under the influence of alcohol or intoxicating drugs shall be permitted to provide services in a nursing facility. (II)

c. No person shall be allowed to provide services in a facility if the person has a disease:

- (1) Which is transmissible through required workplace contact, (I, II, III)
- (2) Which presents a significant risk of infecting others, (I, II, III)
- (3) Which presents a substantial possibility of harming others, and (I, II, III)
- (4) For which no reasonable accommodation can eliminate the risk. (I, II, III)

Refer to Guidelines for Infection Control in Hospital Personnel, Centers for Disease Control, U.S. Department of Health and Human Services, PB85-923402 to determine (1), (2), (3) and (4).

d. Reserved.

e. Individuals with either physical or mental disabilities may be employed for specific duties, but only if that disability is unrelated to that individual's ability to perform the duties of the job. (III)

f. Persons employed in all departments, except the nursing department of a nursing facility shall be qualified through formal training or through prior experience to perform the type of work for which they have been employed. Prior experience means at least 240 hours of full-time employment in a field related to their duties. Persons may be hired in laundry, housekeeping, activities and dietary without experience or training if the facility institutes a formal in-service training program to fit the job description in question and documents such as having taken place within 30 days after the initial hiring of such untrained employees. (III)

g. Rescinded, effective 7/14/82.

h. The health services supervisor shall be a qualified nurse as defined in these regulations. (II)

i. Those persons employed as nurse's aides, orderlies, or attendants in a nursing facility who have not completed the state-approved 75-hour nurse's aide program shall be required to participate in a structured on-the-job training program of 20 hours' duration to be conducted prior to any resident contact, except that contact required by the training program. This educational program shall be in addition to facility orientation. Each individual shall demonstrate competencies covered by the curriculum. This shall be observed and documented by an R.N. and maintained in the personnel file. No aide shall work independently until this is accomplished, nor shall the aide's hours count toward meeting the minimum hours of nursing care required by the department. The curriculum shall be approved by the department. An aide who has completed the state-approved 75-hour course may model skills to be learned.

Further, such personnel shall be enrolled in a state-approved 75-hour nurse's aide program to be completed no later than six months from the date of employment. If the state-approved 75-hour program has been completed prior to employment, the on-the-job training program requirement is waived. The 20-hour course is in addition to the 75-hour course and is not a substitute in whole or in part. The 75-hour program, approved by the department, may be provided by the facility or academic institution.

Newly hired aides who have completed the state-approved 75-hour course shall demonstrate competencies taught in the 20-hour course upon hire. This shall be observed and documented by an R.N. and maintained in the personnel file.

All personnel administering medications must have completed the state-approved training program in medication administration. (II)

j. There shall be an organized ongoing in-service educational and training program planned in advance for all personnel in all departments. (II, III)

k. Nurse aides, orderlies or attendants in a nursing facility who have received training other than the Iowa state-approved program, must pass a challenge examination approved by the department of inspections and appeals. Evidence of prior formal training in a nursing aide, orderly, attendant, or other comparable program must be presented to the facility or institution conducting the challenge examination before the examination is given. The approved facility or institution, following department of inspections and appeals guidelines, shall make the determination of who is qualified to take the examination. Documentation of the challenge examinations administered shall be maintained.

58.11(2) *Nursing supervision and staffing.*

a. Rescinded IAB 8/7/91, effective 7/19/91.

b. Where only part-time nurses are employed, one nurse shall be designated health service supervisor. (III)

c. A qualified nurse shall be employed to relieve the supervising nurses, including charge nurses, on holidays, vacation, sick leave, days off, absences or emergencies. Pertinent information for contacting such relief person shall be posted at the nurse's station. (III)

d. When the health service supervisor serves as the administrator of a facility 50 beds and over, a qualified nurse must be employed to relieve the health service supervisor of nursing responsibilities. (III)

e. The department may establish on an individual facility basis the numbers and qualifications of the staff required in the facility using as its criteria the services being offered and the needs of the residents. (III)

f. Additional staffing, above the minimum ratio, may be required by the department commensurate with the needs of the individual residents. (III)

g. The minimum hours of resident care personnel required for residents needing intermediate nursing care shall be 2.0 hours per resident day computed on a seven-day week. A minimum of 20 percent of this time shall be provided by qualified nurses. If the maximum medical assistance rate is reduced below the 74th percentile, the requirement will return to 1.7 hours per resident per day computed on a seven-day week. A minimum of 20 percent of this time shall be provided by qualified nurses. (II, III)

h. The health service supervisor's hours worked per week shall be included in computing the 20 percent requirement.

i. A nursing facility of 75 beds or more shall have a qualified nurse on duty 24 hours per day, seven days a week. (II, III)

j. In facilities under 75 beds, if the health service supervisor is a licensed practical nurse, the facility shall employ a registered nurse, for at least four hours each week for consultation, who must be on duty at the same time as the health service supervisor. (II, III)

(1) This shall be an on-site consultation and documentation shall be made of the visit. (III)

(2) The registered nurse-consultant shall have responsibilities clearly outlined in a written agreement with the facility. (III)

(3) Consultation shall include but not be limited to the following: counseling the health service supervisor in the management of the health services; (III) reviewing and evaluating the health services in determining that the needs of the residents are met; (II, III) conducting a review of medications at least monthly if the facility does not employ a registered nurse part-time. (II, III)

k. Facilities with 75 or more beds must employ a health service supervisor who is a registered nurse. (II)

l. There shall be at least two people who shall be capable of rendering nursing service, awake, dressed, and on duty at all times. (II)

m. Physician's orders shall be implemented by qualified personnel. (II, III)

58.11(3) *Employee criminal record checks, child abuse checks and dependent adult abuse checks and employment of individuals who have committed a crime or have a founded abuse.* The facility shall comply with the requirements found in Iowa Code section 135C.33 and rule 481—50.9(135C) related to completion of criminal record checks, child abuse checks, and dependent adult abuse checks and to employment of individuals who have committed a crime or have a founded abuse. (I, II, III)

[ARC 0903C, IAB 8/7/13, effective 9/11/13; ARC 5421C, IAB 2/10/21, effective 3/17/21]

481—58.12(135C) Admission, transfer, and discharge.

58.12(1) *General admission policies.*

a. No resident shall be admitted or retained in a nursing facility who is in need of greater services than the facility can provide. (II, III)

b. No nursing facility shall admit more residents than the number of beds for which it is licensed, except guest rooms for visitors. (II, III)

c. There shall be no more beds erected than is stipulated on the license. (II, III)

d. There shall be no more beds erected in a room than its size and other characteristics will permit. (II, III)

e. The admission of a resident to a nursing facility shall not give the facility or any employee of the facility the right to manage, use, or dispose of any property of the resident except with the written authorization of the resident or the resident's legal representative. (III)

f. The admission of a resident shall not grant the nursing facility the authority or responsibility to manage the personal affairs of the resident except as may be necessary for the safety of the resident and safe and orderly management of the facility as required by these rules. (III)

g. A nursing facility shall provide for the safekeeping of personal effects, funds, and other property of its residents. The facility may require that items of exceptional value or which would convey unreasonable responsibilities to the licensee be removed from the premises of the facility for safekeeping. (III)

h. Rescinded, effective 7/14/82.

i. Funds or properties received by the nursing facility belonging to or due a resident, expendable for the resident's account, shall be trust funds. (III)

j. Infants and children under the age of 16 shall not be admitted to health care facilities for adults unless given prior written approval by the department. A distinct part of a health care facility, segregated from the adult section, may be established based on a program of care submitted by the licensee or applicant which is commensurate with the needs of the residents of the health care facility and has received the department's review and approval. (III)

k. No health care facility, and no owner, administrator, employee or representative thereof shall act as guardian, trustee, or conservator for any resident's property, unless such resident is related to the person acting as guardian within the third degree of consanguinity.

l. Within 30 days of a resident's admission to a health care facility receiving reimbursement through the medical assistance program under Iowa Code chapter 249A, the facility shall ask the resident or the resident's personal representative whether the resident is a veteran and shall document the response. If the facility determines that the resident is a potential veteran, the facility shall report the resident's name along with the names of the resident's spouse and any dependent children, as well as the name of the contact person for this information, to the Iowa department of veterans affairs. Where appropriate, the facility may also report such information to the Iowa department of human services.

If a resident is eligible for benefits through the United States Department of Veterans Affairs or other third-party payor, the facility first shall seek reimbursement from the identified payor source before seeking reimbursement from the medical assistance program established under Iowa Code chapter 249A.

The provisions of this paragraph shall not apply to the admission of an individual as a resident to a state mental health institute for acute psychiatric care or to the admission of an individual to the Iowa Veterans Home. (II, III)

58.12(2) Discharge or transfer.

a. Prior notification shall be made to the resident, as well as the resident's next of kin, legal representative, attending physician, and sponsoring agency, if any, prior to transfer or discharge of any resident. (III)

b. Proper arrangements shall be made by the nursing facility for the welfare of the resident prior to transfer or discharge in the event of an emergency or inability to reach the next of kin or legal representative. (III)

c. The licensee shall not refuse to discharge or transfer a resident when the physician, family, resident, or legal representative requests such a discharge or transfer. (II, III)

d. Advance notification will be made to the receiving facility prior to the transfer of any resident. (III)

e. When a resident is transferred or discharged, the appropriate record as set forth in 58.15(2) "k" of these rules will accompany the resident. (II, III)

f. Prior to the transfer or discharge of a resident to another health care facility, arrangements to provide for continuity of care shall be made with the facility to which the resident is being sent. (II, III)

481—58.13(135C) Contracts. Each contract shall:

58.13(1) State the base rate or scale per day or per month, the services included, and the method of payment; (III)

58.13(2) Contain a complete schedule of all offered services for which a fee may be charged in addition to the base rate. Furthermore, the contract shall: (III)

a. Stipulate that no further additional fees shall be charged for items not contained in complete schedule of services as set forth in 58.13(3); (III)

b. State the method of payment of additional charges; (III)

c. Contain an explanation of the method of assessment of such additional charges and an explanation of the method of periodic reassessment, if any, resulting in changing such additional charges; (III)

d. State that additional fees may be charged to the resident for nonprescription drugs, other personal supplies, and services by a barber, beautician, etc.; (III)

58.13(3) Contain an itemized list of those services, with the specific fee the resident will be charged and method of payment, as related to the resident's current condition, based on the nursing assessment at the time of admission, which is determined in consultation with the administrator; (III)

58.13(4) Include the total fee to be charged initially to the specific resident; (III)

58.13(5) State the conditions whereby the facility may make adjustments to the facility's overall fees for resident care as a result of changing costs. (III) Furthermore, the contract shall provide that the facility shall give:

a. Written notification to the resident, or responsible party when appropriate, of changes in the overall rates of both base and additional charges at least 30 days prior to effective date of such changes; (III)

b. Notification to the resident, or responsible party when appropriate, of changes in additional charges, based on a change in the resident's condition. Notification must occur prior to the date such revised additional charges begin. If notification is given orally, subsequent written notification must also be given within a reasonable time, not to exceed one week, listing specifically the adjustments made; (III)

58.13(6) State the terms of agreement in regard to refund of all advance payments in the event of transfer, death, voluntary or involuntary discharge; (III)

58.13(7) State the terms of agreement concerning the holding and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons. The terms shall contain a provision that the bed will be held at the request of the resident or the resident's responsible party.

a. The facility shall ask the resident or responsible party if the resident wants the bed held. This request shall be made before the resident leaves or within 48 hours after the resident leaves. The inquiry and the response shall be documented. (II)

b. The facility shall reserve the bed when requested for as long as payments are made in accordance with the contract. (II)

58.13(8) State the conditions under which the involuntary discharge or transfer of a resident would be effected; (III)

58.13(9) State the conditions of voluntary discharge or transfer; (III)

58.13(10) Set forth any other matters deemed appropriate by the parties to the contract. No contract or any provision thereof shall be drawn or construed so as to relieve any health care facility of any requirement or obligation imposed upon it by this chapter or any standards or rules in force pursuant to this chapter; (III)

58.13(11) Each party shall receive a copy of the signed contract. (III)

481—58.14(135C) Medical services.

58.14(1) Each resident in a nursing facility shall designate a licensed physician who may be called when needed. Professional management of a resident's care shall be the responsibility of the hospice program when:

a. The resident is terminally ill, and

b. The resident has elected to receive hospice services under the federal Medicare program from a Medicare-certified hospice program, and

c. The facility and the hospice program have entered into a written agreement under which the hospice program takes full responsibility for the professional management of hospice care.

58.14(2) Each resident admitted to a nursing facility shall have had a physical examination prior to admission. If the resident is admitted directly from a hospital, a copy of the hospital admission physical

and discharge summary may be made part of the record in lieu of an additional physical examination. A record of the examination, signed by the physician, shall be a part of the resident's record. (III)

58.14(3) Arrangements shall be made to have a physician available to furnish medical care in case of emergency. (II, III)

58.14(4) Rescinded, effective 7/14/82.

58.14(5) The person in charge shall immediately notify the physician of any accident, injury, or adverse change in the resident's condition. (I, II, III)

58.14(6) A schedule listing the names and telephone numbers of the physicians shall be posted in each nursing station. (III)

58.14(7) Residents shall be admitted to a nursing facility only on a written order signed by a physician certifying that the individual being admitted requires no greater degree of nursing care than the facility is licensed to provide. (III)

58.14(8) Physician delegation of tasks. Each resident, including private pay residents, shall be visited by or shall visit the resident's physician at least twice a year. The year period shall be measured from the date of admission and is not to include preadmission physicals.

a. For a skilled nursing patient, the resident must be seen by a physician for the initial comprehensive visit. Additional visits are required at least once every 30 days for 90 days after admission and at least once every 60 days thereafter. After the initial comprehensive visit, alternate required visits may be performed by an advanced registered nurse practitioner, clinical nurse specialist or physician assistant who is working in collaboration with a physician, as outlined in Table 1. (III)

b. Notwithstanding the provisions of 42 CFR 483.40, any required physician task or visit in a nursing facility may also be performed by an advanced registered nurse practitioner, clinical nurse specialist, or physician assistant who is working in collaboration with a physician, as outlined in Table 1. (III)

c. In dually certified skilled nursing/nursing facilities, the advanced registered nurse practitioner, clinical nurse specialist, and physician assistant must follow the skilled nursing facility requirements for services for skilled nursing facility stays. For nursing facility stays in skilled nursing/nursing facilities, any required physician task or visit may be performed by an advanced registered nurse practitioner, clinical nurse specialist, or physician assistant working in collaboration with the physician. (III)

d. Nurse practitioners, clinical nurse specialists, and physician assistants may perform other tasks that are not reserved to the physician such as visits outside the normal schedule needed to address new symptoms or other changes in medical status. (III)

Table 1: Authority for non-physician practitioners to perform visits, sign orders, and sign certifications/recertifications when permitted by state law*

	Initial Comprehensive Visit/Orders	Other Required Visits ¹	Other Medically Necessary Visits and Orders ²	Certification/Recertification
Skilled Nursing Facilities				
Physician assistant, nurse practitioner and clinical nurse specialist employed by the facility	May not perform/May not sign	May perform alternate visits	May perform and sign	May not sign
Physician assistant, nurse practitioner and clinical nurse specialist not a facility employee	May not perform/May not sign	May perform alternate visits	May perform and sign	May sign subject to state requirements

	Initial Comprehensive Visit/Orders	Other Required Visits ¹	Other Medically Necessary Visits and Orders ²	Certification/Recertification
Nursing Facilities				
Nurse practitioner, clinical nurse specialist, and physician assistant employed by the facility	May not perform/May not sign	May not perform	May perform and sign	Not applicable ⁺
Nurse practitioner, clinical nurse specialist, and physician assistant not a facility employee	May perform/May sign	May perform	May perform and sign	Not applicable ⁺

*As permitted by state law governing the scope and practice of nurse practitioners, clinical nurse specialists, and physician assistants.

¹ Other required visits include the skilled nursing resident monthly visits that may be alternated between physician and advanced registered nurse practitioners, clinical nurse specialists, or physician assistants after the initial comprehensive visit is completed.

² Medically necessary visits may be performed prior to the initial comprehensive visit.

⁺ This requirement relates specifically to coverage of Part A Medicare stays, which can take place only in a Medicare-certified skilled nursing facility.

[ARC 1048C, IAB 10/2/13, effective 11/6/13; ARC 1398C, IAB 4/2/14, effective 5/7/14]

481—58.15(135C) Records.

58.15(1) Resident admission record. The licensee shall keep a permanent record on all residents admitted to a nursing facility with all entries current, dated, and signed. This shall be a part of the resident clinical record. (III) The admission record form shall include:

- a. Name and previous address of resident; (III)
- b. Birth date, sex, and marital status of resident; (III)
- c. Church affiliation; (III)
- d. Physician's name, telephone number, and address; (III)
- e. Dentist's name, telephone number, and address; (III)
- f. Name, address, and telephone number of next of kin or legal representative; (III)
- g. Name, address, and telephone number of person to be notified in case of emergency; (III)
- h. Mortician's name, telephone number, and address; (III)
- i. Pharmacist's name, telephone number, and address. (III)

58.15(2) Resident clinical record. There shall be a separate clinical record for each resident admitted to a nursing facility with all entries current, dated, and signed. (III) The resident clinical record shall include:

- a. Admission record; (III)
- b. Admission diagnosis; (III)
- c. Physical examination: The record of the admission physical examination and medical history shall portray the current medical status of the resident and shall include the resident's name, sex, age, medical history, tuberculosis status, physical examination, diagnosis, statement of chief complaints, estimation of restoration potential and results of any diagnostic procedures. The report of the physical examination shall be signed by the physician. (III)
- d. Physician's certification that the resident requires no greater degree of nursing care than the facility is licensed to provide; (III)
- e. Physician's orders for medication, treatment, and diet in writing and signed by the physician quarterly; (III)
- f. Progress notes.
 - (1) Physician shall enter a progress note at the time of each visit; (III)

(2) Other professionals, i.e., dentists, social workers, physical therapists, pharmacists, and others shall enter a progress note at the time of each visit; (III)

g. All laboratory, X-ray, and other diagnostic reports; (III)

h. Nurse's record including:

(1) Admitting notes including time and mode of transportation; room assignment; disposition of valuables; symptoms and complaints; general condition; vital signs; and weight; (II, III)

(2) Routine notes including physician's visits; telephone calls to and from the physician; unusual incidents and accidents; change of condition; social interaction; and P.R.N. medications administered including time and reason administered, and resident's reaction; (II, III)

(3) Discharge or transfer notes including time and mode of transportation; resident's general condition; instructions given to resident or legal representative; list of medications and disposition; and completion of transfer form for continuity of care; (II, III)

(4) Death notes including notification of physician and family to include time, disposition of body, resident's personal possessions and medications; and complete and accurate notes of resident's vital signs and symptoms preceding death; (III)

i. Medication record.

(1) An accurate record of all medications administered shall be maintained for each resident. (II, III)

(2) Schedule II drug records shall be kept in accordance with state and federal laws; (II, III)

j. Death record. In the event of a resident's death, notations in the resident's record shall include the date and time of the resident's death, the circumstances of the resident's death, the disposition of the resident's body, and the date and time that the resident's family and physician were notified of the resident's death; (III)

k. Transfer form.

(1) The transfer form shall include identification data from the admission record, name of transferring institution, name of receiving institution, and date of transfer; (III)

(2) The nurse's report shall include resident attitudes, behavior, interests, functional abilities (activities of daily living), unusual treatments, nursing care, problems, likes and dislikes, nutrition, current medications (when last given), and condition on transfer; (III)

(3) The physician's report shall include reason for transfer, medications, treatment, diet, activities, significant laboratory and X-ray findings, and diagnosis and prognosis; (III)

l. Consultation reports shall indicate services rendered by allied health professionals in the facility or in health-centered agencies such as dentists, physical therapists, podiatrists, oculists, and others. (III)

58.15(3) Resident personal record. Personal records may be kept as a separate file by the facility.

a. Personal records may include factual information regarding personal statistics, family and responsible relative resources, financial status, and other confidential information.

b. Personal records shall be accessible to professional staff involved in planning for services to meet the needs of the resident. (III)

c. When the resident's records are closed, the information shall become a part of the final record. (III)

d. Personal records shall include a duplicate copy of the contract(s). (III)

58.15(4) Incident record.

a. Each nursing facility shall maintain an incident record report and shall have available incident report forms. (III)

b. Report of incidents shall be in detail on a printed incident report form. (III)

c. The person in charge at the time of the incident shall prepare and sign the report. (III)

d. The report shall cover all accidents where there is apparent injury or where hidden injury may have occurred. (III)

e. The report shall cover all accidents or unusual occurrences within the facility or on the premises affecting residents, visitors, or employees. (III)

f. A copy of the incident report shall be kept on file in the facility. (III)

58.15(5) Retention of records.

- a. Records shall be retained in the facility for five years following termination of services. (III)
- b. Records shall be retained within the facility upon change of ownership. (III)
- c. Rescinded, effective 7/14/82.
- d. When the facility ceases to operate, the resident's record shall be released to the facility to which the resident is transferred. If no transfer occurs, the record shall be released to the individual's physician. (III)

58.15(6) Reports to the department. The licensee shall furnish statistical information concerning the operation of the facility to the department on request. (III)

58.15(7) Personnel record.

- a. An employment record shall be kept for each employee, consisting of the following information: name and address of employee, social security number of employee, date of birth of employee, date of employment, experience and education, references, position in the home, criminal history and dependent adult abuse background checks, and date and reason for discharge or resignation. (III)
- b. The personnel records shall be made available for review upon request by the department. (III)

481—58.16(135C) Resident care and personal services.

58.16(1) Beds shall be made daily and adjusted as necessary. A complete change of linen shall be made at least once a week and more often if necessary. (III)

58.16(2) Residents shall receive sufficient supervision so that their personal cleanliness is maintained. (II, III)

58.16(3) Residents shall have clean clothing as needed to present a neat appearance, to be free of odors, and to be comfortable. Clothing shall be based on resident choice and shall be appropriate to residents' activities and to the weather. (III)

58.16(4) Rescinded, effective 7/14/82.

58.16(5) Residents shall be encouraged to leave their rooms and make use of the recreational room or living room of the facility. (III)

58.16(6) Residents shall not be required to pass through another's bedroom to reach a bathroom, living room, dining room, corridor, or other common areas of the facility. (III)

58.16(7) Rescinded, effective 7/14/82.

58.16(8) Uncontrollable residents shall be transferred or discharged from the facility in accordance with contract arrangements and requirements of Iowa Code chapter 135C. (II, III)

58.16(9) Except for those who request differently, residents who are not bedfast shall be fully dressed each day to maintain self-esteem and promote the residents' normal lifestyles. (III)

58.16(10) Residents shall receive a bath of their choice, based on the facility's accommodations, as needed to maintain proper hygiene. (II, III)

481—58.17 Rescinded, effective 7/14/82.

481—58.18(135C) Nursing care.

58.18(1) Individual health care plans shall be based on resident treatment decisions, the nature of the illness or disability, treatment, and care prescribed. Goals shall be developed by each discipline providing service, treatment, and care. These plans shall be in writing, revised as necessary, and kept current. They shall be made available to all those rendering the services and for review by the department. (III)

58.18(2) Rescinded IAB 4/2/14, effective 5/7/14.

58.18(3) The facility shall provide resident and family education as an integral part of restorative and supportive care. (III)

58.18(4) The facility shall provide prompt response from qualified staff for the resident's use of the nurse call system. (II, III) (Prompt response being considered as no longer than 15 minutes.)

[ARC 1398C, IAB 4/2/14, effective 5/7/14]

481—58.19(135C) Required nursing services for residents. The resident shall receive and the facility shall provide, as appropriate, the following required nursing services under the 24-hour direction of qualified nurses with ancillary coverage as set forth in these rules:

58.19(1) Activities of daily living.

- a. Bathing; (II, III)
- b. Daily oral hygiene (denture care); (II, III)
- c. Routine shampoo; (II, III)
- d. Nail care; (III)
- e. Shaving; (III)
- f. Daily care and application of prostheses (glasses, hearing aids, glass eyes, limb prosthetics, braces, or other assistive devices); (II, III)
 - g. Ambulation with equipment if applicable, or transferring, or positioning; (I, II, III)
 - h. Daily routine range of motion; (II, III)
 - i. Mobility (assistance with wheelchair, mechanical lift, or other means of locomotion); (I, II, III)
 - j. Elimination.
 - (1) Assistance to and from the bathroom and perineal care; (II, III)
 - (2) Bedpan assistance; (II, III)
 - (3) Care for incontinent residents; (II, III)
 - (4) Bowel and bladder training programs including in-dwelling catheter care (i.e., insertion and irrigation), enema and suppository administration, and monitoring and recording of intake and output, including solid waste; (I, II, III)
 - k. Colostomy care (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse); (I, II, III)
 - l. Ileostomy care (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse); (I, II, III)
- m. All linens necessary; (III)
- n. Nutrition and meal service.
 - (1) Regular, therapeutic, modified diets, and snacks; (I, II, III)
 - (2) Mealtime preparation of resident; (II, III)
 - (3) Assistance to and from meals; (II, III)
 - (4) In-room meal service or tray service; (II, III)
 - (5) Assistance with food preparation and meal assistance including total assistance if needed; (II, III)
 - (6) Assistance with adaptive devices; (II, III)
 - (7) Enteral nutrition (to be performed by a registered nurse or licensed practical nurse only); (I, II, III)
 - (8) Sufficient fluid intake to maintain proper hydration and health; (I, II, III)
- o. Promote initiation of self-care for elements of resident care; (II, III)
- p. Oral suctioning (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse). (I, II)

58.19(2) Medication and treatment.

- a. Administration of all medications as ordered by the physician including oral, instillations, topical, injectable (to be injected by a registered nurse or licensed practical nurse only); (I, II)
- b. Provision of the appropriate care and treatment of wounds, including pressure sores, to promote healing, prevent infection, and prevent new sores from developing; (I, II)
- c. Blood glucose monitoring; (I, II)
- d. Vital signs, blood pressure, and weights; (I, II)
- e. Ambulation and transfer; (II, III)
- f. Provision of restraints; (I, II)
- g. Administration of oxygen (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse); (I, II)
- h. Provision of all treatments; (I, II, III)

i. Provision of emergency medical care, including arranging for transportation, in accordance with written policies and procedures of the facility; (I, II, III)

j. Provision of accurate assessment and timely intervention for all residents who have an onset of adverse symptoms which represent a change in mental, emotional, or physical condition. (I, II, III)
[ARC 1398C, IAB 4/2/14, effective 5/7/14; ARC 2560C, IAB 6/8/16, effective 7/13/16]

481—58.20(135C) Duties of health service supervisor. Every nursing facility shall have a health service supervisor who shall:

58.20(1) Direct the implementation of the physician's orders; (I, II)

58.20(2) Plan for and direct the nursing care, services, treatments, procedures, and other services in order that each resident's needs and choices, where practicable, are met; (II, III)

58.20(3) Review the health care needs and choices, where practicable, of each resident admitted to the facility and assist the attending physician in planning for the resident's care; (II, III)

58.20(4) Develop and implement a written health care plan in cooperation with, to the extent practicable, the resident, the resident's family or the resident's legal representative, and others in accordance with instructions of the attending physician as follows:

a. The written health care plan, based on the assessment and reassessment of the resident's health needs and choices, where practicable, is personalized for the individual resident and indicates care to be given, goals to be accomplished, and methods, approaches, and modifications necessary to achieve best results; (III)

b. The health service supervisor is responsible for preparing, reviewing, supervising the implementation, and revising the written health care plan; (III)

c. The health care plan is readily available for use by all personnel caring for the resident; (III)

58.20(5) Initiate preventative and restorative nursing procedures for each resident so as to achieve and maintain the highest possible degree of function, self-care, and independence based on resident choice, where practicable; (II, III)

58.20(6) Supervise health services personnel to ensure they perform the following restorative measures in their daily care of residents:

a. Maintaining good bodily alignment and proper positioning; (II, III)

b. Making every effort to keep the resident active except when contraindicated by physician's orders, and encouraging residents to achieve independence in activities of daily living by teaching self-care, transfer, and ambulation activities; (III)

c. Assisting residents to adjust to their disabilities, to use their prosthetic devices, and to redirect their interests as necessary; (III)

d. Assisting residents to carry out prescribed therapy exercises between visits of the therapist; (III)

e. Assisting residents with routine range of motion exercises; (III)

58.20(7) Plan and conduct nursing staff orientation and in-service programs and provide for training of nurse's aides; (III)

58.20(8) Plan with the resident and the resident's physician and family and health-related agencies for the care of the resident upon discharge; (III)

58.20(9) Designate a responsible person to be in charge during absences; (III)

58.20(10) Be responsible for all assignments and work schedules for all health services personnel to ensure that the health needs of the residents are met; (III)

58.20(11) Ensure that all nurse's notes are descriptive of the care rendered including the resident's response; (III)

58.20(12) Visit each resident routinely to be knowledgeable of the resident's current condition; (III)

58.20(13) Evaluate in writing the performance of each individual on the health care staff on at least an annual basis. This evaluation shall be available for review in the facility to the department; (III)

58.20(14) Keep the administrator informed of the resident's status; (III)

58.20(15) Teach and coordinate rehabilitative health care including activities of daily living, promotion and maintenance of optimal physical and mental functioning; (III)

58.20(16) Supervise serving of meals to ensure that individuals unable to assist themselves are promptly fed and that special eating adaptive devices are available as needed; (II, III)

58.20(17) Make available a nursing procedure manual which shall include all procedures practiced in the facility; (III)

58.20(18) Participate with the administrator in the formulation of written policies and procedures for resident services; (III)

58.20(19) The person in charge shall immediately notify the family of any accident, injury, or adverse change in the resident's condition requiring physician's notification. (III)

481—58.21(135C) Drugs, storage, and handling.

58.21(1) Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

a. A cabinet with a lock, convenient to nursing service, shall be provided and used for storage of all drugs, solutions, and prescriptions; (III)

b. The drug storage cabinet shall be kept locked when not in use; (III)

c. The medication cabinet key shall be in the possession of the person directly responsible for issuing medications; (II, III)

d. Double-locked storage of Schedule II drugs shall not be required under single unit package drug distribution systems in which the quantity stored does not exceed a three-day supply and a missing dose can be readily detected. (II)

58.21(2) Drugs for external use shall be stored separately from drugs for internal use. (III)

58.21(3) Medications requiring refrigeration shall be kept in a refrigerator and separated from food and other items. A method for locking these medications shall be provided. (III)

58.21(4) All potent, poisonous, or caustic materials shall be stored separately from drugs. They shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet, or storeroom and made accessible only to authorized persons. (I, II)

58.21(5) All flammable materials shall be specially stored and handled in accordance with applicable local and state fire regulations. (II)

58.21(6) A properly trained person shall be charged with the responsibility of administering nonparenteral medications.

a. The individual shall have knowledge of the purpose of the drugs, their dangers, and contraindications.

b. This person shall be a licensed nurse or physician or shall have successfully completed a department-approved medication aide course or passed a department-approved medication aide challenge examination administered by an area community college.

c. Prior to taking a department-approved medication aide course, the individual shall:

(1) Successfully complete an approved nurse aide course, nurse aide training and testing program or nurse aide competency examination.

(2) Be employed in the same facility for at least six consecutive months prior to the start of the medication aide course. This requirement is not subject to waiver.

(3) Have a letter of recommendation for admission to the medication aide course from the employing facility.

d. A person who is a nursing student or a graduate nurse may take the challenge examination in place of taking a medication aide course. This individual shall do all of the following before taking the medication aide challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination;

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination;

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating the individual is competent in medication administration.

(4) Successfully complete a department-approved nurse aide competency evaluation.

e. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination.

The requirements of paragraph “*c*” of this subrule do not apply to this individual.

58.21(7) Unless the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by personally preparing the dose, observing the actual act of swallowing the oral medication, and charting the medication. (II) In facilities where the unit dose system is used, the person assigned the responsibility must complete the procedure by observing the actual act of swallowing the medication and charting the medication. Medications shall be prepared on the same shift of the same day that they are administered, (II) unless the unit dose system is used.

58.21(8) An accurate written record of medications administered shall be made by the individual administering the medication. (III)

58.21(9) Records shall be kept of all Schedule II drug medications received and dispensed in accordance with the controlled drug and substance Act. (III)

58.21(10) Any unusual resident reaction shall be reported to the physician at once. (II)

58.21(11) A policy shall be established by the facility in conjunction with a licensed pharmacist to govern the distribution of prescribed medications to residents who are on leave from the facility. (III)

a. Medication may be issued to residents who will be on leave from a facility for less than 24 hours. Notwithstanding the prohibition against paper envelopes in 58.21(14) “*a*,” non-child-resistant containers may be used. Each container may hold only one medication. A label on each container shall indicate the date, the resident’s name, the facility, the medication, its strength, dose, and time of administration.

b. Medication for residents on leave from a facility longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy examiners.

c. Medication distributed as above may be issued only by a nurse responsible for administering medication. (I, II, III)

58.21(12) Emergency medications. A nursing facility shall provide emergency medications pursuant to the following requirements: (III)

a. Prescription drugs as well as nonprescription items must be prescribed or approved by the physician, in consultation with the pharmacist, who provides emergency service to the facility; (III)

b. The emergency medications shall be stored in an accessible place; (III)

c. A list of the emergency medications and quantities of each item shall be maintained by the facility; (III)

d. The container holding the emergency medications shall be closed with a seal which may be broken when drugs are required in an emergency or for inspection; (III)

e. Any item removed from the emergency medications shall be replaced within 48 hours; (III)

f. A permanent record shall be kept of each time the emergency medications are used; (III)

g. The emergency medications shall be inspected by a pharmacist at least once every three months to determine the stability of items. (III)

58.21(13) Drug handling.

a. Bulk supplies of prescription drugs shall not be kept in a nursing facility unless a licensed pharmacy is established in the facility under the direct supervision and control of a pharmacist. (III)

b. Inspection of drug storage condition shall be made by the health service supervisor and a registered pharmacist not less than once every three months. The inspection shall be verified by a report signed by the nurse and pharmacist and filed with the administrator. The report shall include, but not be limited to, certifying absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current physician’s order, and drugs improperly stored. (III)

c. If the facility permits licensed nurses to dilute or reconstitute drugs at the nursing station, distinctive supplementary labels shall be available for the purpose. The notation on the label shall be so made as to be indelible. (III)

d. Dilution and reconstitution of drugs and their labeling shall be done by the pharmacist whenever possible. If not possible, the following shall be carried out only by the licensed nurse:

(1) Specific directions for dilution or reconstitution and expiration date should accompany the drug; (III)

(2) A distinctive supplementary label shall be affixed to the drug container when diluted or reconstituted by the nurse for other than immediate use. (III) The label shall bear the following: resident's name, dosage and strength per unit/volume, nurse's name, expiration date, and date and time of dilution. (III)

58.21(14) Drug safeguards.

a. All prescribed medications shall be clearly labeled indicating the resident's full name, physician's name, prescription number, name and strength of drug, dosage, directions for use, date of issue, and name and address and telephone number of pharmacy or physician issuing the drug. Where unit dose is used, prescribed medications shall, as a minimum, indicate the resident's full name, physician's name, name and strength of drug, and directions for use. Standard containers shall be utilized for dispensing drugs. Paper envelopes shall not be considered standard containers. (III)

b. Medication containers having soiled, damaged, illegible or makeshift labels, or medication samples shall be returned to the issuing pharmacist, pharmacy, or physician for relabeling or disposal. (III)

c. There shall be no medications or any solution in unlabeled containers. (II, III)

d. The medications of each resident shall be kept or stored in the originally received containers. (II, III)

e. Labels on containers shall be clearly legible and firmly affixed. No label shall be superimposed on another label of a drug container. (II, III)

f. When a resident is discharged or leaves the facility, the unused prescription shall be sent with the resident or with a legal representative only upon the written order of a physician. (III)

g. Unused prescription drugs prescribed for residents who are deceased shall be returned to the supplying pharmacist. (III)

h. Prescriptions shall be refilled only with the permission of the attending physician. (II, III)

i. No medications prescribed for one resident may be administered to or allowed in the possession of another resident. (II)

j. Instructions shall be requested of the Iowa board of pharmacy examiners concerning disposal of unused Schedule II drugs prescribed for residents who have died or for whom the Schedule II drug was discontinued. (III)

k. There shall be a formal routine for the proper disposal of discontinued medications within a reasonable but specified time. These medications shall not be retained with the resident's current medications. Discontinued drugs shall be destroyed by the responsible nurse with a witness and a notation made to that effect or returned to the pharmacist for destruction or resident credit. Drugs listed under the Schedule II drugs shall be disposed of in accordance with the provisions of the Iowa board of pharmacy examiners. (II, III)

l. All medication orders which do not specifically indicate the number of doses to be administered or the length of time the drug is to be administered shall be stopped automatically after a given time period. The automatic stop order may vary for different types of drugs. The physician, in consultation with the pharmacist serving the home, shall institute policies and provide procedures for review and endorsement of stop orders on drugs. This policy shall be conveniently located for personnel administering medications. (II, III)

m. No resident shall be allowed to keep possession of any medications unless the attending physician has certified in writing on the resident's medical record that the resident is mentally and physically capable of doing so. (II)

n. Residents who have been certified in writing by the physician as capable of taking their own medications may retain these medications in their bedroom, but locked storage must be provided. (II)

o. No medications or prescription drugs shall be administered to a resident without a written order signed by the attending physician. (II)

p. A qualified nurse shall:

(1) Establish a medication schedule system which identifies the time and dosage of each medication prescribed for each resident, is based on the resident's desired routine, and is approved by the resident's physician. (II, III)

(2) Establish a medication record containing the information specified above needed to monitor each resident's drug regimen. (II, III)

q. Telephone orders shall be taken by a qualified nurse. Orders shall be written into the resident's record and signed by the person receiving the order. Telephone orders shall be submitted to the physician for signature within 48 hours. (III)

r. A pharmacy operating in connection with a nursing facility shall comply with the provisions of the pharmacy law requiring registration of pharmacies and the regulations of the Iowa board of pharmacy examiners. (III)

s. In a nursing facility with a pharmacy or drug supply, service shall be under the personal supervision of a pharmacist licensed to practice in the state of Iowa. (III)

58.21(15) Drug administration.

a. Injectable medications shall be administered as permitted by Iowa law by a qualified nurse, physician, pharmacist, or physician assistant (PA). In the case of a resident who has been certified by the resident's physician or physician assistant (PA) as capable of taking the resident's own insulin, the resident may inject the resident's own insulin. (II)

b. An individual inventory record shall be maintained for each Schedule II drug prescribed for each resident. (II)

c. The health service supervisor shall be responsible for the supervision and direction of all personnel administering medications. (II)

[ARC 1050C, IAB 10/2/13, effective 11/6/13]

481—58.22(135C) Rehabilitative services. Rehabilitative services shall be provided to maintain function or improve the resident's ability to carry out the activities of daily living.

58.22(1) Physical therapy services.

a. Each facility shall have a written agreement with a licensed physical therapist to provide physical therapy services. (III)

b. Physical therapy shall be rendered only by a physical therapist licensed to practice in the state of Iowa. All personnel assisting with the physical therapy of residents must be under the direction of a licensed physical therapist. (II, III)

c. The licensed physical therapist shall:

(1) Evaluate the resident and prepare a physical therapy treatment plan conforming to the medical orders and goals; (III)

(2) Consult with other personnel in the facility who are providing resident care and plan with them for the integration of a physical therapy treatment program into the overall health care plan; (III)

(3) Instruct the nursing personnel responsible for administering selected restorative procedures between treatments; (III)

(4) Present programs in the facility's in-service education programs. (III)

d. Treatment records in the resident's medical chart shall include:

(1) The physician's prescription for treatment; (III)

(2) An initial evaluation note by the physical therapist; (III)

(3) The physical therapy care plan defining clearly the long-term and short-term goals and outlining the current treatment program; (III)

(4) Notes of the treatments given and changes in the resident's condition; (III)

(5) A complete discharge summary to include recommendations for nursing staff and family. (III)

e. There shall be adequate facilities, space, appropriate equipment, and storage areas as are essential to the treatment or examinations of residents. (III)

58.22(2) Other rehabilitative services.

a. The facility shall arrange for specialized and supportive rehabilitative services when such services are ordered by a physician. (III) These may include audiology and occupational therapy.

- b.* Audiology services shall be under the direction of a person licensed in the state of Iowa by the board of speech pathology and audiology. (II, III)
- c.* Occupational therapy services shall be under the direction of a qualified occupational therapist who is currently registered by the American Occupational Therapy Association. (II, III)
- d.* The appropriate professional shall:
 - (1) Develop the treatment plan and administer or direct treatment in accordance with the physician's prescription and rehabilitation goals; (III)
 - (2) Consult with other personnel within the facility who are providing resident care and plan with them for the integration of a treatment program into the overall health care plan. (III)

481—58.23(135C) Dental, diagnostic, and other services.

58.23(1) Dental services.

- a.* The nursing facility personnel shall assist residents to obtain regular and emergency dental services. (III)
- b.* Transportation arrangements shall be made when necessary for the resident to be transported to the dentist's office. (III)
- c.* Dental services shall be performed only on the request of the resident, responsible relative, or legal representative. The resident's physician shall be advised of the resident's dental problems. (III)
- d.* All dental reports or progress notes shall be included in the clinical record. (III)
- e.* Nursing personnel shall assist the resident in carrying out dentist's recommendations. (III)
- f.* Dentists shall be asked to participate in the in-service program of the facility. (III)

58.23(2) Diagnostic services.

- a.* The nursing facility shall make provisions for promptly securing required clinical laboratory, X-ray, and other diagnostic services. (III)
- b.* All diagnostic services shall be provided only on the written, signed order of a physician. (III)
- c.* Agreements shall be made with the local hospital laboratory or independent laboratory to perform specific diagnostic tests when they are required. (III)
- d.* Transportation arrangements for residents shall be made, when necessary, to and from the source of service. (III)
- e.* Copies of all diagnostic reports shall be requested by the facility and included in the resident's clinical record. (III)
- f.* The physician ordering the specific diagnostic service shall be promptly notified of the results. (III)
- g.* Simple tests such as customarily done by nursing personnel for diabetic residents may be performed in the facility. (III)

58.23(3) Other services.

- a.* The nursing facility shall assist residents to obtain such supportive services as requested by the physician. (III)
- b.* Transportation arrangements shall be made when necessary. (III)
- c.* Services could include the need for prosthetic devices, glasses, hearing aids, and other necessary items. (III)

481—58.24(135C) Dietary.

58.24(1) Organization of dietetic services. The facility shall meet the needs of the residents and provide the services listed in this standard. If a service is contracted out, the contractor shall meet the same standard. A written agreement shall be formulated between the facility and the contractor and shall convey to the department the right to inspect the food service facilities of the contractor. (III)

- a.* There shall be written policies and procedures for dietetic services that include staffing, nutrition, menu planning, therapeutic diets, preparation, food service, ordering, receiving, storage, sanitation, and staff hygiene. The policies and procedures shall be made available for use by dietetic services. (III)

b. There shall be written job descriptions for each position in dietetic services. The job descriptions shall be made available for use by dietetic services. (III)

58.24(2) Dietary staffing.

a. The facility shall employ a qualified dietary supervisor who:

- (1) Is a qualified dietitian as defined in 58.24(2)“e”; or
- (2) Is a graduate of a dietetic technician training program approved by the Academy of Nutrition and Dietetics; or
- (3) Is a certified dietary manager certified by the certifying board for dietary managers of the Association of Nutrition and Foodservice Professionals and maintains that credential through 45 hours of ANFP-approved continuing education; or
- (4) Has completed an ANFP-approved course curriculum necessary to take the certification examination required to become a certified dietary manager; or
- (5) Has documented evidence of at least two years’ satisfactory work experience in food service supervision and who is in an approved dietary manager association program and will successfully complete the program within 24 months of the date of enrollment; or
- (6) Has completed the 90-hour training course approved by the department and is a certified food protection manager who has received training from and passed a test that is part of an American National Standards Institute (ANSI)-accredited Certified Food Protection Manager Program. (II, III)

b. The supervisor shall have overall supervisory responsibility for dietetic services and shall be employed for a sufficient number of hours to complete management responsibilities that include:

- (1) Participating in regular conferences with the consultant dietitian, the administrator and other department heads; (III)
- (2) Writing menus with consultation from the dietitian and seeing that current menus are posted and followed and that menu changes are recorded; (III)
- (3) Establishing and maintaining standards for food preparation and service; (II, III)
- (4) Participating in selection, orientation, and in-service training of dietary personnel; (II, III)
- (5) Supervising activities of dietary personnel; (II, III)
- (6) Maintaining up-to-date records of residents identified by name, location and diet order; (III)
- (7) Visiting residents to learn individual needs and communicating with other members of the health care team regarding nutritional needs of residents when necessary; (II, III)
- (8) Keeping records of repairs of equipment in dietetic services. (III)

c. A minimum of one person with supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food protection manager who has received training from and passed a test that is part of an American National Standards Institute (ANSI)-accredited Certified Food Protection Manager Program.

d. The facility shall employ sufficient supportive personnel to carry out the following functions:

- (1) Preparing and serving adequate amounts of food that are handled in a manner to be bacteriologically safe; (II, III)
- (2) Washing and sanitizing dishes, pots, pans and equipment at temperatures required by procedures described in the Food Code as defined in Iowa Code section 137F.2; (II, III)
- (3) Serving therapeutic diets as prescribed by the physician and following the planned menu. (II, III)

e. The facility may assign simultaneous duties in the kitchen and laundry, housekeeping, or nursing service to appropriately trained personnel. Proper sanitary and personal hygiene procedures shall be followed as outlined under the rules pertaining to staff hygiene. (II, III)

f. If the dietetic service supervisor is not a licensed dietitian, a consultant dietitian is required. The consultant dietitian shall be licensed by the state of Iowa pursuant to Iowa Code chapter 152A.

g. Consultants’ visits shall be scheduled to be of sufficient duration and at a time convenient to:

- (1) Record, in the resident’s medical record, any observations, assessments and information pertinent to medical nutrition therapy; (I, II, III)
- (2) Work with residents and staff on resident care plans; (III)

(3) Consult with the administrator and others on developing and implementing policies and procedures; (III)

(4) Write or approve general and therapeutic menus; (III)

(5) Work with the dietetic supervisor on developing procedures, recipes and other management tools; (III)

(6) Present planned in-service training and staff development for food service employees and others. Documentation of consultation shall be available for review in the facility by the department. (III)

h. In facilities licensed for more than 15 beds, dietetic services shall be available for a minimum of a 12-hour span extending from the time of preparation of breakfast through supper. (III)

58.24(3) Nutrition and menu planning.

a. Menus shall be planned and followed to meet the nutritional needs of each resident in accordance with the physician's orders and in consideration of the resident's choices and preferences. (II, III)

b. Menus shall be planned to provide 100 percent of the daily recommended dietary allowances as established by the Food and Nutrition Board of the National Research Council of the National Academy of Sciences. A current copy of the Simplified Diet Manual or other suitable diet manual shall be available and used in the planning and serving of all meals. (II)

c. At least three meals or their equivalent shall be served daily at regular hours. (II)

(1) There shall be no more than a 14-hour span between a substantial evening meal and breakfast except as provided in subparagraph (3) below. (II, III)

(2) The facility shall offer snacks at bedtime daily. (II, III)

(3) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast of the following day. The current resident group must agree to this meal span and a nourishing snack must be served. (II)

d. Menus shall include a variety of foods prepared in various ways. (III)

e. Menus shall be written at least one week in advance. The current menu shall be located in an accessible place in the dietetic services department for easy use by persons purchasing, preparing and serving food. (III)

f. Records of menus as served shall be filed and maintained for 30 days and shall be available for review by department personnel. When substitutions are necessary, they shall be of similar nutritive value and recorded. (III)

g. A file of tested recipes adjusted to the number of people to be served in the facility shall be maintained. (III)

h. Alternate foods shall be offered to residents who refuse the food served. (II, III)

58.24(4) Therapeutic diets and nutritional status.

a. The facility shall ensure that each resident has a nutritional assessment completed by the licensed dietitian within 14 days of admission that addresses the residents' medical condition and therapeutic dietary needs, desires and rights in regard to their nutritional plan. (I, II, III)

b. Therapeutic diets shall be prescribed by the resident's physician. A current edition of the Simplified Diet Manual or other suitable diet manual shall be readily available to physicians, nurses and dietetic services personnel. A current diet manual shall be used as a guide for writing menus for therapeutic diets. A licensed dietitian shall be responsible for writing and approving the therapeutic menu and reviewing procedures for preparation and service of food. (II, III)

c. Personnel responsible for planning, preparing and serving therapeutic diets shall receive instructions on those diets. (II, III)

d. The facility shall ensure that each resident maintains acceptable parameters of nutritional status, such as body weight, unless the resident's clinical condition demonstrates that this is not possible. (I, II, III)

58.24(5) Food handling, preparation and service. All food shall be handled, prepared and served in compliance with the requirements of the Food and Drug Administration Food Code adopted under provisions of Iowa Code section 137F.2. (I, II, III) In addition, the following shall apply.

- a. Methods used to prepare foods shall be those which conserve nutritive value and flavor and meet the taste preferences of the residents. (III)
- b. Foods shall be attractively served. (III)
- c. Foods shall be cut up, chopped, ground or blended to meet individual needs. (I, II, III)
- d. Self-help devices shall be provided as needed. (II, III)
- e. Disposables shall not be used routinely. Plasticware, china and glassware that are unsightly, unsanitary or hazardous because of chips, cracks or loss of glaze shall be discarded. (II, III)
- f. All food that is transported through public corridors shall be covered. (III)
- g. Residents may be allowed in the food preparation area. (III)
- h. The food preparation area may be used as a dining area for residents, staff or food service personnel if the facility engages in person-directed care. (III)
- i. There shall be effective written procedures established for cleaning all work and serving areas. (III)
- j. A schedule of cleaning duties to be performed daily shall be posted. (III)
- k. An exhaust system and hood shall be clean, operational and maintained in good repair. (III)
- l. The food service area shall be located so it will not be used as a passageway by residents, guests or non-food service staff. (III)

58.24(6) *Paid nutritional assistants.* A paid nutritional assistant means an individual who meets the requirements of this subrule and who is an employee of the facility or an employee of a temporary employment agency employed by the facility. A facility may use an individual working in the facility as a paid nutritional assistant only if that individual has successfully completed a state-approved training program for paid nutritional assistants. (I, II, III)

a. *Training program requirements.*

- (1) A state-approved training program for paid nutritional assistants must include, at a minimum, eight hours of training in the following areas:
 - 1. Feeding techniques.
 - 2. Assistance with feeding and hydration.
 - 3. Communication and interpersonal skills.
 - 4. Appropriate responses to resident behavior.
 - 5. Safety and emergency procedures, including the Heimlich maneuver.
 - 6. Infection control.
 - 7. Resident rights.
 - 8. Recognizing changes in residents that are inconsistent with their normal behavior and reporting these changes to the supervisory nurse.
- (2) In addition to the training program requirements specified in subparagraph (1), the training program must include at least four hours of classroom study, two hours of supervised laboratory work, and two hours of supervised clinical experience.
- (3) A facility that offers a paid nutritional assistant training program must provide sufficient supplies in order to teach the objectives of the course.
- (4) All paid nutritional assistant training program instructors shall be registered nurses. Other qualified health care professionals may assist the instructor in teaching the classroom portion and clinical or laboratory experience. The ratio of students to instructor shall not exceed ten students per instructor in the clinical setting.
- (5) Each individual enrolled in a paid nutritional assistant training program shall complete a 50-question multiple choice written test and must obtain a score of 80 percent or higher. In addition, the individual must successfully perform the feeding of a resident in a clinical setting. A registered nurse shall conduct the final competency determination.
- (6) If an individual does not pass either the written test or competency demonstration, the individual may retest the failed portion a second time. If the individual does not pass either the written test or competency demonstration portion the second time, the individual shall not be allowed to retest.

b. Program approval. A facility or other entity may not offer or teach a paid nutritional assistant training program until the department has approved the program. Individuals trained in a program not approved by the department will not be allowed to function as paid nutritional assistants.

(1) A facility or other institution offering a paid nutritional assistant training program must provide the following information about the training program to the department before offering the program or teaching paid nutritional assistants:

1. Policies and procedures for program administration.
2. Qualifications of the instructors.
3. Maintenance of program records, including attendance records.
4. Criteria for determining competency.
5. Program costs and refund policies.
6. Lesson plans, including the objectives to be taught, skills demonstrations, assignments, quizzes, and classroom, laboratory and clinical hours.

(2) The facility or other institution offering a paid nutritional assistant training program must submit the materials specified in subparagraph (1) for department review. The department shall, within ten days of receipt of the material, advise the facility or institution whether the program is approved, or request additional information to assist the department in determining whether the curriculum meets the requirements for a paid nutritional assistant training program. Before approving any paid nutritional assistant training program, the department shall determine whether the curriculum meets the requirements specified in this subrule. The department shall maintain a list of facilities and institutions eligible to provide paid nutritional assistant training. (I, II, III)

(3) A facility shall maintain a record of all individuals who have successfully completed the required training program and are used by the facility as paid nutritional assistants. The individual shall complete the training program with a demonstration of knowledge and competency skills necessary to serve as a paid nutritional assistant. (I, II, III)

(4) The facility or other institution providing the training shall, within ten calendar days of an individual's successful completion of the training program, provide the individual with a signed and dated certificate of completion. A facility that employs paid nutritional assistants shall maintain on file copies of the completed certificate and skills checklist for each individual who has successfully completed the training program. (I, II, III)

c. Working restrictions.

(1) A paid nutritional assistant must work under the supervision of a registered nurse or a licensed practical nurse. In an emergency, a paid nutritional assistant must call a supervisory nurse on the resident call system for help. (I, II, III)

(2) A facility must ensure that a paid nutritional assistant feeds only residents who have no complicated feeding problems. Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube, parenteral or intravenous feedings. The facility must base resident selection on the charge nurse's assessment and the resident's latest assessment and plan of care. (I, II, III)

[ARC 2560C, IAB 6/8/16, effective 7/13/16]

481—58.25(135C) Social services program.

58.25(1) The administrator or designee shall be responsible for developing a written, organized orientation program for all residents. (III)

58.25(2) The program shall be planned and implemented to resolve or reduce personal, family, business, and emotional problems that may interfere with the medical or health care, recovery, and rehabilitation of the individual. (III)

58.25(3) The social services plan, including specific goals and regular evaluation of progress, shall be incorporated into the overall plan of care. (III)

481—58.26(135C) Resident activities program.

58.26(1) *Organized activities.* Each nursing facility shall provide an organized resident activity program for the group and for the individual resident which shall include suitable activities for evenings and weekends. (III)

a. The activity program shall be designed to meet the needs and interests of each resident and to assist residents in continuing normal activities within limitations set by the resident's physician. This shall include helping residents continue in their individual interests or hobbies. (III)

b. The program shall include individual goals for each resident. (III)

c. The program shall include both group and individual activities. (III)

d. No resident shall be forced to participate in the activity program. (III)

e. The activity program shall include suitable activities for those residents unable to leave their rooms. (III)

f. The program shall be incorporated into the overall health plan and shall be designed to meet the goals as written in the plan.

58.26(2) *Coordination of activities program.*

a. Each nursing facility shall employ a person to direct the activities program. (III)

¹*b.* Staffing for the activity program shall be provided on the minimum basis of 35 minutes per licensed bed per week. (II, III)

c. The activity coordinator shall have completed the activity coordinators' orientation course offered through the department within six months of employment or have comparable training and experience as approved by the department. (III)

d. The activity coordinator shall attend workshops or educational programs which relate to activity programming. These shall total a minimum of ten contact hours per year. These programs shall be approved by the department. (III)

e. There shall be a written plan for personnel coverage when the activity coordinator is absent during scheduled working hours. (III)

58.26(3) *Duties of activity coordinator.* The activity coordinator shall:

a. Have access to all residents' records excluding financial records; (III)

b. Coordinate all activities, including volunteer or auxiliary activities and religious services; (III)

c. Keep all necessary records including:

(1) Attendance; (III)

(2) Individual resident progress notes recorded at regular intervals (at least quarterly). A copy of these notes shall be placed in the resident's clinical record; (III)

(3) Monthly calendars, prepared in advance. (III)

d. Coordinate the activity program with all other services in the facility; (III)

e. Participate in the in-service training program in the facility. This shall include attending as well as presenting sessions. (III)

58.26(4) *Supplies, equipment, and storage.*

a. Each facility shall provide a variety of supplies and equipment of a nature calculated to fit the needs and interests of the residents. (III) These may include: books (standard and large print), magazines, newspapers, radio, television, and bulletin boards. Also appropriate would be board games, game equipment, songbooks, cards, craft supplies, record player, movie projector, piano, outdoor equipment, etc.

b. Storage shall be provided for recreational equipment and supplies. (III)

c. Locked storage should be available for potentially dangerous items such as scissors, knives, and toxic materials. (III)

¹ Objection filed 2/14/79; see Objection at end of chapter.

481—58.27(135C) Certified volunteer long-term care ombudsman program. A certified volunteer long-term care ombudsman appointed in accordance with Iowa Code section 231.45 as amended by

2013 Iowa Acts, Senate File 184, shall operate within the scope of the rules for volunteer ombudsmen promulgated by the office of long-term care ombudsman and Iowa department on aging.
[ARC 1205C, IAB 12/11/13, effective 1/15/14]

481—58.28(135C) Safety. The licensee of a nursing facility shall be responsible for the provision and maintenance of a safe environment for residents and personnel. (III)

58.28(1) Fire safety.

a. All nursing facilities shall meet the fire safety rules and regulations as promulgated by the state fire marshal. (I, II)

b. The size of the facility and needs of the residents shall be taken into consideration in evaluating safety precautions and practices.

58.28(2) Safety duties of administrator. The administrator shall have a written emergency plan to be followed in the event of fire, tornado, explosion, or other emergency. (III)

a. The plan shall be posted. (III)

b. In-service shall be provided to ensure that all employees are knowledgeable of the emergency plan. (III)

58.28(3) Resident safety.

a. Residents shall be permitted to smoke only where proper facilities are provided. Smoking shall not be permitted in bedrooms. Smoking by residents considered to be careless shall be prohibited except when the resident is under direct supervision. (II, III)

b. Smoking is prohibited in all rooms where oxygen is being administered or in rooms where oxygen is stored. (II, III)

c. Whenever full or empty tanks of oxygen are being used or stored, they shall be securely supported in an upright position. (II, III)

d. Smoking shall be permitted only in posted areas. (II, III)

e. Each resident shall receive adequate supervision to protect against hazards from self, others, or elements in the environment. (I, II, III)

f. Residents shall be protected against physical or environmental hazards to themselves. (I, II, III)
[ARC 1398C, IAB 4/2/14, effective 5/7/14]

481—58.29(135C) Resident care.

58.29(1) There shall be a readily available supply of self-help and ambulation devices such as wheelchairs, walkers, and such other devices maintained in good repair that will meet the current needs of all residents. (III)

58.29(2) The facility shall ensure that each ambulatory resident has well-fitting shoes to provide support and prevent slipping. (III)

58.29(3) Equipment for personal care shall be maintained in a safe and sanitary condition. (II, III)

58.29(4) The expiration date for sterile equipment shall be exhibited on its wrappings. (III)

58.29(5) Residents who have been known to wander shall be provided with appropriate means of identification. (II, III)

58.29(6) Electric heating pads, blankets, or sheets shall be used only on the written order of a physician, when allowed by the Life Safety Code or applicable state or local fire regulations. (II, III)

481—58.30 Rescinded, effective 7/14/82.

481—58.31(135C) Housekeeping.

58.31(1) Written procedures shall be established and implemented for daily and weekly cleaning schedules. (III)

58.31(2) Each resident unit shall be cleaned on a routine schedule. (III)

58.31(3) All rooms, corridors, storage areas, linen closets, attics, and basements shall be kept in a clean, orderly condition, free of unserviceable furniture and equipment and accumulations of refuse. (III)

58.31(4) A hallway or corridor shall not be used for storage of equipment. (III)

58.31(5) All odors shall be kept under control by cleanliness and proper ventilation. (III)

58.31(6) Clothing worn by personnel shall be clean and washable. (III)

58.31(7) Housekeeping and maintenance personnel shall be provided with well-constructed and properly maintained equipment appropriate to the function for which it is to be used. (III)

58.31(8) All furniture, bedding, linens, and equipment shall be cleaned periodically and before use by another resident. (III)

58.31(9) Polishes used on floors shall provide a nonslip finish. (III)

58.31(10) *Throw or scatter rugs shall not be permitted. (III)

*Objection. For text of Objection, see IAC Supp., Part I, 9/7/77. For text of Filed rules, 470—Chapter 58, see IAC Supp. 10/5/77.

58.31(11) Entrances, exits, steps, and outside walkways shall be kept free from ice, snow, and other hazards. (II, III)

58.31(12) Residents shall not have access to storage areas for all cleaning agents, bleaches, insecticides, or any other poisonous, dangerous, or flammable materials. (II, III)

58.31(13) Sufficient numbers of noncombustible trash containers, which have covers, shall be available. (III)

58.31(14) Definite procedures shall be established for training housekeeping personnel. (III)

58.31(15) Rescinded IAB 12/6/06, effective 1/10/07.

58.31(16) There shall be provisions for the cleaning and storage of housekeeping equipment and supplies for each nursing unit. (III)

58.31(17) Bathtubs, shower stalls, or lavatories shall not be used for laundering, cleaning of utensils and mops, or for storage. (III)

58.31(18) Bedside utensils shall be stored in enclosed cabinets. (III)

58.31(19) Kitchen sinks shall not be used for the cleaning of mops, soaking of laundry, cleaning of bedside utensils, nursing utensils, or dumping of wastewater. (III)

58.31(20) Personal possessions of residents which may constitute hazards to themselves or others shall be removed and stored. (III)

481—58.32(135C) Maintenance.

58.32(1) Each facility shall establish a maintenance program in writing to ensure the continued maintenance of the facility, to promote good housekeeping procedures, and to ensure sanitary practices throughout the facility. (III)

58.32(2) The building, grounds, and other buildings shall be maintained in a clean, orderly condition and in good repair. (III)

58.32(3) Draperies and furniture shall be clean and in good repair. (III)

58.32(4) Cracks in plaster, peeling wallpaper or paint, and tears or splits in floor coverings shall be promptly repaired or replaced in a professional manner. (III)

58.32(5) The electrical systems, including appliances, cords, and switches, shall be maintained to guarantee safe functioning and comply with the national electrical code. (III)

58.32(6) All plumbing fixtures shall function properly and comply with the state plumbing code. (III)

58.32(7) Yearly inspections of the heating and cooling systems shall be made to guarantee safe operation. Documentation of these inspections shall be available for review. (III)

58.32(8) The building, grounds, and other buildings shall be kept free of breeding areas for flies, other insects, and rodents. (III)

58.32(9) The facility shall be kept free of flies, other insects, and rodents. (III)

58.32(10) Maintenance personnel.

a. A written program shall be established for the orientation of maintenance personnel. (III)

b. Maintenance personnel shall:

(1) Follow established written maintenance programs; (III)

(2) Be provided with appropriate, well-constructed, and properly maintained equipment. (III)

481—58.33(135C) Laundry.

58.33(1) All soiled linens shall be collected in and transported to the laundry room in closed, leakproof laundry bags or covered, impermeable containers. (III)

58.33(2) Except for related activities, the laundry room shall not be used for other purposes. (III)

58.33(3) Procedures shall be written for the proper handling of wet, soiled, and contaminated linens. (III)

58.33(4) Residents' personal laundry shall be marked with an identification. (III)

58.33(5) Bed linens, towels, and washcloths shall be clean and stain-free. (III)

481—58.34(135C) Garbage and waste disposal.

58.34(1) All garbage shall be gathered, stored, and disposed of in a manner that will not permit transmission of disease, create a nuisance, or provide a breeding or feeding place for vermin or insects. (III)

58.34(2) All containers for refuse shall be watertight, rodent-proof, and have tight-fitting covers. (III)

58.34(3) All containers shall be thoroughly cleaned each time the containers are emptied. (III)

58.34(4) All wastes shall be properly disposed of in compliance with local ordinances and state codes. (III)

58.34(5) Special provision shall be made for the disposal of soiled dressings and similar items in a safe, sanitary manner. (III)

481—58.35(135C) Buildings, furnishings, and equipment.

58.35(1) Buildings—general requirements.

a. For purposes of computation of usable floor space in bedrooms and other living areas of the facility, that part of the room having no less than seven feet of ceiling height shall be used. Usable floor space may include irregularities in the rooms such as alcoves and offsets with approval of the department. Usable floor space shall not include space needed for corridor door swings or wardrobes being used as a substitute for closet space. (III)

b. Battery-operated, portable emergency lights in good working condition shall be available at all times, at a ratio of one light per one employee on duty from 6 p.m. to 6 a.m. (III)

c. All windows shall be supplied with curtains and shades or drapes which are kept clean and in good repair. (III)

d. Light fixtures shall be so equipped to prevent glare and to prevent hazards to the residents. (III)

e. Exposed heating pipes, hot water pipes, or radiators in rooms and areas used by residents and within reach of residents shall be covered or protected to prevent injury or burns to residents. (II, III)

f. All fans located within seven feet of the floor shall be protected by screen guards of not more than one-half-inch mesh. (III)

g. Whenever glass sliding doors or transparent panels are used, they shall be marked conspicuously. (III)

h. The facility shall meet the equivalent requirements of the appropriate group occupancy of the state building code. (III)

i. No part of any room shall be enclosed, subdivided, or partitioned unless such part is separately lighted and ventilated and meets such other requirements as its usage and occupancy dictates, except closets used for the storage of residents' clothing. (III)

58.35(2) Furnishings and equipment.

a. All furnishings and equipment shall be durable, cleanable, and appropriate to its function and in accordance with the department's approved program of care. (III)

b. All resident areas shall be decorated, painted, and furnished to provide a home-like atmosphere. (III)

c. Upholstery materials shall be moisture- and soil-resistant, except on furniture provided by the resident and the property of the resident. (III)

58.35(3) Dining and living rooms.

a. Every facility shall have a dining room and a living room easily accessible to all residents. (III)

- b. Dining rooms and living rooms shall at no time be used as bedrooms. (III)
 - c. Dining rooms and living rooms shall be available for use by residents at appropriate times to provide periods of social and diversional individual and group activities. (III)
 - d. A combination dining room and living room may be permitted if the space requirements of a multipurpose room as provided in 58.35(3)“e” are met. (III)
 - e. Multipurpose rooms. When space is provided for multipurpose dining and activities and recreational purposes, the area shall total at least 30 square feet per licensed bed for the first 100 beds and 27 square feet per licensed bed for all beds in excess of 100. An open area of sufficient size shall be provided to permit group activities such as religious meetings or presentation of demonstrations or entertainment. (III)
 - f. Living rooms.
 - (1) Living rooms shall be maintained for the use of residents and their visitors and may be used for recreational activities. (III)
 - (2) Living rooms shall be suitably provided with parlor furniture, television and radio receivers in good working order, recreational material such as games, puzzles, and cards, and reading material such as current newspapers and magazines. Furnishings and equipment of the room should be such as to allow group activities. (III)
 - (3) Card tables or game tables shall be made available. The tables should be of a height to allow a person seated in a wheelchair to partake in the games or card playing. (III)
 - (4) Chairs of proper height and appropriate to their use shall be provided for seating residents at game tables and card tables. (III)
 - g. Dining rooms.
 - (1) Dining rooms shall be furnished with dining tables and chairs appropriate to the size and function of the facility. These rooms and furnishings shall be kept clean and sanitary. (III)
 - (2) Dining tables and chairs shall be provided. (III)
 - (3) Dining tables should be so constructed that a person seated in a wheelchair can dine comfortably. (III)
 - (4) Tables shall be of sturdy construction with smooth, durable, nonpermeable tops that can be cleaned with a detergent sanitizing solution. (III)
 - (5) Dining chairs shall be sturdy and comfortable. Some arm chairs should be provided for ease of movement for some residents. (III)
 - (6) Residents shall be encouraged to eat in the dining room. (III)
- 58.35(4) Bedrooms.**
- a. Each resident shall be provided with a standard, single, or twin bed that is substantially constructed and in good repair. Rollaway beds, metal cots, or folding beds are not acceptable. Seventy-five percent of the beds shall have a spring with an adjustable head and foot section. A resident shall have the right to sleep in a chair per the resident’s request and to have the bed removed from the room to allow for additional space. (III)
 - b. Each bed shall be equipped with the following: casters or glides unless a low bed and mattress are being used for fall precautions; a clean, comfortable, well-constructed mattress approximately five inches thick and standard in size for the bed; clean, comfortable pillows of average size; and moisture-proof covers and sheets as necessary to keep the mattress and pillows dry and clean. (III)
 - c. Each resident shall have a bedside table with a drawer to accommodate personal possessions. (III)
 - d. There shall be a comfortable chair, either a rocking chair or armchair, per resident bed. The resident’s personal wishes shall be considered. (III)
 - e. There shall be drawer space for each resident’s clothing. In a multiple bedroom, drawer space shall be assigned each resident. (III)
 - f. Walls, ceilings, and floors shall have easily cleanable surfaces and shall be kept clean and in good repair. (III)
 - g. Beds and other furnishings shall not obstruct free passage to and through doorways. (III)
 - h. Clothing shall be hung in closets or wardrobes available in each room. (III)

- i.* Beds shall not be placed with the head of the bed in front of a window or radiator. (III)
- j.* Beds shall not be placed in such a manner that the side of the bed is against the radiator or in close proximity to it unless it is covered so as to protect the resident from contact with it or from excessive heat. (III)
- k.* Reading lamps shall be provided each resident in the resident's room. (III)
- l.* Each room shall have sufficient accessible mirrors to serve the resident's needs. Mirrors are not required if the room is located in a CCDI unit and the mirrors cause concern for the resident. (III)
- m.* Sturdy, adjustable overbed tables shall be provided for each resident who is unable to eat in the dining room. (III)
- n.* Each resident bedroom shall have a door. The door shall be the swing type and shall not swing into the corridor. (III)

58.35(5) Heating. A centralized heating system capable of maintaining a minimum temperature of 78°F (26°C) shall be provided. Portable units or space heaters are prohibited from being used in the facility except in an emergency. (III)

58.35(6) Water supply.

- a.* Every facility shall have an adequate water supply from an approved source. A municipal source of supply shall be considered as meeting this requirement. (III)
- b.* Private sources of supply shall be tested annually and the report submitted with the annual application for license. (III)
- c.* A bacterially unsafe source of supply shall be grounds for denial, suspension, or revocation of license. (III)
- d.* The department may require testing of private sources of supply at its discretion in addition to the annual test. The facility shall supply reports of such tests as directed by the department. (III)
- e.* Hot and cold running water under pressure shall be available in the facility. (III)
- f.* Prior to construction of a new facility or new water source, private sources of supply shall be surveyed and shall comply with the requirements of the department of health. (III)

58.35(7) Nonambulatory residents.

- a.* All nonambulatory residents shall be housed on the grade level floor. (II, III)
- b.* These provisions in "a" above relating to nonambulatory residents are not applicable if the facility has a suitably sized elevator.

481—58.36(135C) Family and employee accommodations.

58.36(1) Children under 14 years of age shall not be allowed into the service areas. (III)

58.36(2) The residents' bedrooms shall not be occupied by employees or family members of the licensee. (III)

58.36(3) In facilities where the total occupancy of family, employees, and residents is five or less, one toilet and one tub or shower shall be the minimum requirement. (III)

58.36(4) In facilities where the total occupancy of family, employees, and residents is more than five, separate bathing and toilet facilities shall be required for the family or employees distinct from such areas provided for residents. (III)

58.36(5) In all health care facilities, if the family or employees live within the facility, separate living quarters and recreation facilities shall be required for the family or employees distinct from such areas provided for residents. (III)

481—58.37(135C) Animals. Animals may be permitted within the facility with prior approval of the department and under controlled conditions. (III)

481—58.38(135C) Supplies.

58.38(1) Linen supplies.

- a.* There shall be an adequate supply of linen so that each resident shall have at least three washcloths, hand towels, and bath towels per week. (III)
- b.* A complete change of bed linens shall be available in the linen storage area for each bed. (III)

c. Sufficient lightweight, clean, serviceable blankets shall be available. All blankets shall be laundered as often as necessary for cleanliness and freedom from odors. (III)

d. Each bed shall be provided with clean, washable bedspreads. There shall be a supply available when changes are necessary. (III)

e. Uncrowded and convenient storage shall be provided for linens, pillows, and bedding. (III)

58.38(2) *First-aid kit.* A first-aid emergency kit shall be available on each floor in every facility. (II, III)

58.38(3) *Supplies and equipment for nursing services.*

a. All nursing care equipment shall be properly sanitized or sterilized before use by another resident. (II)

b. There shall be disposable or one-time use items available with provisions for proper disposal to prevent reuse except as allowed by 58.10(8) “*h,*” 481—paragraph 59.12(10) “*h,*” or 481—paragraph 64.12(14) “*h.*” (I, II, III)

c. Convenient, safe storage shall be provided for bath and toilet supplies, bathroom scales, mechanical lifts, and shower chairs. (III)

d. Sanitary and protective storage shall be provided for all equipment and supplies. (III)

e. All items that must be sterilized shall be autoclaved unless sterile disposable items are furnished which are promptly disposed of after a single use. (III)

f. Supplies and equipment for nursing and personal care sufficient in quantities to meet the needs of the residents shall be provided and, as a minimum, include the following: (III)

Bath basins	Rectal tubes
Soap containers	Catheters and catheterization equipment
Denture cups	Douche nozzle
Emesis basins	Oxygen therapy equipment
Mouthwash cups	Naso-gastric feeding equipment
Bedpans	Wheelchairs
Urinals	Moisture-proof draw sheets
Enema equipment	Moisture-proof pillow covers
Commodes	Moisture-proof mattress covers
Quart graduate measure	Foot tubs
Thermometer for measurement of bath water temperature	Metal pitcher
Oral thermometer	Disinfectant solutions
Rectal thermometer	Alcohol
Basins for sterilizing thermometers	Lubricating jelly
Basins for irrigations	Skin lotion
Asepto syringes	Applicators
Sphygmomanometer	Tongue blades
Paper towels	Toilet paper
Paper handkerchiefs	Rubber gloves or disposable gloves
Insulin syringes	Scales for nonambulatory patients
2 cc hypodermic syringes	Tourniquet
	Suction machine

Weight scales	Medicine dispensing containers
Hypodermic needles	Bandages
Stethoscope	Adhesive
Ice caps	Portable linen hampers
Hot water bottles	Denture identification equipment
	Tracheotomy care equipment

481—58.39(135C) Residents’ rights in general.

58.39(1) Each facility shall ensure that policies and procedures are written and implemented which include, at a minimum, all of the following provisions (subrules 58.39(2) to 58.39(6)) and which govern all areas of service provided by the facility. These policies and procedures shall be available to staff, residents, their families or legal representatives and the public and shall be reviewed annually. (II)

58.39(2) Policies and procedures shall address the admission and retention of persons with histories of dangerous or disturbing behavior. For the purposes of the subrule, persons with histories of dangerous or disturbing behavior are those persons who have been found to be seriously mentally impaired pursuant to Iowa Code section 229.13 or 812.1 within six months of the request for admission to the facility. In addition to establishing the criteria for admission and retention of persons so defined, the policies and procedures shall provide for:

a. Reasonable precautions to prevent the resident from harming self, other residents, or employees of the facility.

b. Treatment of persons with mental illness as defined in Iowa Code section 229.1(1) and which is provided in accordance with the individualized health care plan.

c. Ongoing and documented staff training on individualized health care planning for persons with mental illness.

58.39(3) Policies and procedures regarding the admission, transfer, and discharge of residents shall ensure that:

a. Only those persons are accepted whose needs can be met by the facility directly or in cooperation with community resources or other providers of care with which it is affiliated or has contracts. (II)

b. As changes occur in residents’ physical or mental condition, necessitating services or care which cannot be adequately provided by the facility, they are transferred promptly to other appropriate facilities. (II)

58.39(4) Policies and procedures regarding the use of chemical and physical restraints shall define the use of said restraints and identify the individual who may authorize the application of physical restraints in emergencies, and describe the mechanism for monitoring and controlling their use. (II)

58.39(5) Policies and procedures shall include a method for submitting complaints and recommendations by residents or their responsible party and for ensuring a response and disposition by the facility. (II)

58.39(6) Policies and procedures shall include provisions governing access to, duplication of, and dissemination of information from the residents’ records. (II)

58.39(7) Policies and procedures shall include a provision that each resident shall be fully informed of the resident’s rights and responsibilities as a resident and of all rules governing resident conduct and responsibilities. This information must be provided upon admission, or in the case of residents already in the facility, upon the facility’s adoption or amendment of residents’ rights policies. (II)

a. The facility shall make known to residents what they may expect from the facility and its staff, and what is expected from them. The facility shall communicate these expectations during the period of not more than two weeks before or five days after admission. The communication shall be in writing, e.g., in a separate handout or brochure describing the facility, and interpreted verbally, e.g., as part of a preadmission interview, resident counseling, or in individual or group orientation sessions following admission. (II)

b. Residents' rights and responsibilities shall be presented in language understandable to the resident. If the facility serves residents who are non-English speaking or deaf or hard of hearing, steps shall be taken to translate the information into a foreign or sign language. In the case of blind residents, either Braille or a recording shall be provided. Residents shall be encouraged to ask questions about their rights and responsibilities and these questions shall be answered. (II)

c. A statement shall be signed by the resident, or the resident's responsible party, indicating an understanding of these rights and responsibilities, and shall be maintained in the record. The statement shall be signed no later than five days after admission, and a copy of the signed statement shall be given to the resident or responsible party, if applicable. In the case of an intellectually disabled resident, the signature shall be witnessed by a person not associated with or employed by the facility. The witness may be a parent, guardian, Medicaid agency representative, etc. (II)

d. In order to ensure that residents continue to be aware of these rights and responsibilities during their stay, a written copy shall be prominently posted in a location that is available to all residents. (II)

e. All residents shall be advised within 30 days following changes made in the statement of residents' rights and responsibilities. Appropriate means shall be utilized to inform non-English speaking, deaf or hard-of-hearing, or blind residents of such changes. (II)

58.39(8) Each resident or responsible party shall be fully informed in a contract as required in rule 481—58.13(135C), prior to or at the time of admission and during the resident's stay, of services available in the facility, and of related charges including any charges for services not covered under the Title XIX program or not covered by the facility's basic per diem rate. (II)

58.39(9) Each resident or responsible party shall be fully informed by a physician of the resident's health and medical condition unless medically contraindicated (as documented by a physician in the resident's record). Each resident shall be afforded the opportunity to participate in the planning of the resident's total care and medical treatment, which may include, but is not limited to, nursing care, nutritional care, rehabilitation, restorative therapies, activities, and social work services. Each resident only participates in experimental research conducted under the U.S. Department of Health and Human Services' protection from research risks policy and then only upon the resident's informed written consent. Each resident has the right to refuse treatment except as provided by Iowa Code chapter 229. In the case of a confused or intellectually disabled individual, the responsible party shall be informed by the physician of the resident's medical condition and be afforded the opportunity to participate in the planning of the resident's total care and medical treatment, to be informed of the medical condition, and to refuse to participate in experimental research. (II)

a. The requirement that residents shall be informed of their conditions, involved in the planning of their care, and advised of any significant changes in either shall be communicated to every physician responsible for the medical care of residents in the facility. (II)

b. The administrator or designee shall be responsible for working with attending physicians in the implementation of this requirement. (II)

c. If the physician determines or in the case of a confused or intellectually disabled resident the responsible party determines that informing the resident of the resident's condition is contraindicated, this decision and reasons for it shall be documented in the resident's record by the physician. (II)

d. The resident's plan of care shall be based on the physician's orders. It shall be developed upon admission by appropriate facility staff and shall include participation by the resident if capable. Residents shall be advised of alternative courses of care and treatment and their consequences when such alternatives are available. The resident's preference about alternatives shall be elicited and honored if feasible.

e. Any clinical investigation involving residents must be under the sponsorship of an institution with a human subjects review board functioning in accordance with the requirements of Public Law 93-348, as implemented by Part 46 of Title 45 of the Code of Federal Regulations, as amended to December 1, 1981 (45 CFR 46). A resident being considered for participation in experimental research must be fully informed of the nature of the experiment, e.g., medication, treatment, and understand the

possible consequences of participating or not participating. The resident's (or responsible party's) written informed consent must be received prior to participation. (II)

This rule is intended to implement Iowa Code section 135C.23(2).
[ARC 0766C, IAB 5/29/13, effective 7/3/13; ARC 5711C, IAB 6/16/21, effective 7/21/21]

481—58.40(135C) Involuntary discharge or transfer.

58.40(1) *Involuntary discharge or transfer permitted.* A facility may involuntarily discharge or transfer a resident for only one of the following reasons:

- a. Medical reasons;
- b. The resident's welfare or that of other residents;
- c. Nonpayment for the resident's stay, as described in the contract for the resident's stay;
- d. Due to action pursuant to Iowa Code chapter 229;
- e. By reason of negative action by the Iowa department of human services; or
- f. By reason of negative action by the quality improvement organization (QIO). (I, II, III)

58.40(2) *Medical reasons.* Medical reasons for transfer or discharge shall be based on the resident's needs and shall be determined and documented in the resident's record by the primary care provider. Transfer or discharge may be required in order to provide a different level of care to the resident. (II)

58.40(3) *Welfare of a resident.* Welfare of a resident or that of other residents refers to a resident's social, emotional, or physical well-being. A resident may be transferred or discharged because the resident's behavior poses a continuing threat to the resident (e.g., suicidal) or to the well-being of other residents or staff (e.g., the resident's behavior is incompatible with other residents' needs and rights). Written documentation that the resident's continued presence in the facility would adversely affect the resident's own welfare or that of other residents shall be made by the administrator or designee and shall include specific information to support this determination. (II)

58.40(4) *Involuntary discharge or transfer prohibited—payment source.* A resident shall not be transferred or discharged solely because the cost of the resident's care is being paid under Iowa Code chapter 249A or because the resident's source of payment is changing from private support to payment under Iowa Code chapter 249A. (I, II)

58.40(5) *Notice.* Involuntary transfer or discharge of a resident from a facility shall be preceded by a written notice to the resident and the responsible party. (II, III)

- a. The notice shall contain all of the following information:
 - (1) The stated reason for the proposed transfer or discharge. (II)
 - (2) The effective date of the proposed transfer or discharge. (II)
 - (3) A statement, in not less than 12-point type, that reads as follows:

You have a right to appeal the facility's decision to transfer or discharge you. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after the department's receipt of your request and you will not be transferred before a final decision is rendered. Extension of the 14-day requirement may be permitted in emergency circumstances upon request to the department's designee. If you lose the hearing, you will not be transferred before the expiration of either (1) 30 days following your receipt of the original notice of the discharge or transfer, or (2) 5 days following final decision of such hearing, including the exhaustion of all appeals, whichever occurs later. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. (II)

- b. The notice shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department; the resident's responsible party; the resident's primary care provider; the person or agency responsible for the resident's placement, maintenance, and

care in the facility; and the department on aging's office of the long-term care ombudsman. The notice shall indicate that copies have been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent.

c. The notice required by paragraph 58.40(5) "a" shall be provided at least 30 days in advance of the proposed transfer or discharge unless one of the following occurs:

(1) An emergency transfer or discharge is mandated by the resident's health care needs and is in accordance with the written orders and medical justification of the primary care provider. Emergency transfers or discharges may also be mandated in order to protect the health, safety, or well-being of other residents and staff from the resident being transferred. (II)

(2) The transfer or discharge is subsequently agreed to by the resident or the resident's responsible party, and notification is given to the responsible party, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility.

(3) The discharge or transfer is the result of a final, nonappealable decision by the department of human services or the QIO.

d. A hearing requested pursuant to this subrule shall be held in accordance with subrule 58.40(7).

58.40(6) *Emergency transfer or discharge.* In the case of an emergency transfer or discharge, the resident must be given a written notice prior to or within 48 hours following the transfer or discharge. (II, III)

a. A copy of this notice shall be placed in the resident's file. The notice shall contain all of the following information:

- (1) The stated reason for the transfer or discharge. (II)
- (2) The effective date of the transfer or discharge. (II)
- (3) A statement, in not less than 12-point type, that reads as follows:

You have a right to appeal the facility's decision to transfer or discharge you on an emergency basis. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after the department's receipt of your request. You may be transferred or discharged before the hearing is held or before a final decision is rendered. If you win the hearing, you have the right to be transferred back into the facility. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. (II)

b. The notice shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department; the resident's responsible party; the resident's primary care provider; the person or agency responsible for the resident's placement, maintenance, and care in the facility; and the department on aging's office of the long-term care ombudsman. The notice shall indicate that copies have been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent.

c. A hearing requested pursuant to this subrule shall be held in accordance with subrule 58.40(7). **58.40(7) *Hearing.***

a. Request for hearing.

- (1) The resident must request a hearing within 7 days of receipt of the written notice.
- (2) The request must be made to the department, either in writing or verbally.

b. The hearing shall be held no later than 14 days after the department's receipt of the request unless either party requests an extension due to emergency circumstances.

c. Except in the case of an emergency discharge or transfer, a request for a hearing shall stay a transfer or discharge pending a final decision, including the exhaustion of all appeals. (II)

d. The hearing shall be heard by a department of inspections and appeals administrative law judge pursuant to Iowa Code chapter 17A and 481—Chapter 9. The hearing shall be public unless the resident

or resident's legal representative requests in writing that the hearing be closed. In a determination as to whether a transfer or discharge is authorized, the burden of proof by a preponderance of the evidence rests on the party requesting the transfer or discharge.

e. Notice of the date, time, and place of the hearing shall be sent by certified mail or delivered in person to the facility, the resident, the responsible party, and the office of the long-term care ombudsman not later than 5 full business days after the department's receipt of the request. The notice shall also inform the facility and the resident or the responsible party that they have a right to appear at the hearing in person or be represented by an attorney or other individual. The appeal shall be dismissed if neither party is present or represented at the hearing. If only one party appears or is represented, the hearing shall proceed with one party present. The office of the long-term care ombudsman shall have the right to appear at the hearing.

f. The administrative law judge's written decision shall be mailed by certified mail to the facility, resident, responsible party, and the office of the long-term care ombudsman within 10 working days after the hearing has been concluded.

g. If the basis for an involuntary transfer or discharge is the result of a negative action by the Iowa department of human services or the QIO, an appeal shall be filed with those agencies as appropriate. Continued payment shall be consistent with rules of those agencies.

58.40(8) *Nonpayment.* If nonpayment is the basis for involuntary transfer or discharge, the resident shall have the right to make full payment up to the date that the discharge or transfer is to be made and then shall have the right to remain in the facility. (II)

58.40(9) *Discussion of involuntary transfer or discharge.* Within 48 hours after notice of involuntary transfer or discharge has been received by the resident, the facility shall discuss the involuntary transfer or discharge with the resident, the resident's responsible party, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. (II)

a. The facility administrator or other appropriate facility representative serving as the administrator's designee shall provide an explanation and discussion of the reasons for the resident's involuntary transfer or discharge. (II)

b. The content of the explanation and discussion shall be summarized in writing, shall include the names of the individuals involved in the discussion, and shall be made part of the resident's record. (II)

c. The provisions of this subrule do not apply if the involuntary transfer or discharge has already occurred pursuant to subrule 58.40(6) and emergency notice is provided within 48 hours.

58.40(10) *Transfer or discharge planning.*

a. The facility shall develop a plan to provide for the orderly and safe transfer or discharge of each resident to be transferred or discharged. (II)

b. To minimize the possible adverse effects of the involuntary transfer, the resident shall receive counseling services by the sending facility before the involuntary transfer and by the receiving facility after the involuntary transfer. Counseling shall be documented in the resident's record. (II)

c. The counseling requirement in paragraph 58.40(10) "b" does not apply if the discharge has already occurred pursuant to subrule 58.40(6) and emergency notice is provided within 48 hours.

d. Counseling, if required, shall be provided by a licensed mental health professional as defined in Iowa Code section 228.1(6). (II)

e. The health care facility that receives a resident who has been involuntarily transferred shall immediately formulate and implement a plan of care which takes into account possible adverse effects the transfer may cause. (II)

58.40(11) *Transfer upon revocation of license or voluntary closure.* Residents shall not have the right to a hearing to contest an involuntary discharge or transfer resulting from the revocation of the facility's license by the department of inspections and appeals. In the case of the voluntary closure of a facility, a period of 30 days must be allowed for an orderly transfer of residents to other facilities.

58.40(12) *Intrafacility transfer.*

a. Residents shall not be arbitrarily relocated from room to room within a licensed health care facility. (I, II) Involuntary relocation may occur only in the following situations, which shall be documented in the resident's record: (II)

- (1) Resident's incompatibility with or disturbance to other roommates.
 - (2) For the welfare of the resident or other residents of the facility.
 - (3) For medical, nursing or psychosocial reasons, as judged by the primary care provider, nurse or social worker in the case of a facility which groups residents by medical, nursing or psychosocial needs.
 - (4) To allow a new admission to the facility that would otherwise not be possible due to separation of roommates by sex.
 - (5) In the case of a resident whose source of payment was previously private, but who now is eligible for Title XIX (Medicaid) assistance, the resident may be transferred from a private room to a semiprivate room or from one semiprivate room to another.
 - (6) Reasonable and necessary administrative decisions regarding the use and functioning of the building.
 - b.* Unreasonable and unjustified reasons for changing a resident's room without the concurrence of the resident or responsible party include:
 - (1) Change from private pay status to Title XIX, except as outlined in subparagraph 58.40(12) "a"(5). (II)
 - (2) As punishment or behavior modification, except as specified in subparagraph 58.40(12) "a"(1). (II)
 - (3) Discrimination on the basis of race or religion. (II)
 - c.* If intrafacility relocation is necessary for reasons outlined in paragraph 58.40(12) "a," the resident shall be notified at least 48 hours prior to the transfer and the reason therefor shall be explained. The responsible party shall be notified as soon as possible. The notification shall be documented in the resident's record and signed by the resident or responsible party. (II)
 - d.* If emergency relocation is required in order to protect the safety or health of the resident or other residents, the notification requirements may be waived. The conditions of the emergency shall be documented. The family or responsible party shall be notified immediately or as soon as possible of the condition that necessitates emergency relocation, and such notification shall be documented. (II)
 - e.* A transfer to a part of a facility that has a different license must be handled the same way as a transfer to another facility and not as an intrafacility transfer. (II, III)
- [ARC 1752C, IAB 12/10/14, effective 1/14/15; ARC 3523C, IAB 12/20/17, effective 1/24/18]

481—58.41(135C) Residents' rights. Each resident shall be encouraged and assisted throughout the resident's period of stay, to exercise rights as a resident and as a citizen and may voice grievances and recommend changes in policies and services to administrative staff or to outside representatives of the resident's choice, free from interference, coercion, discrimination, or reprisal. (II)

58.41(1) The facility shall provide ongoing opportunities for residents to be aware of and to exercise their rights as residents. Residents shall be kept informed of issues or pending decisions of the facility that affect them and their views shall be solicited prior to action. (II)

58.41(2) The facility shall implement a written procedure for registering and resolving grievances and recommendations by residents or their responsible party. The procedure shall ensure protection of the resident from any form of reprisal or intimidation. The written procedure shall include:

- a.* Designation of an employee responsible for handling grievances and recommendations. (II)
- b.* A method of investigating and assessing the validity of a grievance or recommendation. (II)
- c.* Methods of resolving grievances. (II)
- d.* Methods of recording grievances and actions taken. (II)

58.41(3) The facility shall post in a prominent area the name, telephone number, and address of the ombudsman, survey agency, local law enforcement agency, and certified volunteer long-term care ombudsman and the text of Iowa Code section 135C.46 to provide to residents a further course of redress. (II)

[ARC 1205C, IAB 12/11/13, effective 1/15/14]

481—58.42(135C) Financial affairs—management. Each resident who has not been assigned a guardian or conservator by the court may manage the resident's own personal financial affairs, and

to the extent, under written authorization by the resident that the facility assists in management, the management shall be carried out in accordance with Iowa Code section 135C.24. (II)

58.42(1) The facility shall maintain a written account of all residents' funds received by or deposited with the facility. (II)

58.42(2) An employee shall be designated in writing to be responsible for resident accounts. (II)

58.42(3) The facility shall keep on deposit personal funds over which the resident has control in accordance with Iowa Code section 135C.24(2). Should the resident request these funds, they shall be given to the resident on request with receipts maintained by the facility and a copy to the resident. In the case of a confused or intellectually disabled resident, the resident's responsible party shall designate a method of disbursing the resident's funds. (II)

58.42(4) If the facility makes financial transactions on a resident's behalf, the resident must receive or acknowledge that the resident has seen an itemized accounting of disbursements and current balances at least quarterly. A copy of this statement shall be maintained in the resident's financial or business record. (II)

58.42(5) A resident's personal funds shall not be used without the written consent of the resident or the resident's guardian. (II)

58.42(6) A resident's personal funds shall be returned to the resident when the funds have been used without the written consent of the resident or the resident's guardian. The department may report findings that resident funds have been used without written consent to the audits division or the local law enforcement agency, as appropriate. (II)

[ARC 0766C, IAB 5/29/13, effective 7/3/13]

481—58.43(135C) Resident abuse prohibited. Each resident shall receive kind and considerate care at all times and shall be free from mental, physical, sexual, and verbal abuse, exploitation, neglect, and physical injury. Each resident shall be free from chemical and physical restraints except as follows: when authorized in writing by a physician for a specified period of time; when necessary in an emergency to protect the resident from injury to the resident or to others, in which case restraints may be authorized by designated professional personnel who promptly report the action taken to the physician; and in the case of an intellectually disabled individual when ordered in writing by a physician and authorized by a designated qualified intellectual disabilities professional for use during behavior modification sessions. Mechanical supports used in normative situations to achieve proper body position and balance shall not be considered to be a restraint. (II)

58.43(1) Mental abuse includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation. (II)

58.43(2) Physical abuse includes, but is not limited to, corporal punishment and the use of restraints as punishment. (II)

58.43(3) Drugs such as tranquilizers may not be used as chemical restraints to limit or control resident behavior for the convenience of staff. (II)

58.43(4) Physicians' orders are required to utilize all types of physical restraints and shall be renewed at least quarterly. (II) Physical restraints are defined as the following:

Type I—the equipment used to promote the safety of the individual but is not applied directly to their person. Examples: divided doors and totally enclosed cribs.

Type II—the application of a device to the body to promote safety of the individual. Examples: vest devices, soft-tie devices, hand socks, geriatric chairs.

Type III—the application of a device to any part of the body which will inhibit the movement of that part of the body only. Examples: wrist, ankle or leg restraints and waist straps.

58.43(5) Physical restraints are not to be used to limit resident mobility for the convenience of staff and must comply with life safety requirements. If a resident's behavior is such that it may result in injury to the resident or others and any form of physical restraint is utilized, it should be in conjunction with a treatment procedure(s) designed to modify the behavioral problems for which the resident is restrained, or as a last resort, after failure of attempted therapy. (I, II)

58.43(6) Each time a Type II or III restraint is used documentation on the nurse's progress record shall be made which includes type of restraint and reasons for the restraint and length of time resident was restrained. The documentation of the use of Type III restraint shall also include the time of position change. (II)

58.43(7) Each facility shall implement written policies and procedures governing the use of restraints which clearly delineate at least the following:

- a.* Physicians' orders shall indicate the specific reasons for the use of restraints. (II)
- b.* Their use is temporary and the resident will not be restrained for an indefinite amount of time. (I, II)
- c.* A qualified nurse shall make the decision for the use of a Type II or Type III restraint for which there shall be a physician's order. (II)
- d.* A resident placed in a Type II or III restraint shall be checked at least every 30 minutes by appropriately trained staff. No form of restraint shall be used or applied in such a manner as to cause injury or the potential for injury and provide a minimum of discomfort to resident restrained. (I, II)
- e.* Reorders are issued only after the attending physician reviews the resident's condition. (II)
- f.* Their use is not employed as punishment, for the convenience of the staff, or as a substitute for supervision or program. (I, II)
- g.* The opportunity for motion and exercise shall be provided for a period of not less than ten minutes during each two hours in which Type II and Type III restraints are employed, except when resident is sleeping. However, when resident awakens, this shall be provided. This shall be documented each time. A check sheet may serve this purpose. (I, II)
- h.* Locked restraints or leather restraints shall not be permitted except in life-threatening situations. Straight jackets and secluding residents behind locked doors shall not be employed. (I, II)
- i.* Nursing assessment of the resident's need for continued application of a Type III restraint shall be made every 12 hours and documented on the nurse's progress record. Documentation shall include the type of restraint, reason for the restraint and the circumstances. Nursing assessment of the resident's need for continued application of either a Type I or Type II restraint and nursing evaluation of the resident's physical and mental condition shall be made every 30 days and documented on the nurse's progress record. (II)
- j.* A divided door equipped with a securing device that may be readily opened by personnel shall be considered an appropriate means of temporarily confining a resident in the resident's room. (II)
- k.* Divided doors shall be of the type that when the upper half is closed the lower section shall close. (II)
- l.* Methods of restraint shall permit rapid removal of the resident in the event of fire or other emergency. (I, II)
- m.* The facility shall provide orientation and ongoing education programs in the proper use of restraints.

58.43(8) In the case of an intellectually disabled individual who participates in a behavior modification program involving use of restraints or aversive stimuli, the program shall be conducted only with the informed consent of the individual's parent or responsible party. Where restraints are employed, an individualized program shall be developed by the interdisciplinary team with specific methodologies for monitoring its progress. (II)

a. The resident's responsible party shall receive a written account of the proposed plan of the use of restraints or aversive stimuli and have an opportunity to discuss the proposal with a representative(s) of the treatment team. (II)

b. The responsible party must consent in writing prior to the use of the procedure. Consent may also be withdrawn in writing. (II)

58.43(9) Allegations of dependent adult abuse. Allegations of dependent adult abuse shall be reported and investigated pursuant to Iowa Code chapter 235E and 481—Chapter 52. (I, II, III)

58.43(10) and **58.43(11)** Rescinded IAB 12/11/13, effective 1/15/14.

This rule is intended to implement Iowa Code sections 135C.14, 235B.3(1), and 235B.3(11).
[ARC 0766C, IAB 5/29/13, effective 7/3/13; ARC 1204C, IAB 12/11/13, effective 1/15/14]

481—58.44(135C) Resident records. Each resident shall be ensured confidential treatment of all information contained in the resident's records, including information contained in an automatic data bank. The resident's written consent shall be required for the release of information to persons not otherwise authorized under law to receive it. (II)

58.44(1) The facility shall limit access to any medical records to staff and consultants providing professional service to the resident. This is not meant to preclude access by representatives of state and federal regulatory agencies. (II)

58.44(2) Similar procedures shall safeguard the confidentiality of residents' personal records, e.g., financial records and social services records. Only those personnel concerned with the financial affairs of the residents may have access to the financial records. This is not meant to preclude access by representatives of state and federal regulatory agencies. (II)

58.44(3) The resident, or the resident's responsible party, shall be entitled to examine all information contained in the resident's record and shall have the right to secure full copies of the record at reasonable cost upon request, unless the physician determines the disclosure of the record or section thereof is contraindicated in which case this information will be deleted prior to making the record available to the resident or responsible party. This determination and the reasons for it must be documented in the resident's record. (II)

481—58.45(135C) Dignity preserved. The resident shall be treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and in care for personal needs. (II)

58.45(1) Staff shall display respect for residents when speaking with, caring for, or talking about them, as constant affirmation of their individuality and dignity as human beings. (II)

58.45(2) Schedules of daily activities shall allow maximum flexibility for residents to exercise choice about what they will do and when they will do it. Residents' individual preferences regarding such things as menus, clothing, religious activities, friendships, activity programs, entertainment, sleeping and eating, also times to retire at night and arise in the morning shall be elicited and considered by the facility. (II)

58.45(3) Residents shall be examined and treated in a manner that maintains the privacy of their bodies. A closed door or a drawn curtain shall shield the resident from passersby. People not involved in the care of the residents shall not be present without the resident's consent while the resident is being examined or treated. (II)

58.45(4) Privacy of a resident's body also shall be maintained during toileting, bathing, and other activities of personal hygiene, except as needed for resident safety or assistance. (II)

58.45(5) Staff shall knock and be acknowledged before entering a resident's room unless the resident is not capable of a response. This shall not apply in emergency conditions. (II)

481—58.46(135C) Resident work. No resident may be required to perform services for the facility, except as provided by Iowa Code sections 35D.14 and 347B.5. (II)

58.46(1) Residents may not be used to provide a source of labor for the facility against their will. Physician's approval is required for all work programs. (I, II)

58.46(2) If the plan of care requires activities for therapeutic or training reasons, the plan for these activities shall be professionally developed and implemented. Therapeutic or training goals must be clearly stated and measurable and the plan shall be time limited and reviewed at least quarterly. (II)

58.46(3) Residents who perform work for the facility must receive remuneration unless the work is part of their approved training program. Persons on the resident census performing work shall not be used to replace paid employees in fulfilling staffing requirements. (II)

481—58.47(135C) Communications. Each resident may communicate, associate, and meet privately with persons of the resident's choice, unless to do so would infringe upon the rights of other residents, and may send and receive personal mail unopened. (II)

58.47(1) Subject to reasonable scheduling restrictions, visiting policies and procedures shall permit residents to receive visits from anyone they wish. Visiting hours shall be posted. (II)

58.47(2) Reasonable, regular visiting hours shall not be less than 12 hours per day and shall take into consideration the special circumstances of each visitor. A particular visitor(s) may be restricted by the facility for one of the following reasons:

a. The resident refuses to see the visitor(s). (II)

b. The resident's physician documents specific reasons why such a visit would be harmful to the resident's health. (II)

c. The visitor's behavior is unreasonably disruptive to the functioning of the facility (this judgment must be made by the administrator and the reasons shall be documented and kept on file). (II)

58.47(3) Decisions to restrict a visitor are reviewed and reevaluated: each time the medical orders are reviewed by the physician; at least quarterly by the facility's staff; or at the resident's request. (II)

58.47(4) Space shall be provided for residents to receive visitors in reasonable comfort and privacy. (II)

58.47(5) Telephones consistent with ANSI standards (405.1134(c)) shall be available and accessible for residents to make and receive calls with privacy. Residents who need help shall be assisted in using the telephone. (II)

58.47(6) Arrangements shall be made to provide assistance to residents who require help in reading or sending mail. (II)

58.47(7) Residents shall be permitted to leave the facility and environs at reasonable times unless there are justifiable reasons established in writing by the attending physician, qualified intellectual disabilities professional or facility administrator for refusing permission. (II)

58.47(8) Residents shall not have their personal lives regulated beyond reasonable adherence to meal schedules, bedtime hours, and other written policies which may be necessary for the orderly management of the facility and as required by these rules. However, residents shall be encouraged to participate in recreational programs. (II)

[ARC 0766C, IAB 5/29/13, effective 7/3/13]

481—58.48(135C) Resident activities. Each resident may participate in activities of social, religious, and community groups at the resident's discretion unless contraindicated for reasons documented by the attending physician or qualified intellectual disabilities professional as appropriate in the resident's record. (II)

58.48(1) Residents who wish to meet with or participate in activities of social, religious, or other community groups in or outside of the facility shall be informed, encouraged, and assisted to do so. (II)

58.48(2) All residents shall have the freedom to refuse to participate in these activities. (II)

[ARC 0766C, IAB 5/29/13, effective 7/3/13]

481—58.49(135C) Resident property. Each resident may retain and use personal clothing and possessions as space permits and provided such use is not otherwise prohibited by these rules. (II)

58.49(1) Residents shall be permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility. The personal property shall be kept in a safe location which is convenient to the resident. (II)

58.49(2) Residents shall be advised, prior to or at the time of admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items, e.g., cleaning and laundry. (II)

58.49(3) Any personal clothing or possessions retained by the facility for the resident during the resident's stay shall be identified and recorded on admission and a record placed on the resident's chart. The facility shall be responsible for secure storage of the items, and they shall be returned to the resident promptly upon request or upon discharge from the facility. (II)

58.49(4) A resident's personal property shall not be used without the written consent of the resident or the resident's guardian. (II)

58.49(5) A resident's personal property shall be returned to the resident when it has been used without the written consent of the resident or the resident's guardian. The department may report findings

that a resident's property has been used without written consent to the local law enforcement agency, as appropriate. (II)

481—58.50(135C) Family visits. Each resident, if married, shall be ensured privacy for visits by the resident's spouse; if both are residents in the facility, they shall be permitted to share a room if available. (II)

58.50(1) The facility shall provide for needed privacy in visits between spouses. (II)

58.50(2) Spouses who are residents in the same facility shall be permitted to share a room, if available, unless one of their attending physicians documents in the medical record those specific reasons why an arrangement would have an adverse effect on the health of the resident. (II)

58.50(3) Family members shall be permitted to share a room, if available, if requested by both parties, unless one of their attending physicians documents in the medical record those specific reasons why such an agreement would have an adverse effect on the health of the resident. (II)

481—58.51(135C) Choice of physician and pharmacy. Each resident shall be permitted free choice of a physician and a pharmacy, if accessible. The facility may require the pharmacy selected to utilize a drug distribution system compatible with the system currently used by the facility.

A facility shall not require the repackaging of medications dispensed by the Veterans Administration or an institution operated by the Veterans Administration for the purpose of making the drug distribution system compatible with the system used by the facility. (II)

481—58.52(135C) Incompetent resident.

58.52(1) Each facility shall provide that all rights and responsibilities of the resident devolve to the resident's responsible party when a resident is adjudicated incompetent in accordance with state law or, in the case of a resident who has not been adjudicated incompetent under the laws of the state, in accordance with 42 CFR 483.10. This subrule is not intended to limit the authority of any individual acting pursuant to Iowa Code chapter 144A. (II)

58.52(2) The fact that a resident has been adjudicated incompetent does not absolve the facility from advising the resident of these rights to the extent the resident is able to understand them. The facility shall also advise the responsible party, if any, and acquire a statement indicating an understanding of residents' rights. (II)

481—58.53(135C) County care facilities. In addition to Chapter 58 licensing rules, county care facilities licensed as nursing facilities must also comply with department of human services rules, 441—Chapter 37. Violation of any standard established by the department of human services is a Class II violation pursuant to 481—56.2(135C).

481—58.54(73GA,ch 1016) Special unit or facility dedicated to the care of persons with chronic confusion or a dementing illness (CCDI unit or facility).

58.54(1) A nursing facility which chooses to care for residents in a distinct part shall obtain a license for a CCDI unit or facility. In the case of a distinct part, this license will be in addition to its ICF license. The license shall state the number of beds in the unit or facility. (III)

a. Application for this category of care shall be submitted on a form provided by the department. (III)

b. Plans to modify the physical environment shall be submitted to the department. The plans shall be reviewed based on the requirements of 481—Chapter 61. (III)

58.54(2) A statement of philosophy shall be developed for each unit or facility which states the beliefs upon which decisions will be made regarding the CCDI unit or facility. Objectives shall be developed for each CCDI unit or facility as a whole. The objectives shall be stated in terms of expected results. (II, III)

58.54(3) A résumé of the program of care shall be submitted to the department for approval at least 60 days before a separate CCDI unit or facility is opened. A new résumé of the program of care shall be submitted when services are substantially changed. (II, III)

The résumé of the program of care shall:

- a. Describe the population to be served; (II, III)
- b. State philosophy and objectives; (II, III)
- c. List admission and discharge criteria; (II, III)
- d. Include a copy of the floor plan; (II, III)
- e. List the titles of policies and procedures developed for the unit or facility; (II, III)
- f. Propose a staffing pattern; (II, III)
- g. Set out a plan for specialized staff training; (II, III)
- h. State visitor, volunteer, and safety policies; (II, III)
- i. Describe programs for activities, social services and families; (II, III) and
- j. Describe the interdisciplinary care planning team. (II, III)

58.54(4) Separate written policies and procedures shall be implemented in each CCDI unit or facility.

There shall be:

a. Admission and discharge policies and procedures which state the criteria to be used to admit residents and the evaluation process which will be used. These policies shall require a statement from the attending physician agreeing to the placement before a resident can be moved into a CCDI unit or facility. (II, III)

b. Safety policies and procedures which state the actions to be taken by staff in the event of a fire, natural disaster, emergency medical or catastrophic event. Safety procedures shall also explain steps to be taken when a resident is discovered to be missing from the unit or facility and when hazardous cleaning materials or potentially dangerous mechanical equipment is being used in the unit or facility. The facility shall identify its method for security of the unit or facility and the manner in which the effectiveness of the security system will be monitored. (II, III)

c. Program and service policies and procedures which explain programs and services offered in the unit or facility including the rationale. (III)

d. Policies and procedures concerning staff which state minimum numbers, types and qualifications of staff in the unit or facility. (II, III)

e. Policies about visiting which suggest times and ensure the residents' rights to free access to visitors. (II, III)

f. Quality assurance policies and procedures which list the process and criteria which will be used to monitor and to respond to risks specific to the residents. This shall include, but not be limited to, drug use, restraint use, infections, incidents and acute behavioral events. (II, III)

58.54(5) Preadmission assessment of physical, mental, social and behavioral status shall be completed to determine whether the applicant meets admission criteria. This assessment shall be completed by a registered nurse and a staff social worker or social work consultant and shall become part of the permanent record upon admission of the resident. (II, III)

58.54(6) All staff working in a CCDI unit or facility shall have training appropriate to the needs of the residents. (II, III)

a. Upon assignment to the unit or facility, everyone working in the unit or facility shall be oriented to the needs of people with chronic confusion or dementing illnesses. They shall have special training appropriate to their job description within 30 days of assignment to the unit or facility. (II, III) The orientation shall be at least six hours. The following topics shall be covered:

- (1) Explanation of the disease or disorder; (II, III)
- (2) Symptoms and behaviors of memory-impaired people; (II, III)
- (3) Progression of the disease; (II, III)
- (4) Communication with CCDI residents; (II, III)
- (5) Adjustment to care facility residency by the CCDI unit or facility residents and their families; (II, III)
- (6) Inappropriate and problem behavior of CCDI unit or facility residents and how to deal with it; (II, III)
- (7) Activities of daily living for CCDI residents; (II, III)
- (8) Handling combative behavior; (II, III) and

(9) Stress reduction for staff and residents. (II, III)

b. Licensed nurses, certified aides, certified medication aides, social services personnel, housekeeping and activity personnel shall have a minimum of six hours of in-service training annually. This training shall be related to the needs of CCDI residents. The six-hour training shall count toward the required annual in-service training. (II, III)

58.54(7) There shall be at least one nursing staff person on a CCDI unit at all times. (I, II, III)

58.54(8) The CCDI unit or facility license may be revoked, suspended or denied pursuant to Iowa Code chapter 135C and Iowa Administrative Code 481—Chapter 50.

This rule is intended to implement 1990 Iowa Acts, chapter 1016.

481—58.55(135C) Another business or activity in a facility. A facility is allowed to have another business or activity in a health care facility or in the physical structure of the facility, if the other business or activity meets the requirements of applicable state and federal laws, administrative rules, and federal regulations.

To obtain the approval of the department and the state fire marshal, the facility must submit to the department a written request for approval which identifies the service(s) to be offered by the business and addresses the factors outlined in paragraphs “*a*” through “*f*” of subrule 58.55(1). (I, II, III)

58.55(1) The following factors will be considered by the department in determining whether a business or activity will interfere with the use of the facility by residents, interfere with services provided to residents, or be disturbing to residents:

- a.* Health and safety risks for residents;
- b.* Noise created by the proposed business or activity;
- c.* Odors created by the proposed business or activity;
- d.* Use of the facility’s corridors or rooms as thoroughfares to the business or activity in regard to safety and disturbance of residents and interference with delivery of services;
- e.* Proposed staffing for the business or activity; and
- f.* Sharing of services and staff between the proposed business or activity and the facility.

58.55(2) Approval of the state fire marshal shall be obtained before approval of the department will be considered.

58.55(3) A business or activity conducted in a health care facility or in the same physical structure as a health care facility shall not reduce space, services or staff available to residents below minimums required in these rules and 481—Chapter 61. (I, II, III)

481—58.56(135C) Respite care services. Respite care services means an organized program of temporary supportive care provided for 24 hours or more to a person in order to relieve the usual caregiver of the person from providing continual care to the person. A nursing facility which chooses to provide respite care services must meet the following requirements related to respite services and must be licensed as a nursing facility.

58.56(1) A nursing facility certified as a Medicaid nursing facility or Medicare skilled nursing facility must meet all Medicaid and Medicare requirements including CFR 483.12, admission, transfer and discharge rights.

58.56(2) A nursing facility which chooses to provide respite care services is not required to obtain a separate license or pay a license fee.

58.56(3) Rule 481—58.40(135C) regarding involuntary discharge or transfer rights, does not apply to residents who are being cared for under a respite care contract.

58.56(4) Pursuant to rule 481—58.13(135C), the facility shall have a contract with each resident in the facility. When the resident is there for respite care services, the contract shall specify the time period during which the resident will be considered to be receiving respite care services. At the end of that period, the contract may be amended to extend that period of time. The contract shall specifically state the resident may be involuntarily discharged while being considered as a respite care resident. The contract shall meet other requirements under 481—58.13(135C), except the requirements under subrule 58.13(7).

58.56(5) Respite care services shall not be provided by a health care facility to persons requiring a level of care which is higher than the level of care the facility is licensed to provide.

481—58.57(135C) Training of inspectors.

58.57(1) Subject to the availability of funding, all nursing facility inspectors shall receive 12 hours of annual continuing education in gerontology, wound care, dementia, falls, or a combination of these subjects.

58.57(2) An inspector shall not be personally liable for financing the training required under subrule 58.57(1).

58.57(3) The department shall consult with the collective bargaining representative of the inspector in regard to the training required under this rule.

[ARC 8433B, IAB 12/30/09, effective 2/3/10]

These rules are intended to implement Iowa Code sections 10A.202, 10A.402, 135C.6(1), 135C.14, 135C.25, 135C.32, 135C.36 and 227.4 and 1990 Iowa Acts, chapter 1016.

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[◇] Two or more ARCs

¹ Effective date of 470—58.15(2) “c” delayed 70 days by the Administrative Rules Review Committee, IAB 2/26/86.
 Effective date of 470—58.15(2) “c” delayed until the expiration of 45 calendar days into the 1987 session of the General Assembly pursuant to Iowa Code section 17A.8(9), IAB 6/4/86.

² See IAB, Inspections and Appeals Department.

OBJECTION

At its February 13 meeting the Administrative Rules Review Committee voted the following objection: [Subrules 57.23(2)“b,” 58.26(2)“b,” 59.31(2)“b,” 63.21(3)“b,” published IAB 12/13/78]

The committee objects to the amendments to 470* IAC 57.23(2)“b,” 58.26(2)“b,” 59.31(2)“b” and 63.21(3)“b,” which strike the phrase “Twenty-five percent of the staffing may be provided by qualified volunteers. The time shall be spent in working with the organized program activity.”, on the grounds these provisions are unreasonable. It is the understanding of the committee these deletions in effect require facilities to employ a person to coordinate recreation activities. It is the feeling of the committee this would result in higher per bed costs without demonstrably improving the services rendered to the patient. Volunteers have always played a major role in health care institutions, and no evidence has been submitted indicating a decline in that role or in public interest in donating time and energy.

These amendments appear in the 12-13-78 IAB, and have been filed under the emergency provisions of chapter 17A, 1979 Code.

*Chapter 57 transferred to Inspections and Appeals[481], IAC 7/15/87.

CHAPTER 60
MINIMUM PHYSICAL STANDARDS
FOR RESIDENTIAL CARE FACILITIES
[Prior to 7/15/87, Health Department[470] Ch 60]

481—60.1(135C) Definitions. Definitions in 481—57.1(135C) and 481—63.1(135C) of the rules of this department are hereby incorporated by reference as part of this chapter.

481—60.2(135C) Waivers. Procedures for waivers in rule 481—57.2(135C) or 481—63.2(135C) are hereby incorporated by reference as part of this chapter. Certain occupancies, conditions in the area, or the site may make compliance with the rules impractical or impossible. Certain conditions may justify minor modification of the rules. In specific cases, waivers to the rules may be permitted by the reviewing authority.

[ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—60.3(135C) General requirements.

60.3(1) Residential care facilities shall contain the elements described herein and shall be built in accordance with construction requirements outlined. (III)

60.3(2) This chapter covers both new and existing construction. In various sections of the rules specific provisions for existing structures, differing from those for new construction, are provided by a notation at the end of the rule as follows:

a. Exception 1: Rule does not pertain to facilities licensed for less than 16 beds; or units housing fewer than 16 beds which are in distinctly separate buildings, located on a contiguous parcel of land, separated only by a public or private street. (Refer to Iowa Code chapter 414, municipal zoning, section 22, zoning for family homes, for additional information.)

b. Exception 2: Rule does not pertain to facilities licensed before May 1, 1972.

c. Exception 3: Rule does not pertain to facilities with construction plans approved by the department before May 1, 1977.

d. Exception 4: Rule does not pertain to facilities licensed before March 30, 1988.

e. Exception 5: Rule does not pertain to facilities licensed as residential care facilities for eight or fewer beds.

f. Exception 6: Rule does not pertain to facilities built according to plans approved by the department prior to May 6, 1992.

60.3(3) The rules and regulations apply to all residential care facilities and the renovations, additions, functional alterations, or change of space utilization to existing residential care facilities construction after the effective date of these rules. Conversion of a building or any of the parts not currently licensed as a residential care facility must meet the rules governing construction of new residential care facilities. (III)

60.3(4) Building site is subject to departmental approval as based upon the following criteria:

a. Submit a vicinity map indicating the site location and address on an 8½- by 11-inch sheet. If possible, include a city map. (III)

b. Neighborhood environment shall be free from excessive noise, dirt, polluted or odorous air. (III)

c. There shall be an area available for outdoor activities calculated at 40 square feet per licensed bed. (III) (Exception 4) Open air porches may be included in meeting requirements.

d. Each facility shall have on-site parking space to satisfy the needs of residents, employees, staff, and visitors. (III)

The following shall be provided:

(1) In facilities of 16 beds or greater, provide one space for each five beds, plus one space for each shift staff member and employee. (Exception 4)

(2) In facilities of 15 beds or fewer, provide one space for each three beds, plus one space for each shift staff member and employee. (Exception 4)

(3) Handicapped parking as appropriate, or a minimum of one space. (Exception 4)

e. Accessibility shall be provided for emergency and delivery vehicles. (III)

60.3(5) When construction is contemplated, whether for a new building, an addition to an existing building, functional alteration to an existing building, or conversion of an existing building, the licensee or applicant for license shall:

a. File a detailed and comprehensive program of care as set forth in rules 481—57.3(135C) or 481—63.3(135C), for departmental review and approval, including a description of the specific needs of the residents to be served and any other information the department may require. (III)

b. Submit a preliminary site plan and floor plan for departmental review. The design must meet the requirements of all applicable state statutes, state fire codes, federal standards, and local ordinances. The most stringent rules of the above regulations apply in resolving conflicts. (III)

c. Submit legible working drawings and specifications showing all elements of construction, fixed equipment, and mechanical and electrical systems to the department and to the state fire marshal for review. Such construction documents shall be prepared by or under the direct supervision of a registered architect or engineer, working within the appropriate field of registration, licensed to practice in Iowa. All construction documents shall be certified by and bear the seal of the architect or engineer responsible for the project. Each project shall be evaluated for its impact on the facility. Projects not affecting primary structural elements may, at the discretion of the department, be excluded from this rule. (III)

d. Receive written approval from the department and the state fire marshal's office before start of construction. If on-site construction above the foundation is not started within 12 months of the date of final approval of the working drawings and specifications, this approval shall be void and the plans and specifications shall be resubmitted for reconsideration of approval. (III)

e. All changes to the approved plans and specifications shall be approved in writing by the department and the state fire marshal's office prior to making the change. Applicant is responsible for ensuring that construction proceeds as per approved plans and specifications. (III)

f. For new construction, an addition, functional alteration or conversion of an existing building, it shall be the responsibility of the owner or agent to notify the department at all of the following intervals and wait for inspection by the department before proceeding:

- (1) At least 30 days before commencement of construction on the premises; (III)
- (2) At least 30 days before the pouring of the concrete floor slab; (III)
- (3) After completion of the mechanical or electrical rough-in and 30 days before enclosing walls; (III)
- (4) Thirty days before the completion of the project. (III)

g. Certain occupancies, conditions in the area, or the site may make compliance with the rules impractical or impossible. Certain conditions may justify minor modifications of the rules. In specific cases, variations to the rules may be permitted by the reviewing authority after the following conditions are considered:

- (1) The design and planning for the specific property offer improved or compensating features providing equivalent desirability and utility;
- (2) Alternate or special construction methods, techniques, and mechanical equipment, if proposed, offer equivalent durability, utility, safety, structural strength and rigidity, sanitation, odor control, protection from corrosion, decay and insect attack, and quality of workmanship;
- (3) Variations permitted by the department do not individually or in combination with other variations endanger the health, safety, or welfare of any resident;
- (4) Variations are limited to the specific project under consideration and are not construed as establishing a precedent for similar acceptance in other cases;
- (5) Occupancy and function of the building shall be considered;
- (6) Type of licensing shall be considered.

60.3(6) Except as provided in subrule 60.3(8), the facility shall be made accessible to and usable by the physically handicapped in accordance with the requirements of division 7 of the state building code, 661—16.704(103A) and 661—16.705(103A). (III) (Exception 3)

60.3(7) Facilities licensed as residential care facilities for eight or fewer beds shall be accessible to and functional for the physically handicapped. An appropriate number (at least one) of the bathrooms and bedrooms shall be accessible to and usable by the physically handicapped. (III)

60.3(8) No room in a basement shall be occupied for living purposes unless the room meets all the requirements of the department and receives approval of the department as fit for human habitation. (III)

60.3(9) Foundation drainage.

a. A foundation drainage system shall be installed around any portion of a building containing a basement. (III) (Exception 4)

b. The foundation drainage system should be installed at a slope so the water will run to a low point and then run into a sump pit in the basement, to a storm sewer system, or out to surface drainage. (III) (Exception 4)

c. The foundation drainage system shall not be connected to the sanitary sewer system. (III) (Exception 4)

d. The highpoint of the flow line shall be 4 inches below the elevation of the basement floor slab. (III) (Exception 4)

60.3(10) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction will minimize disruptions of existing functions. Access, exitways, and fire protection shall be maintained so the safety of the occupants will not be jeopardized during construction. (III)

60.3(11) Record drawings. Upon completion of the contract, the department shall be provided a complete set of approved legible plans and specifications showing all construction, fixed equipment, mechanical, and electrical systems and addendums as installed or built. (III)

60.3(12) The installation of any equipment found to be hazardous, or which fails to meet the purposes for which it is intended, shall be removed or replaced, or a substitute of suitable equipment shall be required. (III) (Exception 4)

481—60.4(135C) Typical construction. This rule contains construction requirements that are typical in all areas of the building.

60.4(1) Details and finishes shall be designed to provide a high degree of safety for the occupants by minimizing the opportunity for accidents. Hazards such as sharp corners shall be avoided. (III)

60.4(2) Minimum exit corridor widths.

a. Minimum exit corridor widths shall be 6 feet, except that corridors in adjunct areas not intended for the housing or use of residents may be a minimum of 4 feet in width. (III) Handrails may project into corridors. (Exceptions 1 and 3)

b. In facilities of 15 beds or less, the minimum exit corridor widths shall be 5 feet. (III) (Exception 4)

60.4(3) Drinking fountains, telephone booths, and vending machines shall be located so they do not project into the required width of any corridor. (III)

60.4(4) Minimum width of all side-hinged doors to all rooms shall be 3 feet. (III) (Exceptions 3, 4, and 5) Doors to resident toilet rooms and other rooms needing access for wheelchairs shall have a minimum clear opening width of 32 inches. (III)

60.4(5) Approved handrails shall be provided on both sides of corridors used by residents with a clear distance of 1½ inches between handrail and wall. (III) (Exception 4) This rule does not apply to residential care facilities for the mentally retarded licensed for eight or fewer beds.

a. Handrails shall be mounted with their top surfaces 31 to 34 inches above the finished floor. (III) (Exception 3)

b. Handrails shall have the ends rounded and returned to the wall. (III) (Exceptions 2 and 4)

c. All stairways in resident-occupied areas shall have substantial handrails on both sides. (III)

60.4(6) Each open stairway shall be protected with an approved guardrail. (III)

60.4(7) Landings shall be provided at the top and the bottom of each stair run. There shall be an approved landing between the top step and the doorway regardless of the direction of the door swing. (III) (Exception 4)

60.4(8) Toilet and bath facilities shall have an aggregate outside window area of at least 4 square feet. Facilities having a system of mechanical ventilation are exempt from this regulation. (III)

60.4(9) No door shall swing into the exit corridor except doors to spaces such as small closets which are not subject to occupancy or resident bedroom doors as indicated in 481—60.5(6)“i” or as required by the state fire marshal. (III)

60.4(10) All doors opening from corridors shall be swing-type except elevator doors. (III)

60.4(11) Mirrors.

a. Mirrors in resident bathrooms or toilet rooms shall be arranged for convenient use by residents in wheelchairs as well as by residents in a standing position. (III)

b. The bottom of the mirror shall be no higher than 40 inches from the floor. (III) (Exception 3)

60.4(12) All lavatories shall have towel dispensers which hold nonreusable towels. (III)

60.4(13) Screens of 16 mesh per square inch shall be provided at all exterior openings and any doors that are normally left in an open position. (III)

60.4(14) Screen doors shall swing outward and be self-closing. At the discretion of the state fire marshal, screens for fire doors may swing in. (III)

60.4(15) Fire escape porch railings and protected barrier enclosures shall be designed to resist a horizontal thrust of 50 pounds per running foot of railing applied to the top of the railing. (III)

60.4(16) Exposed heating pipes, hot water pipes, or radiators in rooms and areas used by residents and within reach of residents shall be covered or protected to prevent injury or burns to residents. (II, III)

60.4(17) All fans located within 7 feet of the floor shall be protected by screen guards of not more than ¼-inch mesh. On fans with U.L. approved safety guards netting shall not be required. (III)

60.4(18) Finishes shall be as follows:

a. Floors generally shall be easy to clean and shall have the wear resistance appropriate for the location involved. Floors in kitchens and related spaces shall be waterproof and greaseproof. In all areas where floors are subject to wetting, they shall have a slip-resistant finish. (III)

b. Ceilings generally shall be washable or easy to clean. (III) This requirement does not apply to boiler rooms, mechanical and building equipment rooms, shops, and similar spaces.

c. Ceilings in the dietary and food preparation areas shall have a finished ceiling covering all overhead piping and ductwork. (III) (Exception 3)

d. Ceilings shall be acoustically treated in the attendant’s area, day rooms, dining rooms, recreation areas, waiting areas, and corridors in resident areas. (III) (Exceptions 1 and 4)

e. Wall assemblies shall be constructed to present cleanable and continuous surfaces to the interior of resident rooms and resident corridors. (III) (Exception 4)

60.4(19) Partition, floor, and ceiling construction in resident areas shall comply with noise reduction criteria in the following table. The requirements set forth in this table assume installation methods which will not appreciably reduce the efficiency of the assembly as tested. Location of electrical receptacles, grills, ductwork, and other mechanical items, and blocking and sealing of partitions at floors and ceilings shall not compromise the sound isolation required. (III)

Table No. 1
(Exception 2)

	Airborne Sound Transmission Class (STC)*	
	<u>Partitions</u>	<u>Floors</u>
Resident's room to resident's room	35	35
Corridor to resident's room	35	35
Public space to resident's room**	40	40
Service areas to resident's room***	50	50

*Sound transmission (STC) shall be determined by tests in accordance with methods set forth in ASTM Standard E 90 and ASTM Standard E 413.

**Public space includes lobbies, dining rooms, recreation rooms, treatment rooms, and similar places.

***Service areas include kitchens, elevators, elevator machine rooms, laundries, garages, maintenance rooms, boiler and mechanical equipment rooms, and similar spaces of high noise. Mechanical equipment located on the same floor or above residents' rooms, office, nurses stations, and similar occupied spaces shall be effectively isolated from the floor.

60.4(20) The following ceiling heights shall be provided:

- a. Corridors, storage rooms, resident's toilet rooms, and other minor rooms, not less than 7 feet 6 inches. (III) (Exception 2)
- b. All other rooms — not less than 8 feet. (III) (Exception 2)
- c. Ceiling-mounted equipment, luminaries, suspended tracks, rails, and pipes located in the path of normal traffic shall not be less than 6 feet 8 inches above the floor. (III) (Exception 3)

60.4(21) Doors, sidelights, borrowed lights, and windows in which the glazing extends below 31 inches from the floor shall have a horizontal mullion or railing at 31 to 34 inches above the finished floor, and be glazed with safety glass, plastic glazing material, or wire glass where required by the state fire marshal. (III) (Exceptions 3 and 4) All replacement glass shall meet this code with no exception. (III)

60.4(22) All sheet plastic and molded plastic insulation in living spaces, attics, and crawl spaces shall be covered with an approved thermal barrier as defined in NFPA No. 205M-T, "Plastics in Building Construction." The thermal barrier shall be constructed of materials with no less than the fire protection qualities of ½-inch fire resistant gypsum board or as accepted by U.B.C., Sec. 1712(b)2, 1985 Edition. (III) (Exception 3)

60.4(23) Thresholds shall be low profile and expansion joint covers shall be made flush with the floor surface to facilitate the use of wheelchairs and carts. (III)

481—60.5(135C) Supervised care unit.

60.5(1) Definition of a supervised care unit. A supervised care unit shall not contain more than 60 beds and shall have the following rooms or areas: (III)

- Attendant's station,
- Clean workroom,
- Medication room,
- Resident rooms,
- Resident toilets or baths,
- Private room,
- Soiled workroom, and
- Enclosed clean linen storage.

60.5(2) In facilities over 15 beds, an attendant's station with a minimum of 40 square feet shall be provided which is centrally located in the resident area and shall have a well-lighted desk with the necessary equipment for the keeping of required records and supplies. (III)

60.5(3) A clean workroom, which may be combined with the medication room for storage and assembly of clean supplies, shall contain a work counter and sink. (III) (Exceptions 1 and 2)

60.5(4) The medication room shall be well-lighted and shall have the following: (III)

- a. Drug cabinet,
- b. Work counter,
- c. Refrigerator storage,
- d. Chest or compartment with a lock for Schedule II drugs,
- e. Lavatory.

60.5(5) Instead of the requirements in subrule 60.5(4), facilities licensed for 15 beds or less shall contain space for storage of medications which: (III)

- a. Is locked,
- b. Is adjacent to a lavatory,
- c. Provides for Schedule II drugs as defined by Iowa Code chapter 124, which shall be kept in a locked box within the locked medication cabinet,
- d. Has space available for refrigerating medication.

60.5(6) Resident rooms shall meet as a minimum the following requirements:

a. Bedrooms shall open directly into a corridor or common living area. (III) Bedrooms shall not be used as a thoroughfare. (III)

b. The minimum room area, exclusive of closets, toilet rooms, lockers, wardrobes, vestibules, and corridor door swings shall be 100 square feet in one-bed rooms and 80 square feet per bed in multibed rooms. Usable floor space of a room shall be no less than 8 feet in any major dimension. (III) (Exception 4)

c. Each resident room shall be provided with light and ventilation by means of a window or windows with a net glass area equal to 10 percent of the total floor area. The windows shall be openable without the use of tools. The window sill shall not be higher than 3 feet above the floor. (III) (Exception 4)

d. There shall be a wardrobe or closet in each resident's room. For each resident, the minimum clear dimensions shall be 1 foot 10 inches deep by 2 feet 6 inches wide of clear hanging space. A clothes rod and shelf shall be provided. Where a closet is shared, segregated portions shall be established. Each wardrobe and closet in each resident room shall have a door. (III) (Exceptions 2 and 4)

e. No bedroom shall be located so that its floor will be more than 30 inches below the adjacent grade level. (III)

f. Fixtures or storage shall be provided to hold individual towels and washcloths. (III)

g. No part of any room shall be enclosed, subdivided, or partitioned unless such part is separately lighted and ventilated and meets other requirements its usage and occupancy dictate, except closets used for the storage of resident's clothing. (III)

h. Rooms in which beds are erected shall not be used for purposes other than bedrooms. (III)

i. Each resident bedroom shall have a door. The door shall be the swing type and shall swing in, unless fully recessed. (III)

j. Multibed rooms shall be designed to permit no more than two beds, side-by-side, parallel to the window wall. (III) (Exceptions 2 and 4)

k. Each resident bedroom shall be so designed that the head of the bed shall not be in front of a window or a heat register or radiator. (III)

l. One lavatory shall be provided in each resident room. The lavatory may be omitted from a room when a lavatory is located in an adjoining toilet room which serves that room. (III) (Exception 3)

m. In facilities with eight or fewer beds, one lavatory shall be provided in each resident room. The lavatory may be omitted from a room when a lavatory is located in an adjacent toilet room which serves that room.

n. Multibed rooms shall provide full visual privacy for each resident. (III)

60.5(7) Resident toilet rooms.

a. Each resident room toilet shall have a swing or sliding door (not a pocket door). The door shall not swing into the toilet room. The doorway must have a minimum clear opening width of 32 inches. (III) (Exception 4)

b. An appropriate number of toilets commensurate with the facility's program of care shall be accessible to and usable by handicapped residents (minimum of one). (III) (Exceptions 3 and 4)

c. All toilet rooms shall have mechanical ventilation. (III) (Exception 3)

60.5(8) Central bathing.

a. Minimum numbers of toilet and bath facilities shall be one lavatory and one water closet for each 10 residents, and one tub or shower for each 15 residents or fraction thereof. See 481—60.5(8)“*l*” for grab bars and 481—60.11(4)“*e*”(9) for number of fixtures in smaller facilities. (III)

b. There shall be a minimum of one bathroom with tub or shower, water closet, and lavatory on each floor which has resident bedrooms in multistory buildings. (III)

c. Separate toilets for the sexes shall be provided. (III) (Exception 1)

d. Privacy for dressing and bathing shall be provided in central bathrooms. (III)

e. All bathrooms shall have mechanical ventilation. (III) (Exception 3) See 60.11(3)“*i*.”

f. The number of showers accessible to and usable by handicapped residents shall be commensurate with the facility's program of care. There shall be at least one. (III) (Exception 3)

g. Each bathroom shall have a water closet and a hand-washing lavatory. (III)

h. Toilet and bathing facilities shall not open directly into food preparation areas. (III)

i. Central bathing areas shall have a swinging door which swings into the bathroom. (III)

j. The number of sinks accessible to and usable by handicapped residents shall be commensurate with the facility's program of care. All lavatories shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the front of the fixture. Exposed hot water and drain pipes under lavatories shall be insulated or shielded as per the state building code. (III) (Exception 4)

k. Soap holders shall be provided in showers and bathtubs. (III) (Exception 3)

l. All toilet, bath, and shower facilities shall be supplied with grab bars and adequate safety devices appropriate to the needs of the individual residents. The bars shall have 1½-inch clearance to walls, shall be sufficient strength and anchorage to sustain a concentrated load of 250 pounds, and shall meet division 7 of the Iowa state building code.

m. Raised toilet seats shall be available for residents as needed. (III)

n. In facilities where the total occupancy of family, employees, and residents is more than five, separate bathing and toilet facilities shall be required for the family or employees distinct from such areas provided for residents. (III)

o. Each facility must provide no less than one bathing system accessible to the handicapped. (III) (Exceptions 1 and 4)

p. Bathtubs or showers shall be equipped with screwdriver stop valves in the water supply system. (III) (Exception 4)

q. Showers shall be equipped with a shower head on the end of a flexible hose. (III) (Exception 4)

60.5(9) Private room.

a. At least one single bed resident room shall be provided for purposes of privacy or incompatibility with other residents in the home. This room shall be used for emergency purposes and for short, intermittent periods of time. (III) (Exceptions 2 and 4)

b. The bed in the privacy room shall be counted in the total licensed bed capacity of the facility. The resident of such room shall be informed, and it shall be contained in the resident's contract, that the resident is subject to removal from the room when it becomes necessary to transfer another resident of the facility into it. Where, in the determination of the department, the facility is not making proper use of the room when privacy or isolation is deemed necessary, the department may choose not to license that bed in order to promote its effective use. (III)

60.5(10) A soiled workroom, workcounter, waste and soiled linen receptacles, and a two-compartment sink shall be provided. (III) One compartment of the double sink shall be a minimum of 10 inches deep for cleaning and sanitizing equipment. (III) (Exceptions 1 and 3)

60.5(11) Enclosed clean linen storage, separate from the clean workroom. (III)

481—60.6(135C) Support area.

60.6(1) Definition of a support area. The size of a support area shall depend upon the number and types of beds within the supervised unit. A support area shall contain the following rooms or areas: (III)

- Dining room,
- Activity or recreation area,
- Personal care room,
- Equipment storage.

60.6(2) Multipurpose rooms. Where space is provided for multipurpose dining, activities, or recreational purposes, the area shall total at least 30 square feet per licensed bed for the first 100 beds and 27 feet per licensed bed for all beds in excess of 100. An open area of sufficient size shall be provided to permit group activities such as religious meetings or presentation of demonstrations or entertainment. (III)

60.6(3) Where space is provided to be used only for activities and recreational purposes, the area shall be at least 15 square feet per licensed bed. At least 50 percent of the required area must be in one room. (III)

60.6(4) Where the dining and the lounge recreation areas are separated, each area shall provide a minimum of 180 square feet of usable floor space and be not less than 10 feet in any one dimension. Where space is provided to be used only for dining, the area shall total at least 15 square feet per licensed bed. (III)

60.6(5) Areas appropriate for the activities program shall be provided which shall:

- a. Be readily accessible to wheelchair and ambulatory residents. (III)
- b. Be of sufficient size to accommodate necessary equipment and to permit unobstructed movement of wheelchairs, residents, and personnel responsible for instructing and supervising residents. (III)
- c. Have space to store recreational equipment and supplies for the activities program within, or convenient to, the area or areas. Locked storage shall be available for potentially dangerous items such as scissors, knives and toxic materials. (III)

60.6(6) Personal care room.

- a. A personal care room with barber and beauty shop facilities shall be provided. (III) (Exception 1)
- b. In facilities of less than 100 beds, a multipurpose room with appropriate space and equipment may be utilized for such activities.

60.6(7) An equipment storage room shall be provided. (III) The area of this storage room may be used in calculating the total required general storage area as found in subrule 60.7(5). (Exception 1)

60.6(8) Enclosed clothing storage of at least 2 linear feet per bed for storage of off-season clothing shall be provided. (III) This could be counted as part of the general storage areas requirement and could be installed accessible in the general storage area. (Exception 4)

481—60.7(135C) Service area.

60.7(1) *Definition of a service area.* The size of a service area shall depend upon the number and types of beds within the supervised unit. A service area shall contain the following rooms or areas: (III)

- Dietetic service area,
- Janitor's closet,
- Laundry area,
- General storage area,
- Mechanical room,
- Maintenance shop,
- Yard equipment storage area.

60.7(2) *Dietetic service area.*

- a. Detailed layout plans and specifications of equipment shall be submitted to the department for review and approval before the new construction, alterations, or additions to existing kitchens begin. (III)

b. The construction and installation of equipment of the dietetic service area shall comply with or exceed the minimum standards set forth in the “Food Service Manual” (DHEW Publication No.(FDA) 78-2081, 1976 Edition). (III) (Exception 4)

c. In facilities where the total occupancy of family, employees and residents is more than six, the dietetic service area shall provide food serving facilities for residents and staff outside the food preparation area. (III)

d. The dishwashing area shall be provided with mechanical dishwashing equipment. (III) Either conventional or chemical dishwashing equipment may be used.

(1) Where conventional dishwashing equipment is used, refer to 481—60.11(4) “e”(9) for water temperature requirements. (III)

(2) A three-compartment pot and pan sink shall be provided for warewashing which provides and maintains 110° Fahrenheit to 115° Fahrenheit water for washing and 170° Fahrenheit to 180° Fahrenheit for sanitizing, or a two-compartment sink shall be provided for soaking and washing utensils, with easy access to a dish machine which must be large enough for sanitizing all sizes of utensils used. (III)

(3) Machines (single-tank stationary rack, door-type machines and spray-type glass washers) using chemicals for sanitation may be used, provided that:

1. The temperature of the wash water shall not be less than 120° Fahrenheit. (III)

2. Chemicals added for sanitation purposes shall be automatically dispensed. (III)

3. The wash water shall be kept clean. (III)

4. Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers’ specifications for time and concentration. (III)

5. The chemical sanitizing rinse water temperature shall be not less than 75° Fahrenheit nor less than the temperature specified by the machine’s manufacturer. (III)

6. Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010, January 1987. (III) (See Food Service Sanitation Manual)

7. A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used. (III)

e. The dietetic service area shall be designed to provide a separation of the clean and dirty areas and to eliminate intermingling of the two types of activities. (III) Food preparation and service areas are regarded as clean areas.

f. A hand-washing lavatory without mirror shall be provided in the dietetic service area. (III) (Exception 2) In facilities licensed for eight beds or fewer, the lavatory shall be adjacent or convenient to the dietetic service area. (III)

g. There shall be refrigerated storage for at least a three-day supply of perishable food. (III)

h. No less than 2½ square feet of shelving per resident bed shall be provided for staple food storage. (III) (Exception 3) There shall be available storage for at least a seven-day supply of staple food. (III)

i. A cart storage area shall be provided. (III) (Exceptions 1 and 2)

j. Provisions for maintaining sanitary waste disposal and storage shall be provided on the premises. (III)

k. A toilet room with lavatory conveniently accessible for the dietary staff shall be provided. (III)

l. There shall be an outside service entrance to the food service area which does not open directly into the dietary department. (III) (Exceptions 1 and 2)

m. The food service area shall not be less than 8 square feet per resident bed. (III) (Exception 1)

n. See subrule 60.11(3) for ventilation requirements. (III)

o. Where meals are provided by a health care facility or by a commercial food service, the preparation, storing and serving of the food and the utensil sanitizing procedures shall meet the requirements of these rules. (III)

p. Mechanical ventilation shall be provided in food storerooms to maintain temperatures and humidity at a level appropriate for the type of food being stored. (III) (Exception 4)

q. All cooking systems shall be provided with a properly sized exhaust system. See 60.11(3) “o.” (III) (Exception 4)

r. One janitor's closet shall be in the immediate vicinity of the dietary area for dietary use only. (III) (Exceptions 1 and 2)

60.7(3) Janitor's closet.

a. A janitor's closet shall be provided for storage of housekeeping supplies and equipment, including a floor receptor or service sink. (III) (Exception 1)

b. The door to the janitor's closet shall be equipped with a lock. (III)

c. Locked storage shall be provided for chemicals. (III)

d. A receptor floor drain or service sink shall be provided. (III)

60.7(4) Laundry area.

a. In the laundry a work flow pattern shall be established in which soiled linen is not transported through the clean area to the soiled area. Two distinct areas physically separated, not necessarily by a wall, are required. (III) (Exception 1)

b. A hand-washing lavatory shall be located between the soiled area and the clean area. (III) (Exception 4) In facilities licensed for 15 beds or fewer, a hand-washing lavatory located adjacent to the laundry area may meet this requirement.

c. Refer to 60.11(4) "e"(9) for water temperature requirements. (III)

d. Where linen is processed on site, the following shall be provided:

(1) A clean, dry, well-lighted laundry processing room with equipment sufficient to process seven days' needs within the workweek. (III)

(2) A soiled linen holding area. (III) (Exception 1)

(3) A clean linen, mending, and ironing area. (III) (Exception 1)

(4) Linen cart storage. (III) (Exception 1)

(5) Lockable storage for laundry supplies. (III) (Exception 4)

(6) One janitor's closet or alcove in the immediate vicinity of the laundry. (III) (Exceptions 1 and 2)

e. The laundry room in any facility not using off-site processing but serving more than 20 residents shall contain no less than 125 square feet of available floor space. (III)

f. Where linen is processed off the site, the following shall be provided:

(1) Soiled linen holding room. (III)

(2) Clean linen receiving, holding, inspection, and storage area. (III)

60.7(5) General storage areas.

a. General storage areas totaling not less than 10 square feet per bed shall be provided. (III) Storage areas are not required to be located in the same area. (Exception 4)

b. The equipment storage room space, found in subrule 60.6(7), may be included in this general storage area, but is not required to be located in the same area as referred to in 60.7(5) "a."

c. Storage areas for linens, janitor's supplies, sterile nursing supplies, activities supplies, library books, office supplies, kitchen supplies, and mechanical plant accessories shall not be included as part of the general storage area and are not required to be located in the same area. (III)

d. Thirty percent of the general storage area may be provided in a building outside the facility, readily and easily accessible by the personnel.

60.7(6) Mechanical, electrical, and maintenance areas. The following areas shall be provided:

a. Boiler room or mechanical room, to include a maintenance area in facilities of less than 100 beds, and electrical equipment room. (III)

(1) These rooms may be used for noncombustible material storage.

(2) Any noncombustible material shall not be stored close to or hinder access to any fuel-fired equipment or electrical panels. (III)

(3) These areas shall not be included in calculating the 10 square feet per bed for general storage areas, as required under 60.7(5) "a."

b. Maintenance shop for facilities of 100 beds or more. (III) (Exception 2)

c. Yard equipment storage may be provided in a separate room or building for yard maintenance equipment and supplies. This shall not be included in the general storage area. (III)

- d.* No portable fuel-operated equipment shall be housed inside a facility unless it is separated by at least a two-hour fire separation approved by the state fire marshal's office. (III)
- e.* Rooms containing heating or cooling equipment shall be locked.

481—60.8(135C) Administration and staff area. The size of an administration and staff area shall depend upon the number and types of beds within the supervised unit. An administration and staff area shall contain the following rooms or areas: (III)

1. An administrator's office. (III) (Exception 1)
2. A business office, containing storage for office equipment and supplies. (III) (Exceptions 1 and 2)
3. A reception and information counter or desk, which may be combined in the business office. (III) (Exception 1) In facilities of 15 beds or less, a secured area shall be provided. This area shall contain work space for charting, record storage, and may contain medication storage. (III)
4. A designated room or area for conferences, and in-service training and space for desk for the use of auxiliary personnel such as activity directors, housekeepers, consultants, and volunteers. (III) (Exceptions 1 and 3)
5. A lounge shall be provided for staff. (III) (Exception 1) Toilet rooms with lavatory and water closet shall be provided for the staff. (III) (Exception 1)
6. Closets or compartments for the safekeeping of coats and personal effects of staff. (III)

481—60.9(135C) Definition of public area. The size of the public area shall depend upon the number and types of beds within the supervised unit. A public area shall contain the following rooms or areas: (III)

- 60.9(1)** A vestibule area equipped with coat rack and shelf shall be available. (III)
- 60.9(2)** A public telephone shall be accessible to the residents within the facility to make personal calls. (III)
- 60.9(3)** Drinking fountains shall be available. (III) (Exception 1)
- 60.9(4)** Every facility shall provide a separate toilet for the public, with a lavatory and water closet.
 - a.* Each facility of eight beds or less shall designate a toilet, with lavatory and water closet for public use.
 - b.* Public toilets shall be accessible to and usable by the physically handicapped, equipped with appropriate equipment installed to meet the American Standards National Document A 117.1-1986. (III) (Exception 3)
 - c.* In facilities over 15 beds, there shall be public facilities for both men and women. (III) (Exception 4)
 - d.* Public facilities for both men and women must contain a clear floor area free from obstructions of 60 inches in diameter. (Exception 3)

481—60.10(135C) Elevator requirements. All residential care facilities where resident facilities are located on other than the first floor shall have one or more electric or electrohydraulic elevators, as required. For purposes of this requirement, resident facilities include, but are not limited to, diagnostic, recreation, activity, resident dining, therapy rooms, or additional resident bedrooms. The first floor is that floor first reached from the main front entrance. (III) (Exceptions 1 and 4 apply to rule 60.10(135C)) Elevators, where installed, shall comply with the division of labor rules as promulgated in Iowa Code chapter 89A and 875—Chapters 71 to 77. (III)

481—60.11(135C) Mechanical requirements. In new construction, prior to completion of the contract and final acceptance of the facility, the architect or engineer shall obtain from the contractor certification that all mechanical systems have been tested, balanced, and that the installation and performance of such systems shall conform to the requirements of the plans and specifications. Upon completion of the contract, the owner shall be furnished with a complete set of manufacturer's operating, maintenance, and preventive instructions and parts list with numbers and descriptions for each piece of equipment.

The owner shall also be provided with instruction in the operational use of systems and equipment as required. (III)

60.11(1) Steam and hot water heating and domestic water heating systems shall comply with the following:

a. Boilers shall be installed to comply with the division of labor services rules promulgated under Iowa Code chapter 89 and 875—Chapters 90 to 96, Iowa Administrative Code, and shall be inspected annually. (III)

b. Boiler feed pumps, condensate return pumps, fuel oil pumps, and hot water circulating pumps shall be connected and installed to provide standby service when any pump breaks down. (III) (Exception 4)

c. Supply and return mains and risers of cooling, heating, and steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends. (III) (Exception 3)

60.11(2) Thermal and acoustical insulation.

a. Insulation shall be provided for the following, within the building: (Exception 4)

(1) Steam supply and condensate return piping; (III)

(2) Piping above 125° Fahrenheit, which is exposed to contact by residents; (II, III)

(3) Chilled water, refrigerant and other process piping and equipment operating with fluid temperatures below ambient dewpoint; (III)

(4) Water supply and roof drainage piping on which condensation may occur; (III)

(5) Boilers, smoke-breaching and stacks; (III)

(6) Hot water piping above 180° Fahrenheit, and all hot water boilers, heaters, and piping; (III)

(7) Other piping, ducts, and equipment as necessary to maintain the efficiency of the system. (III)

b. Insulation, including finishes and adhesives on the interior surface of ducts, pipes and equipment, shall have a flame-spread rating of 25 or less and a smoke develop rating of 50 or less, as determined by an independent testing laboratory in accordance with HFPA 255. (III) (Exception 4)

c. Insulation on cold surfaces shall include an exterior vapor barrier. (III)

60.11(3) Air conditioning, heating and ventilating system. (All provisions in 60.11(3)“b” to 60.11(3)“s” are subject to Exception 4).

a. The heating system shall be capable of maintaining a temperature of 78° Fahrenheit in all occupied areas at a winter design temperature of 10° Fahrenheit.

b. The cooling system shall be designed to maintain all living spaces within the comfort zone. The comfort zone is defined in the ANSI/ASHRAE Standard 55-1981 or the 1985 ASHRAE Fundamentals Handbook. (III)

c. All air supply and air exhaust systems shall be mechanically operated and ducted from a central system to and from each room. All fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown in Table 2 shall be considered as minimum acceptable rates, and shall not be construed as precluding the use of higher ventilation rates. (III)

d. The bottoms of ventilation openings shall be not less than 3 inches above the floor of any room. (III)

e. All central systems designed to heat and cool the building with recirculation of air shall be equipped with a minimum 2-inch deep, 8- to 11-pleat per foot, Class 2 Underwriters' Laboratories, self-extinguishing, nonwoven, cotton, downstream, or final filter with a minimum efficiency of 25 to 30 percent and average arrestance of 90 percent, tested in accordance with ASHRAE Standard 52-76. This does not preclude the additional use of a prefilter upstream of the air handling equipment to extend the service life of the downstream, or final filter. (III) (Exception 6)

f. Any alternate ventilation system designed to attain an equivalent degree of odor control and purity of air to resident areas shall be considered for approval under conditions in 481—Chapters 57 and rules 63, 57.2(135C) and 63.2(135C). (III)

g. Rooms containing fuel-fired heating units shall be provided with sufficient outdoor air to maintain combustion rates of equipment and reasonable temperatures in the room and adjoining areas. (III)

- h.* Appropriate ventilation shall be provided in food storerooms to maintain temperature and humidity for the type of food being stored. (III)
- i.* Outdoor ventilation air intakes shall be located as far away as practicable, but not less than 25 feet from the exhaust outlets of any ventilating systems, combustion equipment stacks or noxious fumes. The bottom of outdoor intakes serving central air systems shall be located as high as practical, but not less than 6 feet above grade level, or, if installed through the roof, 3 feet above roof opening. (III)
- j.* The ventilation system shall be designed and balanced to provide the general pressure relationship to adjacent areas shown in the Pressure Relationship and Ventilation Table 2. Through-the-wall air conditioning units will not be used to calculate make up air. (III) (Exception 4)
- k.* Corridors, attics, or crawl spaces shall not be used as a plenum to supply air to or exhaust air from any rooms. (III)
- l.* The air system for resident rooms between smoke stop partitions shall be operated with common switches. (III)
- m.* Actuation of the fire alarm system shall shut down the air distribution system. (III)
- n.* Air handling duct systems shall meet the requirements of NFPA Standard 90A and 90B. Supply and return registers shall not be at the same level and shall be designed to inhibit stratification. (III)
- o.* Fire and smoke dampers shall be constructed, located and installed in accordance with the requirements of NFPA Standards 90A, 90B, and 101. (III)
- p.* Range and dishwasher exhaust hood in food preparation centers shall have a minimum exhaust rate of 60 cubic feet per minute, per square feet of hood face area. Face area is defined for this purpose as the open area from the exposed perimeter of the hood to the average perimeter of the cooking surfaces. All hoods over cooking ranges shall be equipped with grease filters, a fire extinguishing system, and heat actuated fan controls. Cleanout openings shall be provided every 20 feet in horizontal exhaust duct systems serving hoods. Tempered air shall be supplied to balance the exhausted air. Special hood designs shall be evaluated. (III) (Exceptions 1 and 4)
- q.* Mechanical ventilation over cooking equipment and dishwashing equipment shall be properly designed to take hot air out and not bring cold air down on hot food or dishes. (III)
- r.* Filter beds shall be located upstream of the air conditioning equipment, unless a prefilter is employed. In this case the prefilter shall be upstream of the equipment and the main filter bed may be located further downstream. Filter frames shall be durable and carefully dimensioned and shall provide an airtight fit within enclosing ductwork. All joints between filter segments and the enclosing ductwork shall be gasketed or sealed to provide a positive seal against air leakage. (III)
- s.* All under-the-slab perimeter ductwork shall be encased in lightweight or insulating concrete and sloped to a plenum low point. (III)
- t.* Laundry rooms shall be supplied with sufficient tempered outside air to balance the amounts exhausted and for combustion. (III)
- u.* The amounts of air and pressure relationship as set forth in Table 2 shall be provided. (III)
- v.* Condensate piping from cooling coils should be a minimum of 3/4 inch IPS and provided with cleanouts every 10 feet. (III)
- w.* Attics or crawl spaces shall not be used to house heating or cooling equipment.
- x.* All such areas must be accessible through a swinging door.

Table No. 2

PRESSURE RELATIONSHIPS AND VENTILATION OF CERTAIN
AREAS OF RESIDENTIAL CARE FACILITIES

Area Designation	Minimum Total Air Changes Per Hour Supplied to Room	All Air Exhausted Directly to Outdoors	Room Pressure in Relation To Adjacent Space
Resident Room	2	Optional	Equal
Resident Area Corridor	2	Optional	Equal
Lounge and Designated Smoking Area	6	Optional	Negative
Soiled Workroom or Soiled Holding	10	Yes	Negative
Toilet Room	10	Yes	Negative
Bathroom	10	Yes	Negative
Janitor's Closet	10	Yes	Negative
Food Preparation Center	10	Yes	Equal
Dishwashing Room	10	Yes	Negative
Laundry, General	10	Yes	Equal
Soiled Linen Sorting and Storage	10	Yes	Negative

60.11(4) Plumbing and other piping systems.

- a. Every facility shall have a complete interior plumbing system. (III)
- b. All plumbing and other piping systems shall be installed in accordance with the requirements of the Iowa state plumbing code and applicable provisions of local ordinances. (III) (Exception 3)
- c. All water supply systems pipes below grade or in concrete slabs shall be type K, soft copper. No joints will be allowed below the slab.
- d. Rescinded IAB 10/7/09, effective 11/11/09.
- e. Water supply systems. Water supply systems shall meet the following requirements:
 - (1) All facilities shall have a potable water source from a city water system or a private source which complies with the regulations and is approved by the department of natural resources. (III)
 - (2) Systems shall be designed to supply water to the fixtures and equipment at a minimum pressure of 15 pounds per square inch during maximum demand periods. (III)
 - (3) The temperature of the hot water to the resident lavatories, bath, and showers shall range between 110° Fahrenheit and 120° Fahrenheit. (III)
 - (4) Plumbing fixtures in janitor's rooms and soiled workrooms shall be provided with hot water. (III)
 - (5) Each water service main, branch main, riser and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture. (III) (Exception 4)
 - (6) Backflow preventers (vacuum breakers) shall be installed on hose bibbs, janitors' sinks, bedpan flushing attachments, hair care sinks, and on all other threaded fixtures to which hoses or tubing can be attached. (III)
 - (7) Water softeners which supply cold water to the kitchen, drinking fountains, and ice machines shall not add sodium to the water. (III) (Exception 4)
 - (8) Hot water distribution systems shall be arranged to provide hot water as specified at each hot water outlet at all times. (III) (See Table 3) A circulating pump in a hot water system shall meet these requirements. (Exception 4) A circulating pump is not required in facilities licensed for 15 or fewer beds.
 - (9) The hot water system shall be designed to supply 110° Fahrenheit to 120° Fahrenheit hot water for bathing for all residents in accordance with their program of care. For facilities licensed for 15 beds or fewer, one bathing unit shall be provided for each five residents. (III) (Exception 4)

Table No. 3
HOT WATER USE
Resident

	Areas	Dietary	Laundry
Gallons per HR. per Bed**	3	2	2
Temperature (degrees F)	110	120*	160***

*Provisions shall be made to provide 180° Fahrenheit rinse water at dishwasher. (III) (May be provided by a separate booster heater.)

**Quantities indicated for design demand of hot water are for general reference minimums and shall not substitute for accepted engineering design procedures using actual number and types of fixtures to be installed. Design shall also be affected by temperatures of cold water used for mixing, length of run and insulation relative to heat loss, etc. As an example, total quantity of hot water needed will be less when temperature available at the outlet is very nearly that of the source tank and the cold water used for tempering is relatively warm.

***Provisions shall be made to provide 160° Fahrenheit hot water at the laundry equipment when needed. (This may be by steam jet or separate booster heater.) However, it is emphasized that this does not imply that all water used would be at this temperature.

Water temperatures required for acceptable laundry results will vary according to type of cycle, time of operation, and formula of soap and bleach as well as type and degree of soil. Lower temperatures may be adequate for most procedures in many facilities but the higher 160° Fahrenheit shall be available when needed for special conditions.

f. Drainage systems. Drainage systems shall meet the following requirements:

(1) Sewage shall be collected and disposed of in a manner approved by the department. Disposal into a municipal system shall be considered as meeting this requirement. (III)

(2) Private sewage systems shall conform to the rules and regulations promulgated by the department of natural resources. (III)

(3) Piping over food preparation centers, food serving facilities, food storage areas, and other critical areas shall be kept to a minimum and shall not be exposed. Special precautions shall be taken to protect these areas from possible leakage or condensation from necessary overhead piping systems. (III) (Exceptions 1 and 4)

(4) Plastic piping may be used in any drain-waste vent system. (III)

(5) Rescinded IAB 2/8/89, effective 3/15/89.

(6) Pipe cleanouts shall not be more than 50 feet apart in horizontal drain line. (III) (Exception 4)

(7) Floor drains with appropriate grates shall be provided for all mechanical equipment rooms, laundries, kitchens, dishwashing areas, shower stalls and one in front of showers or bath units, soiled utility, basement floors and any other areas where water may collect on the floor. (III)

(8) Foundation drains shall be provided in accordance with subrule 60.3(10). (III)

(9) All tub and shower floor surfaces shall be specified or designated as slip-resistant surfaces.

[ARC 8189B, IAB 10/7/09, effective 11/11/09]

481—60.12(135C) Electrical requirement.

60.12(1) General electrical requirements.

a. All materials, including equipment, conductors, controls, and signaling devices, shall be installed to provide a complete electrical system with the necessary characteristics and capacity to supply the electrical facilities shown in the specifications or indicated on the plans. All materials shall be listed as complying with available standards of Underwriters Laboratories, Inc., or other similarly established standards. (III)

b. Electrical systems and equipment shall meet the minimum requirements of the National Electrical Code. (III)

c. Drop cords, extension cords, or any type of flexible cord shall not be used as a substitute for fixed or hard wiring. Surge protectors may be used for computers and related devices, facsimile, photocopying and scanning machines, and other consumer electronic devices in a resident's room and other locations in a facility provided the surge protector is of metal construction and approved by Underwriters Laboratories, Inc., or other similarly recognized laboratories. Only fixed supplementary electric heating shall be installed. (III)

d. Electrical metallic tubing or rigid heavy wall conduit shall be used throughout the interior of the facility. In areas used for patient care, the grounding terminals of all receptacles and all non-current-carrying conductive surfaces of fixed electrical equipment likely to become energized that are subject to personal contact, shall be grounded by a green insulated copper conductor. The grounding conductor shall be sized in accordance with the requirements of the 1990 "National Electrical Code" and installed in electrical metallic tubing with the branch-circuit conductors supplying these receptacles or fixed equipment. (III) (Exception 4)

60.12(2) Panel boards. Panel boards serving lighting and appliance circuits shall be located on the same floor as the circuits they serve. (Exceptions 4 and 5) All circuits shall be identified on the panel door. (III) This requirement does not apply to emergency system circuits which can be centrally located. (Exception 4)

60.12(3) Lighting. All spaces occupied by people, machinery, and equipment within buildings, approaches thereto, and parking lots shall have electric lighting. (III)

a. All rooms in resident-occupied areas shall have general lighting switched at the entrance to each room. (III)

b. Reading lamps shall be provided in each resident's room. (III)

c. Night lights shall be provided in corridors, at stairways, attendant's stations, residents' bedrooms, and hazardous areas with no less than 1 foot-candle throughout the area at all times. (III)

d. At least one recessed light fixture for night lighting installed no higher than 18 inches above the floor shall be switched at the entrance to each resident's room. (III) (Exception 4)

e. Light fixtures shall be so equipped to prevent glare and to prevent hazards to the residents. (III)

60.12(4) Receptacles (Convenience outlet locations).

a. Each resident room shall have grounding-type receptacles.

b. Receptacles shall be located as follows: one on each side of the head of each bed; one for television, where used and one on another wall. For parallel adjacent beds, only one receptacle is required between the beds. (III) (Exception 3)

c. Receptacles for general and emergency use shall be installed a maximum of 50 feet apart in all corridors and within 25 feet of ends of corridors. (III) (Exception 4)

d. All receptacles within 6 feet of sinks or lavatories and those installed outside the building shall be protected by a local ground fault circuit interrupter. (III)

60.12(5) Call system.

a. Where the facility has a call system installed, the system shall be electrical and all calls shall register at the operational center. (III)

b. Calling systems which provide two-way voice communication shall be equipped with an indicating light at each calling station, and the lights shall remain lighted as long as the voice circuit is operating. (III)

60.12(6) Emergency electric service.

a. Emergency electric on-site engine generator service shall be provided in any facility to provide electricity during an interruption of the normal electric supply that could affect the resident care or safety of the occupants. (Exceptions 1 and 4)

b. In facilities less than 16 beds an emergency battery source of electricity shall be provided in accordance with Section 517-40 of the National Electric Code. (III)

c. The required emergency generating set, including the prime mover, shall not be powered solely by natural gas or cooled solely by domestic water. (III) (Exception 4)

- d.* The emergency generator set shall be of sufficient capacity to supply all lighting and power load demands of the emergency system and shall be located on the premises. (III)
- e.* Emergency electric service shall be provided to the distribution system for lighting as follows:
- (1) Exit ways and all necessary ways of approach thereto, including exit signs and exit direction signs, exterior of exits, exit doorways, stairways, and corridors, (III)
 - (2) Egress as required in NFPA Standard 101, (III)
 - (3) Dining and recreation rooms, (III)
 - (4) Attendant's station, (III)
 - (5) Generator set location, switch-gear location and boiler room, (III)
 - (6) Elevator, where required for emergency. (III)
- f.* Emergency electric service shall be provided to the distribution system for equipment essential to life safety and for the protection of important equipment or vital materials as follows:
- (1) Call board; (III)
 - (2) Alarm system, including fire alarm actuated at manual stations; water flow alarm devices or sprinkler systems, where electrically operated; fire detection and smoke-detecting systems; paging or speaker systems intended for issuing instructions during emergency conditions; and alarms required for nonflammable medical gas systems, where installed; (III)
 - (3) Sewage and sump lift pump, where installed; (III)
 - (4) All required duplex receptacles in resident corridors; (III)
 - (5) One elevator; (III) (Exception 4)
 - (6) Equipment, such as burners and pumps, necessary for operation of one or more boilers and their necessary auxiliaries and controls required for heating and sterilization; (III) and
 - (7) Equipment necessary for maintaining telephone service. (III)
- g.* Emergency electric service shall be provided to the distribution system for heating as follows:
- (1) Where electricity is the only source of power normally used for space heating, the emergency service shall provide for heating of resident rooms or an area of approximately 30 square feet per bed within the facility to accommodate all of the residents for the duration of the emergency; (III)
 - (2) Emergency heating shall not be required where the facility is supplied by at least two service feeders, each supplied by separate sources from an integrated transmission distribution system, each capable of supplying required service, and each so routed, connected and protected that a fault any place between the utility energy source and the facility shall not cause an interruption of more than one of the electric service feeders. (III)
- h.* The emergency electrical system shall be brought to full voltage and frequency and connected within 10 seconds through one or more primary automatic transfer switches. Power to pumps and burners may be brought to full power through the use of manual switches. (III)
- i.* Receptacles connected to the emergency system shall be distinctively marked for identification. (III)
- j.* Storage battery-powered lights, provided to augment the emergency lighting or for continuity of lighting during the interim of transfer switches, shall not be used as a substitute for the requirements of a generator. (III)

481—60.13(135C) Codes and standards.

60.13(1) General. Nothing stated herein shall relieve the sponsor from compliance with building codes, ordinances, and regulations which are enforced by city, county, or state jurisdictions. Where such codes, ordinances, and regulations are not in effect, it shall be the responsibility of the sponsor to consult one of the national building codes generally used in the area for all components of the standards set forth herein, provided the requirements of the code are not inconsistent with the minimum standards herein. (III)

60.13(2) List of referenced codes and standards. The latest revisions of the following codes and standards have been used in whole or in part in these rules and shall be used as references where specific details are required or interpretation is needed:

American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) Handbooks.

American Society for Testing and Materials (ASTM) Standard No. E 84-61, Method of Test for Surface Burning Characteristics of Building Material.

International Conference of Building Officials (ICBO) Uniform Building Code.

Iowa State Building Code.

Iowa State Plumbing Code.

Iowa State Bureau of Labor Standards.

National Fire Protection Association (NFPA) Standard No. 70, National Electrical Code.

National Fire Protection Association (NFPA) Standard No. 90A and Installation of Air Conditioning and Ventilating Systems.

National Fire Protection Association (NFPA) Standard No. 101, Life Safety Code.

Food Service Sanitation Manual (DHEW Publication No. (FDA) 8-2081).

Underwriters Laboratories, Inc. listings.

American National Standards Institute (ANSI) Standard No. A117.1—1986, American Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped.

Copies of nongovernment publications can be obtained from the various agencies at the addresses listed:

American Society for Testing and Materials
1916 Race Street
Philadelphia, Pennsylvania 19103

National Fire Protection Association
Batterymarch Park
Quincy, Massachusetts 02269

Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, Illinois 66062

American National Standards Institute
1430 Broadway
New York, New York 10018
International Conference of Building Officials (ICBO)
Uniform Building Code
5360 South Workman Mill Road
Whittier, California 90601

American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE)
1791 Tullie Circle N.E.
Atlanta, Georgia 30329

Except as noted in the list, copies of government publications can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

These rules are intended to implement Iowa Code sections 10A.502(4) and 135C.2(1)“b.”

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CHAPTER 61
MINIMUM PHYSICAL STANDARDS FOR NURSING FACILITIES
[Prior to 7/15/87, Health Department[470] Ch 61]

481—61.1(135C) Definitions. Definitions in rule 481—58.1(135C) are incorporated by reference as part of this chapter. In addition, the following definition shall apply:

“*Responsible design professional*” means a registered architect or licensed professional engineer who signs the documents submitted pursuant to rule 481—61.3(135C).
[ARC 0763C, IAB 5/29/13, effective 7/3/13]

481—61.2(135C) General requirements. Nursing facilities licensed under this chapter shall be built in accordance with the following construction standards:

61.2(1) Construction shall be in conformance with 661—Chapter 205, Fire Safety Requirements for Hospitals and Health Care Facilities. Projects required to meet the provisions of the state building code shall be deemed to be in compliance with the fire safety requirements of the state building code if the project is in compliance with the provisions of 661—Chapter 205.

61.2(2) Construction shall be in conformance with 661—Chapter 301, State Building Code—General Provisions. Projects meeting the local building code shall be deemed to be in compliance with the state building code provided that the local jurisdiction has established a building department, has adopted a building code by ordinance and enforces the local code through a system which includes both plan review and inspection.

61.2(3) Construction shall be in accordance with the standards set forth in the Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2018 edition, published by the Facility Guidelines Institute.

61.2(4) Nothing in these rules shall relieve a nursing facility from compliance with fire and building codes, ordinances and regulations which are enforced by city, county, state or federal jurisdictions.

61.2(5) New equipment. Any alteration or installation of new equipment shall be accomplished as nearly as practical in conformance with all applicable codes, ordinances, regulations and standards required for new construction. Alteration or installation of new equipment shall not diminish the level of compliance with any codes, ordinances, regulations or standards below that which existed prior to the alteration. Any feature that does not meet the requirement for new buildings but exceeds the requirement for existing buildings shall not be further diminished. Features that exceed requirements for new construction need not be maintained. In no case shall any feature be less than that required for existing buildings. (III)

61.2(6) Existing nursing facilities built in compliance with prior versions of this chapter will be deemed in compliance, with the exception of any renovations, additions, functional alterations, changes of space utilization, or conversions to existing facilities for which construction documents are submitted pursuant to rule 481—61.3(135C) on or after July 1, 2013, which shall meet the standards specified in this chapter. Conversion of a building or any of the parts not currently licensed as a nursing facility must meet the rules governing construction of new facilities, except as provided in Life Safety Code, 2000 edition, sections 18.1.1.4.4 and 19.1.1.4.4.

61.2(7) Final plan approval and final occupancy shall be given by the state fire marshal’s office.
[ARC 0763C, IAB 5/29/13, effective 7/3/13; ARC 4264C, IAB 1/30/19, effective 3/6/19]

481—61.3(135C) Submission of construction documents.

61.3(1) Submissions of architectural technical documents, engineering documents, and plans and specifications to the state fire marshal’s office shall be as required by rule 661—300.4(103A) and are the responsibility of the owner of the building or facility, although the actual submission may be completed by an authorized agent of the owner or the responsible design professional.

61.3(2) Plans, specifications and other supporting information shall be sufficiently clear and complete to show in detail that the proposed work will comply with the construction standards required by rule 481—61.2(135C).

61.3(3) Submittals to the state fire marshal's office shall be certified or stamped and signed as required by Iowa Code chapters 542B and 544A unless the applicant has certified on the submittal to the applicability of a specific exception under Iowa Code section 544A.18 and the submittal does not constitute the practice of engineering as defined by Iowa Code section 542B.2.

61.3(4) The responsible design professional shall certify that the building plans meet the requirements specified in this chapter, unless a waiver has been granted pursuant to rule 481—61.4(135C).

[ARC 0763C, IAB 5/29/13, effective 7/3/13; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—61.4(135C) Waivers.

61.4(1) Procedures in rule 481—58.2(135C) for requesting a waiver are incorporated by reference as part of this chapter.

61.4(2) Certain resident populations, conditions in the area, or the site may justify waivers. In specific cases, waivers to the rules may be granted by the director after the following conditions are met:

a. The design and planning for the specific property shall offer improved or compensating features which provide equivalent desirability and utility;

b. Alternate or special construction methods, techniques, and mechanical equipment shall offer equivalent durability, utility, safety, structural strength and rigidity, sanitation, odor control, protection from corrosion, decay and insect attack, and quality of workmanship;

c. The health, safety or welfare of any resident shall not be endangered;

d. Variations are limited to the specific project under consideration and shall not be construed as establishing a precedent for similar acceptance in other cases;

e. The occupancy and function of the building shall be considered; and

f. The type of licensure shall be considered.

[ARC 0763C, IAB 5/29/13, effective 7/3/13; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—61.5(135C) Additional notification requirements.

61.5(1) When new construction or renovation, addition, functional alteration, change of space utilization, or conversion of an existing building is contemplated, the licensee or applicant for a license shall:

a. File a detailed and comprehensive program of care, as set forth in rule 481—58.3(135C), which includes a description of the specific needs of the residents to be served, and any other information the department may require. (III)

b. Receive written approval from the state fire marshal's office before starting construction. The applicant is responsible for ensuring that construction proceeds according to approved plans and specifications. If construction is not started within 12 months of the date of final approval of the working drawings and specifications, the approval shall be void and the plans and specifications shall be resubmitted. Multiphase projects shall be completed within a time period approved by the state fire marshal's office.

c. Meet requirements for new construction if the project includes changes to structural and life safety components of the building or changes for accessibility of persons with disabilities. Only that portion of the building that is part of the project must meet requirements for new construction.

61.5(2) Inspections.

a. For new construction or renovations, additions, functional alterations, change of space utilization or conversion of an existing building, it is the responsibility of the owner or an agent to notify the state fire marshal's office at all of the following intervals and wait for inspection before proceeding. Inspections shall be conducted in accordance with the following schedule:

(1) Two days prior to the beginning of any construction or demolition.

(2) After installation of any under-slab plumbing and before covering is installed.

(3) After installation of electrical, mechanical and plumbing and prior to covering.

(4) Five days prior to a final occupancy inspection.

b. The following must approve the project before final occupancy: the state fire inspector, the state building inspector and, in jurisdictions without electrical code enforcement, the state electrical inspector. Approval of local or county jurisdictions is as required by those jurisdictions.
[ARC 0763C, IAB 5/29/13, effective 7/3/13]

481—61.6(135C) Construction requirements. This rule contains construction requirements for all areas of the building.

61.6(1) General provisions.

a. Projects shall be constructed in compliance with 661—Chapter 205, Fire Safety Requirements for Hospitals and Health Care Facilities. Projects required to meet the provisions of the state building code shall be deemed to be in compliance with the fire safety requirements of the state building code if the nursing facility is in compliance with the provisions of 661—Chapter 205, Fire Safety Requirements for Hospitals and Health Care Facilities.

b. Projects shall be constructed in compliance with 661—Chapter 301, State Building Code—General Provisions. Projects meeting the local building code shall be deemed to be in compliance with the state building code provided that the local jurisdiction has established a building department, has adopted a building code by ordinance and enforces the local code through a system which includes both plan review and inspection.

c. Projects shall be constructed in compliance with the standards set forth in the Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2018 edition, published by the Facility Guidelines Institute.

d. Final plan approval and final occupancy shall be given by the state fire marshal's office.

61.6(2) Mechanical requirements.

a. Projects shall be constructed in compliance with 661—Chapter 205, Fire Safety Requirements for Hospitals and Health Care Facilities.

b. Projects shall be constructed in compliance with the state mechanical code as provided in rule 661—301.4(103A). Projects meeting the local mechanical code shall be deemed to be in compliance with the state mechanical code provided that the local jurisdiction has established a building department, has adopted a building code by ordinance and enforces the local code through a system which includes both plan review and inspection.

c. Final plan approval and final occupancy shall be given by the state fire marshal's office.

61.6(3) Electrical requirements.

a. Projects shall be constructed in compliance with standards referenced in 661—Chapter 205, Fire Safety Requirements for Hospitals and Health Care Facilities.

b. Projects shall be constructed in compliance with the state electrical code as provided in rule 661—301.5(103A).

61.6(4) Plumbing requirements. Projects shall be constructed in compliance with 641—Chapter 25, State Plumbing Code.

61.6(5) Accessibility requirements. Projects shall be constructed in compliance with 661—Chapter 302, State Building Code—Accessibility of Buildings and Facilities Available to the Public.

61.6(6) Lighting requirements. Light shall be provided in the areas of the building as required in the Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2018 edition, published by the Facilities Guidelines Institute.

61.6(7) Exit door alarm system. An exit door alarm system shall be installed on all exterior doors.
(I, II, III)

[ARC 0763C, IAB 5/29/13, effective 7/3/13; ARC 4264C, IAB 1/30/19, effective 3/6/19]

481—61.7(135C) Nursing care unit.

61.7(1) A seclusion room may be used in an intermediate care facility for persons with mental illness.

61.7(2) When a seclusion room is used, it must meet the following standards. A seclusion room shall:

a. Be located where direct care staff can provide direct supervision; (I, II, III)

b. Have only one door which swings out but does not swing into a corridor; (II, III)

- c. Have only locking devices that are approved by the state fire marshal; (I, II, III)
 - d. Have unbreakable, fire-safe vision panels arranged to permit observation of the resident. The arrangement shall ensure resident privacy and prevent casual observation by visitors or other residents; (I, II, III)
 - e. House only one resident at a time; (I, II, III)
 - f. Have an area of at least 60 square feet, but not more than 100 square feet; (II, III)
 - g. Be constructed to protect against the possibility of hiding, escape, injury and suicide; (I, II, III)
 - h. Have construction of the room area, including floor, walls, ceilings, and all openings, approved in writing by the state fire marshal prior to construction or alteration of a room. Padding materials, if used, shall be approved in writing by the state fire marshal; (I, II, III)
 - i. Contain only vandal- and tamper-resistant fixtures and hardware; (I, II, III)
 - j. Contain no electrical receptacles; (I, II, III)
 - k. Contain an exhaust ventilation system with a fan located at the discharge end of the system, with exhaust discharging to the outside; (II, III)
 - l. Have electrical switches for the light and exhaust ventilation systems installed outside the room; (I, II, III)
 - m. Have an emergency call system for staff located outside the room near the observation window; (II, III) and
 - n. Be built with materials that are easily maintained and sanitized. (III)
- [ARC 0763C, IAB 5/29/13, effective 7/3/13]

481—61.8(135C) Dietetic and other service areas.

61.8(1) *Dietetic service area.* The construction and installation of equipment of the dietetic service area shall comply with the requirements of the Food and Drug Administration Food Code adopted under provisions of Iowa Code section 137F.2. (III)

61.8(2) *General storage areas.* General storage areas totaling not less than 14 square feet per bed shall be provided. If each resident has a 4-foot wide closet in the bedroom, the general storage area per bed may be reduced from 14 square feet to 10 square feet per bed. Storage areas are not required to be located in only one room. (III)

a. Storage areas for linens, janitor's supplies, sterile nursing supplies, activities supplies, library books, office supplies, kitchen supplies and mechanical plant accessories shall not be included as part of the general storage area and are not required to be located in the same area. (III)

b. Thirty percent of the general storage area may be provided in a building outside the facility if the building is easily accessible to personnel. (III)

[ARC 0763C, IAB 5/29/13, effective 7/3/13]

481—61.9(135C) Specialized unit or facility for persons with chronic confusion or a dementing illness (CCDI unit or facility). A CCDI unit or facility shall be designed in accordance with the standards set forth in the Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2018 edition, published by the Facility Guidelines Institute. The following provisions shall also apply:

61.9(1) A CCDI unit or facility shall be designed so that residents, staff and visitors will not pass through the unit in order to reach exits or other areas of the facility unless in an emergency. (III)

61.9(2) If the unit or facility is to be a locked unit or facility, all locking devices shall meet the requirements of the state fire marshal. If the unit or facility is to be unlocked, a system of security monitoring is required. (I, II, III)

61.9(3) The outdoor activity area for the unit or facility shall be secure. Nontoxic plants shall be used in the secured outdoor activity area. (I, II)

61.9(4) There shall be no steps inside the CCDI unit or freestanding CCDI facility. (III)

61.9(5) Dining and activity areas for the unit or facility shall be located within the unit or facility and shall not be used as the primary dining or activity area by other facility residents. (III)

61.9(6) An area shall be provided to allow nurses to prepare daily resident reports. (III)

61.9(7) If the lounge and activity areas are not adjacent to resident rooms, there shall be in clear view of the lounge and activity area one unisex resident toilet room for each ten residents. (III)

[ARC 0763C, IAB 5/29/13, effective 7/3/13; ARC 4264C, IAB 1/30/19, effective 3/6/19]

These rules are intended to implement Iowa Code section 135C.14.

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CHAPTER 63
RESIDENTIAL CARE FACILITY—THREE- TO FIVE-BED SPECIALIZED LICENSE
[Prior to 7/15/87, Health Department[470] Ch 63]

481—63.1(135C) Definitions. For the purpose of these rules, the following terms shall have the meanings indicated in this chapter. The definitions set out in Iowa Code section 135C.1 shall be considered to be incorporated verbatim in the rules.

“*Accommodation*” means the provision of lodging, including sleeping, dining, and living areas.

“*Administrator*” means a person approved by the department who administers, manages, supervises, and is in general administrative charge of a three- to five-bed residential care facility, whether or not such individual has an ownership interest in such facility, and whether or not the functions and duties are shared with one or more individuals.

“*Ambulatory*” means the condition of a person who immediately and without aid of another person is physically and mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

“*Basement*” means that part of a building where the finish floor is more than 30 inches below the finish grade of the building.

“*Board*” means the regular provision of meals.

“*Change of ownership*” means the purchase, transfer, assignment or lease of a licensed three- to five-bed residential care facility.

“*Communicable disease*” means a disease caused by the presence within a person’s body of a virus or microbial agents which may be transmitted either directly or indirectly to other persons.

“*Department*” means the state department of inspections and appeals.

“*Interdisciplinary team*” means the group of persons who develop a single, integrated, individual program plan to meet a resident’s needs for services. The interdisciplinary team consists of, at a minimum, the resident, the resident’s legal guardian if applicable, the resident’s advocate if desired by the resident, a referral agency representative, other appropriate staff members, other providers of services, and other persons relevant to the resident’s needs.

“*Legal representative*” means the resident’s guardian or conservator if one has been appointed or the resident’s power of attorney.

“*Mechanical restraint*” means restriction by the use of a mechanical device of a resident’s mobility or ability to use the hands, arms or legs.

“*Medication*” means any drug, including over-the-counter substances.

“*Nonambulatory*” means the condition of a person who immediately and without the aid of another person is not physically or mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

“*Personal care*” means assistance with the activities of daily living which the recipient can perform only with difficulty. Examples are help in getting in and out of bed, assistance with personal hygiene and bathing, help with dressing and eating, and supervision over medications which can be self-administered.

“*Physical restraint*” means direct physical contact on the part of a staff person to control a resident’s physical activity for the resident’s own protection or for the protection of others.

“*Primary care provider*” means any of the following who provide primary care and meet licensure standards:

1. A physician who is a family or general practitioner or an internist.
2. An advanced registered nurse practitioner.
3. A physician assistant.

“*Program of care*” means all services being provided for a resident in a health care facility.

“*Prone restraint*” means a restraint in which a resident is in a face-down position against the floor or another surface.

“*Rate*” means that daily fee charged for all residents equally and shall include the cost of all minimum services required in these rules.

“*Records*” includes electronic records.

“*Responsible party*” means the person who signs or cosigns the residency agreement required by rule 481—63.12(135C) or the resident’s legal representative. In the event that a resident has neither a legal representative nor a person who signed or cosigned the resident’s residency agreement, the term “responsible party” shall include the resident’s sponsoring agency, e.g., the department of human services, the U.S. Department of Veterans Affairs, a religious group, fraternal organization, or foundation that assumes responsibility and advocates for its client patients and pays for their health care.

“*Restraints*” means the measures taken to control a resident’s physical activity for the resident’s own protection or for the protection of others.

“*Specialized residential care facility license*” means a license for three- to five-bed residential care facilities serving persons with an intellectual disability, chronic mental illness, a developmental disability or brain injury.

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.2(135C,17A) Waiver. A waiver from these rules may be granted by the director of the department in accordance with 481—Chapter 6. A request for waiver will be granted or denied by the director within 120 calendar days of receipt.

[ARC 3740C, IAB 4/11/18, effective 5/16/18; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—63.3(135C) Application for licensure.

63.3(1) Application and licensing—new facility or change of ownership. In order to obtain a specialized residential care facility license for a facility not currently licensed as a specialized residential care facility or for a specialized residential care facility when a change of ownership is contemplated, the applicant must:

- a. Make application at least 30 days prior to the proposed opening date of the facility. Application shall be made on forms provided by the department.
- b. Meet all of the rules, regulations, and standards contained in this chapter and in 481—Chapter 50.
- c. Submit a letter of intent and a written résumé of care. The résumé of care shall meet the requirements of subrule 63.3(2).
- d. Submit a floor plan of each floor of the residential care facility. The floor plan of each floor shall be drawn on 8½" × 11" paper, show room areas in proportion, room dimensions, window and door locations, designation of the use of each room, and the room numbers for all rooms, including bathrooms.
- e. Submit a photograph of the front and side of the residential care facility.
- f. Submit the fee for a specialized residential care facility license in accordance with 481—paragraph 50.3(2)“a.”
- g. Comply with all other local statutes and ordinances in existence at the time of licensure.
- h. Submit a certificate signed by the state or local fire inspection authority as to compliance with fire safety rules and regulations.

63.3(2) Résumé of care. The résumé of care shall describe the following:

- a. Purpose of the facility;
- b. Criteria for admission to the facility;
- c. Ownership of the facility;
- d. Composition and responsibilities of the governing board;
- e. Qualifications and responsibilities of the administrator;
- f. Medical services provided to residents, to include the availability of emergency medical services in the area and the designation of a primary care provider to be responsible for residents in an emergency;
- g. Dental services provided to residents and available in the area;
- h. Nursing services provided to residents, if applicable;
- i. Personal services provided to residents, including supervision of or assistance with activities of daily living;
- j. Activity program;

- k.* Dietary services, including qualifications of the person in charge, consultation service (if applicable) and meal service;
- l.* Other services available as applicable, including social services, physical therapy, occupational therapy, and recreational therapy;
- m.* Housekeeping;
- n.* Laundry;
- o.* Physical plant; and
- p.* Staffing provided to meet residents' needs.

63.3(3) *Renewal application.* In order to obtain a renewal of the specialized residential care facility license, the applicant must submit the following:

- a.* The completed application form 30 days prior to the annual license renewal date of the residential care facility license;
- b.* The fee for a specialized residential care facility license in accordance with 481—paragraph 50.3(2) “a”;
- c.* An approved current certificate signed by the state or local fire inspection authority as to compliance with fire safety rules and regulations;
- d.* Changes to the résumé of care, if any; and
- e.* Changes to the current residency agreement, if any.

[ARC 3740C, IAB 4/11/18, effective 5/16/18; ARC 4577C, IAB 7/31/19, effective 9/4/19]

481—63.4(135C) Issuance of license. Licenses are issued to the person, entity or governmental unit with responsibility for the operation of the facility and for compliance with all applicable statutes, rules and regulations.

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.5(135C) General requirements.

63.5(1) The license shall be displayed in the facility in a conspicuous place which is accessible to the public. (III)

63.5(2) The license shall be valid only in the possession of the licensee to whom it is issued.

63.5(3) The posted license shall accurately reflect the current status of the facility. (III)

63.5(4) The license shall expire one year after the date of issuance or as indicated on the license.

63.5(5) The licensee shall:

- a.* Assume the responsibility for the overall operation of the facility. (I, II, III)
- b.* Be responsible for compliance with all applicable laws and with the rules of the department. (I, II, III)
- c.* Provide an organized continuous 24-hour program of care commensurate with the needs of the residents. (I, II, III)

63.5(6) Each citation or a copy of each citation issued by the department for a class I or class II violation shall be prominently posted by the facility in plain view of the residents, visitors, and persons inquiring about placement in the facility. The citation or copy of the citation shall remain posted until the violation is corrected to the satisfaction of the department. (I, II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.6(135C) Required notifications to the department. The department shall be notified:

63.6(1) Thirty days before any proposed change in the residential care facility's functional operation or addition or deletion of required services; (III)

63.6(2) Thirty days before the beginning of the renovation, addition, functional alteration, change of space utilization, or conversion in the residential care facility or on the premises; (III)

63.6(3) Thirty days before closure of the residential care facility; (III)

63.6(4) Within two weeks of any change in administrator; (III)

63.6(5) Ninety days before a change in the category of license; (III)

63.6(6) Thirty days before a change of ownership. The licensee shall:

- a.* Inform the department of the pending change of ownership; (III)

b. Inform the department of the name and address of the prospective purchaser, transferee, assignee, or lessee; (III)

c. Submit a written authorization to the department permitting the department to release all information of whatever kind from the department's files concerning the licensee's residential care facility to the named prospective purchaser, transferee, assignee, or lessee. (III)
[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.7(135C) Administrator. Each facility shall have one person in charge, duly approved by the department or acting in a provisional capacity in accordance with these rules. (III)

63.7(1) Qualifications of an administrator.

a. The administrator shall be at least 21 years of age and shall have a high school diploma or equivalent. (III) In addition, this person shall meet at least one of the following conditions:

(1) Have a two-year degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field and have a minimum of two years' experience in the field; or (III)

(2) Have a four-year degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field and have a minimum of one year of experience in the field; or (III)

(3) Have a master's degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field and have a minimum of one year of experience in the field; or (III)

(4) Be a licensed nursing home administrator; or (III)

(5) Have completed a one-year educational training program approved by the department for residential care facility administrators; or (III)

(6) Have passed the National Association of Long Term Care Administrator Boards (NAB) RC/AL administrator licensure examination; or

(7) Have two years of direct care experience and at least six months of administrative experience in a residential care facility. (III)

b. The administrator shall have at least one year of documented experience in a supervisory or direct care position working with persons with an intellectual disability, mental illness, a developmental disability, or brain injury.

c. An individual employed as an administrator on May 16, 2018, will be deemed to meet the requirements of this subrule.

63.7(2) Duties of an administrator. The administrator shall:

a. Select and direct competent personnel who provide services for the residential care program. (III)

b. Provide in-service educational programming for all employees with direct resident contact and maintain records of programs and participants. (III) In-service educational programming offered during each calendar year shall include, at minimum, the following topics: (I, II, III)

(1) Infection control.

(2) Emergency preparedness (e.g., fire, tornado, flood, 911).

(3) Meal time procedures/dietary.

(4) Resident activities.

(5) Mental illness, brain injury or intellectual disabilities, including behavioral intervention, de-escalation, and crisis intervention techniques.

(6) Resident safety/supervision.

(7) Resident rights.

(8) Medication education, to include administration, storage and drug interactions.

(9) Resident service plans/programming/goals.

63.7(3) Administrator serving at more than one residential care facility. The administrator may be responsible for no more than 150 beds in total if the administrator is an administrator of more than one facility. (II)

a. An administrator of more than one facility shall designate in writing an administrative staff person in each facility who shall be responsible for directing programs in the facility.

b. The administrative staff person designated by the administrator shall:

(1) Have at least one year of documented experience in a supervisory or direct care position working with persons with an intellectual disability, mental illness, a developmental disability, or brain injury; (II, III)

(2) Be knowledgeable of the operation of the facility; (II, III)

(3) Have access to records concerned with the operation of the facility; (II, III)

(4) Be capable of carrying out administrative duties and of assuming administrative responsibilities; (II, III)

(5) Be at least 21 years of age; (III)

(6) Be empowered to act on behalf of the licensee concerning the health, safety and welfare of the residents; and (II, III)

(7) Have training in emergency response, including how to respond to residents' sudden illnesses. (II, III)

c. If an administrator serves more than one facility, the administrator must designate in writing regular and specific times during which the administrator will be available to consult with staff and residents to provide direction and supervision of resident care and services. (II, III)

63.7(4) Provisional administrator. A provisional administrator may be appointed on a temporary basis by the residential care facility licensee to assume the administrative responsibilities for a residential care facility for a period not to exceed one year when the facility has lost its administrator and has not been able to replace the administrator, provided that the department has been notified and has approved the provisional administrator prior to the date of the provisional administrator's appointment. (III) The provisional administrator must meet the requirements of paragraph 63.7(3) "b."

63.7(5) Temporary absence of administrator.

a. In the temporary absence of the administrator, a responsible person shall be designated in writing to the department to be in charge of the facility. (III) The person designated shall:

(1) Be knowledgeable of the operation of the facility; (III)

(2) Have access to records concerned with the operation of the facility; (III)

(3) Be capable of carrying out administrative duties and of assuming administrative responsibilities; (III)

(4) Be at least 21 years of age; (III)

(5) Be empowered to act on behalf of the licensee during the administrator's absence concerning the health, safety, and welfare of the residents; (III)

(6) Have training in emergency response, including how to respond to residents' sudden illnesses. (II, III)

b. If the administrator is absent for more than six weeks, a provisional administrator must be appointed pursuant to subrule 63.7(4).

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.8(135C) Personnel.

63.8(1) Alcohol and drug use prohibited. No person under the influence of intoxicating drugs or alcoholic beverages shall be permitted to provide services in a residential care facility. (I, II)

63.8(2) Job description. There shall be a written job description developed for each category of worker. The job description shall include the job title, responsibilities and qualifications. (III)

63.8(3) Employee criminal record, child abuse and dependent adult abuse checks and employment of individuals who have committed a crime or have a founded abuse. The facility shall comply with the requirements found in Iowa Code section 135C.33 and rule 481—50.9(135C) related to completion of criminal record checks, child abuse checks, and dependent adult abuse checks and to employment of individuals who have committed a crime or have a founded abuse. (I, II, III)

63.8(4) Personnel record. A personnel record shall be kept for each employee and shall include but not be limited to the following information about the employee: name and address; social security

number; date of birth; date of employment; position; job description; experience and education; results of criminal record checks, child abuse checks and dependent adult abuse checks; and date of discharge or resignation. (III)

63.8(5) *Supervision and staffing.*

- a. The facility shall provide sufficient staff to meet the needs of the residents served. (I, II, III)
- b. Personnel in a specialized residential care facility shall provide 24-hour coverage for residential care services. Personnel shall be available and responsive to residents' needs at all times while on duty. (I, II, III)
- c. Direct care staff shall be present in the facility unless all residents are involved in activities away from the facility. (I, II, III)
- d. Staff shall be aware of and provide supervision levels based on the present needs of the residents in the staff's care. The facility shall document the supervision of residents who require more than general supervision, as defined by facility policy. (I, II, III)

- e. The facility shall maintain an accurate record of actual hours worked by employees. (III)

63.8(6) *Physical examination and screening.* Employees shall have a physical examination within 12 months prior to beginning employment and every four years thereafter. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59. (I, II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18; ARC 4577C, IAB 7/31/19, effective 9/4/19]

481—63.9(135C) General policies. The licensee shall establish and implement written policies and procedures as set forth in this rule. The policies and procedures shall be available for review by the department, other agencies designated by Iowa Code section 135C.16(3), staff, residents, residents' families or legal representatives, and the public and shall be reviewed by the licensee annually. (II)

63.9(1) *Facility operation.* The licensee shall establish written policies for the operation of the facility, including but not limited to the following: (III)

- a. Personnel; (III)
- b. Admission; (III)
- c. Evaluation services; (II, III)
- d. Programming and individual program plans; (II, III)
- e. Registered sex offender management; (II, III)
- f. Crisis intervention; (II, III)
- g. Discharge or transfer; (III)
- h. Medication management, including self-administration of medications and chemical restraints; (III)
- i. Resident property; (II, III)
- j. Resident finances; (II, III)
- k. Records; (III)
- l. Health and safety; (II, III)
- m. Nutrition; (III)
- n. Physical facilities and maintenance; (III)
- o. Resident rights; (II, III)
- p. Investigation and reporting of alleged dependent adult abuse; (II, III)
- q. Investigation and reporting of accidents or incidents; (II, III)
- r. Transportation of residents; (II, III)
- s. Resident supervision; (II, III)
- t. Smoking; (III)
- u. Visitors; (III)
- v. Disaster/emergency planning; (III) and
- w. Infection control. (III)

63.9(2) *Personnel policies.* Written personnel policies shall include the hours of work and attendance at educational programs. (III)

63.9(3) Infection control. The facility shall have a written and implemented infection control program, which shall include policies and procedures based on guidelines issued by the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. The infection control program shall address the following:

- a. Techniques for hand washing; (I, II, III)
- b. Techniques for the handling of blood, body fluids, and body wastes; (I, II, III)
- c. Dressings, soaks or packs; (I, II, III)
- d. Infection identification; (I, II, III)
- e. Resident care procedures to be used when there is an infection present; (I, II, III)
- f. Sanitation techniques for resident care equipment; (I, II, III)
- g. Techniques for sanitary use and reuse of feeding syringes and single-resident use and reuse of urine collection bags; (I, II, III) and
- h. Techniques for use and disposal of needles, syringes, and other sharp instruments. (I, II, III)

63.9(4) Resident care techniques. The facility shall have written and implemented procedures to be followed if a resident needs any of the following treatment or devices:

- a. Intravenous or central line catheter; (I, II, III)
- b. Urinary catheter; (I, II, III)
- c. Respiratory suction, oxygen or humidification; (I, II, III)
- d. Decubitus care; (I, II, III)
- e. Tracheostomy; (I, II, III)
- f. Nasogastric or gastrostomy tubes; (I, II, III)
- g. Sanitary use and reuse of feeding syringes and single-resident use and reuse of urine collection bags. (I, II, III)

63.9(5) Emergency care. The facility shall establish written policies for the provision of emergency medical care to residents and employees in case of sudden illness or accident. The policies shall include a list of those individuals to be contacted in case of an emergency. (I, II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.10(135C) Admission, transfer and discharge.

63.10(1) General admission policies.

- a. Residents shall be admitted to a specialized residential care facility only on a written order signed by a primary care provider or psychiatrist, specifying the level of care, and certifying that the individual being admitted requires no more than personal care and supervision and does not require routine nursing care. (II, III)
- b. No residential care facility shall admit or retain a resident who is in need of greater services than the facility can provide. (I, II, III)
- c. No residential care facility shall admit more residents than the number of beds for which the facility is licensed. (II, III)
- d. A residential care facility is not required to admit an individual through court order, referral or other means without the express prior approval of the administrator. (III)
- e. The admission of a resident shall not grant the residential care facility the authority or responsibility to manage the personal affairs of the resident except as may be necessary for the safety of the resident and the safe and orderly management of the residential care facility as required by these rules. (III)
- f. Individuals under the age of 18 shall not be admitted to a residential care facility without prior written approval by the department. A distinct part of a residential care facility, segregated from the adult section, may be established based on a résumé of care that is submitted by the licensee or applicant and is commensurate with the needs of the residents of the residential care facility and that has received the department's review and approval. (III)

g. No health care facility and no owner, administrator, employee or representative thereof shall act as guardian, trustee, or conservator for any resident's property unless such resident is related within the third degree of consanguinity to the person acting as guardian. (III)

63.10(2) Discharge or transfer.

a. Notification shall be made to the legal representative, primary care provider, psychiatrist, if any, and sponsoring agency, if any, prior to the transfer or discharge of any resident. (III)

b. The licensee shall not refuse to discharge or transfer a resident when the primary care provider, family, resident, or legal representative requests such transfer or discharge. (II, III)

c. Advance notification will be made to the receiving facility prior to the transfer of any resident. (III)

d. When a resident is transferred or discharged, the appropriate record will accompany the resident to ensure continuity of care. "Appropriate record" includes the resident's face sheet, service plan, most recent orders of the primary care provider and any notifications of upcoming scheduled appointments. (II, III)

e. When a resident is transferred or discharged, the resident's unused prescriptions shall be sent with the resident or with a legal representative only upon the written order of a primary care provider. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.11(135C) Involuntary discharge or transfer.

63.11(1) Involuntary discharge or transfer permitted. A facility may involuntarily discharge or transfer a resident for only one of the following reasons:

a. Medical reasons;

b. The resident's welfare or that of other residents;

c. Repeated refusal by the resident to participate in the resident's service plan;

d. Due to action pursuant to Iowa Code chapter 229; or

e. Nonpayment for the resident's stay, as described in the residency agreement for the resident's stay.

63.11(2) Medical reasons. Medical reasons for transfer or discharge shall be based on the resident's needs and shall be determined and documented in the resident's record by the primary care provider. Transfer or discharge may be required in order to provide a different level of care to the resident. (II)

63.11(3) Welfare of a resident. Welfare of a resident or that of other residents refers to a resident's social, emotional, or physical well-being. A resident may be transferred or discharged because the resident's behavior poses a continuing threat to the resident (e.g., suicidal) or to the well-being of other residents or staff (e.g., the resident's behavior is incompatible with other residents' needs and rights). Written documentation that the resident's continued presence in the facility would adversely affect the resident's own welfare or that of other residents shall be made by the administrator or designee and shall include specific information to support this determination. (II)

63.11(4) Notice. Involuntary transfer or discharge of a resident from a facility shall be preceded by a written notice to the resident and the responsible party. (II, III)

a. The notice shall contain all of the following information:

(1) The stated reason for the proposed transfer or discharge. (II)

(2) The effective date of the proposed transfer or discharge. (II)

(3) A statement, in not less than 12-point type, that reads as follows: (II)

You have a right to appeal the facility's decision to transfer or discharge you. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department and you will not be transferred prior to a final decision. In emergency circumstances, extension of the 14-day requirement may be permitted upon request to the department's designee. If you lose the hearing, you will not be transferred before the expiration of (1) 30 days following receipt of the original notice of the discharge or transfer, or (2) 5 days following final decision of such hearing, including exhaustion of all appeals, whichever occurs later. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083.

b. The notice shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department; the resident's responsible party; the resident's primary care provider; and the person or agency responsible for the resident's placement, maintenance, and care in the facility. The notice shall indicate that a copy has been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent. (II)

c. The notice required by paragraph 63.11(4)"*a*" shall be provided at least 30 days in advance of the proposed transfer or discharge unless one of the following occurs: (II)

(1) An emergency transfer or discharge is mandated by the resident's health care needs and is in accordance with the written orders and medical justification of the primary care provider. Emergency transfers or discharges may also be mandated in order to protect the health, safety, or well-being of other residents and staff from the resident being transferred. (II)

(2) The transfer or discharge is subsequently agreed to by the resident or the resident's responsible party, and notification is given to the responsible party, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility.

d. A hearing requested pursuant to this subrule shall be held in accordance with subrule 63.11(6).

63.11(5) *Emergency transfer or discharge.* In the case of an emergency transfer or discharge, the resident must be given a written notice prior to or within 48 hours following transfer or discharge. (II, III)

a. A copy of this notice must be placed in the resident's file. The notice must contain all of the following information:

(1) The stated reason for the transfer or discharge. (II)

(2) The effective date of the transfer or discharge. (II)

(3) A statement, in not less than 12-point type, that reads: (II)

You have a right to appeal the facility's decision to transfer or discharge you on an emergency basis. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have the right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department. You may be transferred or discharged before the hearing is held or before a final decision is rendered. If you win the hearing, you have the right to be transferred back into the facility. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083.

b. The notice shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department; the resident's responsible party; the resident's primary care provider; and the person or agency responsible for the resident's placement, maintenance, and care in the facility. The notice shall indicate that a copy has been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent. (II)

c. A hearing requested pursuant to this subrule shall be held in accordance with subrule 63.11(6).

63.11(6) Hearing.

a. Request for hearing.

(1) The resident must request a hearing within 7 days of receiving the written notice.

(2) The request must be made to the department, either in writing or verbally.

b. The hearing shall be held no later than 14 days after receipt of the request by the department unless the resident requests an extension due to emergency circumstances.

c. Except in the case of an emergency discharge or transfer, a request for a hearing shall stay a transfer or discharge pending a final decision, including the exhaustion of all appeals. (II)

d. The hearing shall be heard by a department of inspections and appeals administrative law judge pursuant to Iowa Code chapter 17A and 481—Chapter 10. The hearing shall be public unless the resident or the resident's legal representative requests in writing that the hearing be closed. In a determination as to whether a transfer or discharge is authorized, the burden of proof by a preponderance of evidence rests on the party requesting the transfer or discharge.

e. Notice of the date, time, and place of the hearing shall be sent by certified mail or delivered in person to the facility, the resident, the responsible party, and the office of the long-term care ombudsman not later than 5 full business days after receipt of the request. The notice shall also inform the facility and the resident or the responsible party that they have a right to appear at the hearing in person or be represented by an attorney or other individual. The appeal shall be dismissed if neither party is present or represented at the hearing. If only one party appears or is represented, the hearing shall proceed with one party present. A representative of the office of the long-term care ombudsman shall have the right to appear at the hearing.

f. The administrative law judge's written decision shall be mailed by certified mail to the licensee, resident, responsible party, and the office of the long-term care ombudsman within 10 working days after the hearing has been concluded.

63.11(7) Nonpayment. If nonpayment is the basis for involuntary transfer or discharge, the resident shall have the right to make full payment up to the date that the discharge or transfer is to be made and then shall have the right to remain in the facility. (II)

63.11(8) Discussion of involuntary transfer or discharge. Within 48 hours after notice of involuntary transfer or discharge has been received by the resident, the facility shall discuss the involuntary transfer or discharge with the resident, the resident's responsible party, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. (II)

a. The facility administrator or other appropriate facility representative serving as the administrator's designee shall provide an explanation and discussion of the reasons for the resident's involuntary transfer or discharge. (II)

b. The content of the explanation and discussion shall be summarized in writing, shall include the names of the individuals involved in the discussion, and shall be made part of the resident's record. (II)

c. The provisions of this subrule do not apply if the involuntary transfer or discharge has already occurred pursuant to subrule 63.11(5) and emergency notice is provided within 48 hours.

63.11(9) Transfer or discharge planning.

a. The facility shall develop a plan to provide for the orderly and safe transfer or discharge of each resident to be transferred or discharged. (II)

b. To minimize the possible adverse effects of the involuntary transfer, the resident shall be offered counseling services by the sending facility before the involuntary transfer and by the receiving facility after the involuntary transfer. Counseling, if accepted, shall be provided by a licensed mental health professional as defined in Iowa Code section 228.1(6). Counseling shall be documented in the resident's record. (II)

c. The counseling requirement in paragraph 63.11(9)“b” does not apply if the discharge has already occurred pursuant to subrule 63.11(5) and emergency notice is provided within 48 hours.

d. The receiving health care facility of a resident involuntarily transferred shall immediately formulate and implement a plan of care which takes into account possible adverse effects the transfer may cause. (II)

63.11(10) Transfer upon revocation of license or voluntary closure. Residents shall not have the right to a hearing to contest an involuntary discharge or transfer resulting from the revocation of the facility’s license by the department of inspections and appeals. In the case of the voluntary closure of a facility, a period of 30 days must be allowed for an orderly transfer of residents to other facilities.

63.11(11) Intrafacility transfer.

a. Residents shall not be arbitrarily relocated from room to room within a licensed health care facility. (I, II) Involuntary relocation may occur only in the following situations, which shall be documented in the resident’s record: (II)

(1) Incompatibility with or disturbing to other roommates.

(2) For the welfare of the resident or other residents of the facility.

(3) To allow a new admission to the facility that would otherwise not be possible due to separation of roommates by sex.

(4) In the case of a resident whose source of payment was previously private, but who now is eligible for Title XIX (Medicaid) assistance, the resident may be transferred from a private room to a semiprivate room or from one semiprivate room to another.

(5) Reasonable and necessary administrative decisions regarding the use and functioning of the building.

b. Unreasonable and unjustified reasons for changing a resident’s room without the concurrence of the resident or responsible party include:

(1) Change from private pay status to Title XIX, except as outlined in subparagraph 63.11(11)“a”(4). (II)

(2) As punishment or behavior modification, except as specified in subparagraph 63.11(11)“a”(1). (II)

(3) Discrimination on the basis of race or religion. (II)

c. If intrafacility relocation is necessary for reasons outlined in paragraph 63.11(11)“a,” the resident shall be notified at least 48 hours prior to the transfer and the reason therefor shall be explained. The responsible party shall be notified as soon as possible. The notification shall be documented in the resident’s record and signed by the resident or responsible party. (II, III)

d. If emergency relocation is required in order to protect the safety or health of the resident or other residents, the notification requirements may be waived. The conditions of the emergency shall be documented. The family or responsible party shall be notified immediately or as soon as possible of the condition that necessitates emergency relocation, and such notification shall be documented. (II, III)

e. A transfer to a part of a facility that has a different license must be handled the same way as a transfer to another facility, and not as an intrafacility transfer. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.12(135C) Residency agreement.

63.12(1) Each residency agreement shall:

a. State the base rate or scale per day or per month, the services included, and the method of payment. (III)

b. Contain a complete schedule of all offered services for which a fee may be charged in addition to the base rate. (III) Furthermore, the agreement shall:

(1) Stipulate that no further additional fees shall be charged for items not contained in the complete schedule of services; (III)

(2) State the method of payment for additional charges; (III)

(3) Contain an explanation of the method of assessment of such additional charges and an explanation of the method of periodic reassessment, if any, resulting in changing such additional charges; (III)

(4) State that additional fees may be charged to the resident for nonprescription drugs, other personal supplies, and services provided by a barber, beautician, and such. (III)

c. Contain an itemized list of services to be provided to the resident based on an assessment at the time of the resident's admission and in consultation with the administrator and including the specific fee the resident will be charged for each service and the method of payment. (III)

d. Include the total fee to be charged initially to the resident. (III)

e. State the conditions whereby the facility may make adjustments to its overall fees for resident care as a result of changing costs. (II, III) Furthermore, the agreement shall provide that the facility shall give:

(1) Written notification to the resident, or the responsible party when appropriate, of changes in the overall rates of both base and additional charges at least 30 days prior to the effective date of such changes; (II, III)

(2) Notification to the resident, or the responsible party when appropriate, of changes in additional charges, based on a change in the resident's condition. Notification must occur prior to the date such revised additional charges begin. If notification is given orally, subsequent written notification must also be given within a reasonable time, not to exceed one week, listing specifically the adjustments made. (II, III)

f. State the terms of agreement in regard to a refund of all advance payments in the event of the transfer, death, or voluntary or involuntary discharge of the resident. (II, III)

g. State the terms of agreement concerning the holding of and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons. The terms shall contain a provision that the bed will be held at the request of the resident or the resident's responsible party. (II, III)

(1) The facility shall ask the resident or responsible party whether the resident's bed should be held. This request shall be made before the resident leaves or within 48 hours after the resident leaves. The inquiry and the response shall be documented. (II, III)

(2) The facility shall inform the resident or responsible party that, when requested, the bed may be held beyond the number of days designated by the funding source, as long as payments are made in accordance with the agreement. (II, III)

h. State the conditions under which the involuntary discharge or transfer of a resident would be effected. (II, III)

i. Set forth any other matters deemed appropriate by the parties to the agreement. No agreement or any provision thereof shall be drawn or construed so as to relieve any health care facility of any requirement or obligation imposed upon it by this chapter or any standards or rules in force pursuant to this chapter. (II, III)

63.12(2) Each party to the residency agreement shall be provided a copy of the signed agreement. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.13(135C) Medical examinations.

63.13(1) Each resident in a residential care facility shall have a designated primary care provider who may be contacted when needed. (II, III)

63.13(2) Each resident admitted to a residential care facility shall have a physical examination prior to admission. (II, III)

a. If the resident is admitted directly from a hospital, a copy of the hospital admission physical and discharge summary may be a part of the record in lieu of an additional physical examination. A record of the examination, signed by the primary care provider, shall be a part of the resident's record. (II, III)

b. The record of the admission physical examination and medical history shall portray the current medical status of the resident and shall include the resident's name, sex, age, medical history, physical examination, diagnosis, statement of medical concerns, and results of any diagnostic procedures. (II, III)

c. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59. (I, II, III)

63.13(3) The person in charge shall immediately notify the primary care provider of any accident, injury or adverse change in the resident's condition that has the potential for requiring further medical treatment. (I, II, III)

63.13(4) Each resident shall be visited by or shall visit the resident's primary care provider at least once each year. The one-year period shall be measured from the date of admission and does not include the resident's preadmission physical. (III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.14(135C) Records.

63.14(1) *Resident record.* The licensee shall keep a permanent record on all residents admitted to a specialized residential care facility with all entries current, dated, and signed. (III) The record shall include:

- a. Name and previous address of resident; (III)
- b. Birth date, sex, and marital status of resident; (III)
- c. Church affiliation; (III)
- d. Primary care provider's name, telephone number, and address; (III)
- e. Dentist's name, telephone number, and address; (III)
- f. Name, address, and telephone number of next of kin or legal representative; (III)
- g. Name, address, and telephone number of person to be notified in case of emergency; (III)
- h. Mortuary's name, telephone number, and address; (III)
- i. Pharmacist's name, telephone number, and address; (III)
- j. Physical examination and medical history; (III)
- k. Certification by the primary care provider that the resident requires no more than personal care and supervision, but does not require nursing care; (III)
- l. Primary care provider's orders for medication, treatment, and diet in writing and signed by the primary care provider; (III)
- m. A notation of yearly or other visits to primary care provider or other professional services; (III)
- n. Any change in the resident's condition; (II, III)
- o. If the primary care provider has certified that the resident is capable of taking prescribed medications, the resident shall be required to keep the administrator advised of current medications, treatments, and diet. The administrator shall keep a listing of medication, treatments, and diet prescribed by the primary care provider for each resident; (III)
- p. If the primary care provider has certified that the resident is not capable of taking prescribed medication, it must be administered by a qualified person of the facility. A qualified person shall be defined as either a registered or licensed practical nurse or an individual who has completed the state-approved training course in medication administration, including a medication manager or certified medication aide; (II)
- q. Medications administered by an employee of the facility shall be recorded on a medication record by the individual who administers the medication; (II, III)
- r. A notation describing the resident's condition on admission, transfer, and discharge; (III)
- s. In the event of a resident's death, notations in the resident's record shall include the date and time of the resident's death, the circumstances of the resident's death, the disposition of the resident's body, and the date and time that the resident's family and primary care provider were notified of the resident's death; (III)
- t. A copy of instructions given to the resident, legal representative, or facility in the event of discharge or transfer; (III)
- u. Disposition of valuables; (III)

v. Current individual program plans. (II, III)

63.14(2) Confidentiality of resident records.

a. Each resident shall be ensured confidential treatment of all information contained in the resident's records. The resident's written consent shall be required for the release of information to persons not otherwise authorized under law to receive it. (II)

b. The facility shall limit access to any medical records to staff and consultants providing professional service to the resident. This is not meant to preclude access by representatives of state and federal regulatory agencies. (II)

c. Similar procedures shall safeguard the confidentiality of residents' personal records, e.g., financial records and social services records. Only those personnel concerned with the financial affairs of the residents may have access to the financial records. This is not meant to preclude access by representatives of state and federal regulatory agencies. (II)

d. The resident or the resident's responsible party shall be entitled to examine all information contained in the resident's record and shall have the right to secure full copies of the record at reasonable cost upon request, unless the primary care provider determines the disclosure of the record or section thereof is contraindicated in which case this information will be deleted before the record is made available to the resident or responsible party. This determination and the reasons for it must be documented in the resident's record. (II)

63.14(3) Incident record.

a. Each residential care facility shall maintain an incident record report and shall have available incident report forms. (II, III)

b. Report of incidents shall be in detail on an incident report form. (III)

c. The person in charge at the time of the incident shall oversee the preparation of and sign the incident report. The administrator or designee shall review, sign and date the incident report within 72 hours of the accident, incident or unusual occurrence. (II, III)

d. An incident report shall be completed for every accident or incident where there is apparent injury or where an injury of unknown origin may have occurred. (II)

e. An incident report shall be completed for every accident, incident or unusual occurrence within the facility or on the premises that affects a resident, visitor, or employee. (II, III)

f. A copy of the incident report shall be kept on file in the facility. (II, III)

63.14(4) Retention of records.

a. Records shall be retained in the facility for five years following the termination of services to a resident. (III)

b. Records shall be retained within the facility upon change of ownership. (III)

c. When the facility ceases to operate, a copy of the resident's record shall be released to the facility to which the resident is transferred. (III)

d. When the facility ceases to operate, records shall be maintained for five years in a clean, dry secured storage area. (III)

63.14(5) Electronic records. In addition to the access provided in 481—subrule 50.10(2), an authorized representative of the department shall be provided unrestricted access to electronic records pertaining to the care provided to the residents of the facility. (II, III)

a. If access to an electronic record is requested by the authorized representative of the department, the facility may provide a tutorial on how to use its particular electronic system or may designate an individual who will, when requested, access the system, respond to any questions or assist the authorized representative as needed in accessing electronic information in a timely fashion. (II, III)

b. The facility shall provide a terminal where the authorized representative may access records. (II, III)

c. If the facility is unable to provide direct print capability to the authorized representative, the facility shall make available a printout of any record or part of a record on request in a time frame that does not intentionally prevent or interfere with the department's survey or investigation. (II, III)

63.14(6) Reports to the department. The licensee shall furnish statistical information concerning the operation of the facility to the department on request. (III)

63.14(7) Personnel record.

- a. Personnel records for each employee shall be kept in accordance with subrule 63.8(4). (III)
 - b. The personnel records shall be made available for review upon request by the department. (III)
- [ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.15(135C) Resident care and personal services.

63.15(1) A complete change of bed linens shall be provided at least once a week and more often if necessary. (III)

63.15(2) Residents shall receive sufficient supervision to promote personal cleanliness. (II, III)

63.15(3) Residents shall have clean clothing as needed. Clothing shall be appropriate to residents' activities and to the weather. (III)

63.15(4) Residents shall be encouraged to bathe at least twice a week. (II, III)

63.15(5) All nonambulatory residents shall be housed on the grade level floor unless the facility has a suitably sized elevator. (II)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.16(135C) Drugs.**63.16(1) Drug storage.**

a. Residents who have been certified in writing by their primary care provider as capable of taking their own medications may retain these medications in their bedroom, but locked storage must be provided, with staff and the resident having access, and the drug storage shall be kept locked when not in use. Monitoring of the storage, administration, and documentation by the resident shall be carried out by a person who meets the requirements of subrule 63.16(3) and is responsible for administering medications. (II, III)

b. Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

- (1) Locked storage for drugs, solutions, and prescriptions shall be provided. (III)
- (2) A bathroom shall not be used for drug storage. (III)
- (3) The drug storage shall be kept locked when not in use. (III)
- (4) The drug storage key shall be secured and available only to those employees charged with the responsibility of administering medications. (II, III)
- (5) Schedule II drugs, as defined by Iowa Code chapter 124, shall be kept in a locked box within the locked drug storage. (II, III)
- (6) Medications requiring refrigeration shall be kept locked in a refrigerator and separated from food and other items. (II, III)
- (7) Drugs for external use shall be stored separately from drugs for internal use. (II, III)
- (8) All potent, poisonous, or caustic materials shall be stored separately from drugs, shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet, or storeroom, and shall be made accessible only to authorized persons. (I, II)
- (9) Inspection of drug storage shall be made by the administrator or designee and a registered pharmacist not less than once every three months. The inspection shall be verified by a report signed by the administrator and the pharmacist and filed with the administrator. The report shall include, but not be limited to, certification of the absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current primary care provider's order, and drugs improperly stored. (III)
- (10) Bulk supplies of prescription drugs for multiresident use shall not be kept in a residential care facility. (III)

63.16(2) Drug safeguards.

a. All prescribed medications shall be clearly labeled indicating the resident's full name, primary care provider's name, prescription number, name and strength of drug, dosage, directions for use, date of issue, and name and address and telephone number of pharmacy or primary care provider issuing the drug. Where unit dose is used, prescribed medications shall, at a minimum, indicate the resident's

full name, primary care provider's name, name and strength of drug, and directions for use. Standard containers shall be utilized for dispensing drugs. (III)

b. Sample medications provided by the resident's primary care provider shall clearly identify to whom the medications belong. (III)

c. Medication containers having soiled, damaged, illegible, or makeshift labels shall be returned to the issuing pharmacist, pharmacy, or primary care provider for relabeling or disposal. (III)

d. The medication for each resident shall be kept or stored in the original containers unless the resident is participating in an individualized medication program. (II, III)

e. Unused prescription drugs shall be destroyed by the person in charge, in the presence of a witness, and with a notation made on the resident's record or shall be returned to the supplying pharmacist. (III)

f. Prescriptions shall be refilled only with the permission of the resident's primary care provider. (II, III)

g. Medications prescribed for one resident shall not be administered to or allowed in the possession of another resident. (I, II)

h. Instructions shall be requested from the Iowa board of pharmacy concerning disposal of unused Schedule II drugs prescribed for a resident who has died or for whom the Schedule II drug was discontinued. (III)

i. Discontinued medications shall be destroyed within a specified time by a responsible person, in the presence of a witness, and with a notation made to that effect or shall be returned to the pharmacist for destruction. Drugs listed under the Schedule II drugs shall be destroyed in accordance with the requirements established by the Iowa board of pharmacy. (II, III)

j. All medication orders which do not specifically indicate the number of doses to be administered or the length of time the drug is to be administered shall be stopped automatically after a given time period. The automatic-stop order may vary for different types of drugs. The resident's primary care provider, in conjunction with the pharmacist, shall institute these policies and provide procedures for review and endorsement. (II, III)

k. No resident shall be allowed to possess any medications unless the primary care provider has certified in writing on the resident's medical record that the resident is mentally and physically capable of doing so. (II)

l. No medications or prescription drugs shall be administered to a resident without a written order signed by the primary care provider. (II)

m. The facility shall establish a policy to govern the distribution of prescribed medications to residents who are on leave from the facility. (II, III)

(1) Medications may be issued to residents who will be on leave from a facility for less than 24 hours. Only those medications needed for the time period that the resident will be on leave from the facility may be issued. Non-child-resistant containers may be used. Instructions shall be provided and include the date, the resident's name, the name of the facility, and the name of the medication, its strength, dose and time of administration. (II, III)

(2) Medication for residents on leave from a facility for longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy. (II, III)

(3) Medication for residents on leave from a facility may be issued only by facility personnel responsible for administering medication. (II, III)

63.16(3) Drug administration—authorized personnel.

a. A properly trained person shall be charged with the responsibility of administering medications as ordered by a primary care provider. (II, III)

b. The person shall have knowledge of the purpose of the drugs and their dangers and contraindications. (II, III)

c. The person shall be a licensed nurse or primary care provider or an individual who has completed the state-approved training course in medication administration, including a medication manager or certified medication aide. (II, III)

d. Prior to taking a department-approved medication aide course, the person shall have a letter of recommendation for admission to the medication aide course from the employing facility. (III)

e. A person who is a nursing student or a graduate nurse may take the medication aide challenge examination in place of taking a course. The person shall do all of the following before taking the challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination; (III)

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination; (III)

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating that the person is competent in medication administration. (III)

f. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination. The requirements of paragraph 63.16(3)“*d*” do not apply to this person. (III)

63.16(4) Drug administration.

a. Unless the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by personally preparing the dose, observing the actual act of swallowing the oral medication, and charting the medication. In facilities where the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by observing the actual act of swallowing the oral medication and by charting the medication. Medications shall be prepared on the same shift of the same day that they are administered unless the unit dose system is used. (II)

b. Injectable medications shall be administered as permitted by Iowa law by a registered nurse, licensed practical nurse, primary care provider or pharmacist. For purposes of this subrule, “injectable medications” does not include an epinephrine autoinjector, e.g., an EpiPen. (II, III)

c. A resident certified by the resident's primary care provider as capable of injecting the resident's own insulin may do so. Insulin may be administered pursuant to paragraph 63.16(4)“*b*” or as otherwise authorized by the resident's primary care provider. (II, III) Authorization shall:

(1) Be in writing,

(2) Be maintained in the resident's record,

(3) Be renewed quarterly,

(4) Include the name of the person authorized to administer the insulin,

(5) Include documentation by the primary care provider that the authorized person is qualified to administer insulin to that resident. (II, III)

d. A resident may participate in the administration of the resident's own medication if the primary care provider has certified in writing in the resident's medical record that the resident is mentally and physically capable of participating and has explained in writing in the resident's medical record what the resident's participation may include.

e. An individual inventory record shall be maintained for each Schedule II drug prescribed for each resident, with an accurate count and authorized signatures at every shift. (II)

f. The facility may use a unit dose system.

g. Medication aides and medication managers may administer PRN medications without contacting a licensed nurse or primary care provider if all of the following apply: (I, II, III)

(1) A written order from the resident's primary care provider specifies the purpose of the PRN medication and the frequency, dosage and strength of the PRN medication.

(2) The resident's primary care provider provides in writing specific criteria for administering PRN medications.

(3) The pharmacist assesses the resident's use of PRN medications when conducting the inspection of drug storage as required by subparagraph 63.16(1)“*b*”(9).

h. The pharmacist shall assess the use of PRN medications when conducting the inspection of drug storage as required by subparagraph 63.16(1)“*b*”(9). (II, III)

i. Medications administered by an employee of the facility shall be recorded on a medication record by the individual who administers the medication. (I, II, III)
[ARC 3740C, IAB 4/11/18, effective 5/16/18; ARC 4577C, IAB 7/31/19, effective 9/4/19]

481—63.17(135C) Dental services.

63.17(1) The residential care facility personnel shall assist residents in obtaining annual and emergency dental services and shall arrange transportation for such services. (III)

63.17(2) Dental services shall be performed only on the request of the resident, responsible party, legal representative, or primary care provider. The resident's primary care provider shall be advised of the resident's dental problems. (III)

63.17(3) All dental reports or progress notes shall be included in the resident record as available. The facility shall make reasonable efforts to obtain the records following the provision of services. (III)

63.17(4) Personal care staff shall assist the resident in carrying out the dentist's recommendations. (III)
[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.18(135C) Dietary.

63.18(1) *Dietary staffing.* Personnel who are responsible for food preparation or service, or both food preparation and service, shall have an orientation on sanitation and safe food handling prior to handling food and shall have annual in-service training on food protection. (III)

63.18(2) *Nutrition and menu planning.*

a. Menus shall be planned and followed to meet the nutritional needs of residents in accordance with the primary care provider's orders. Diet orders should be reviewed as necessary, but at least quarterly, by the primary care provider. (II, III)

b. In facilities where residents plan and prepare their own meals, education and support shall be provided to residents regarding proper food preparation, dietary guidelines, and food safety.

c. In facilities where food is regularly prepared for residents, the following shall apply:

(1) Menus shall be planned and served to include foods and amounts necessary to meet federal dietary guidelines. (II, III)

(2) At least three meals or their equivalent shall be offered daily, at regular hours. (II, III)

1. There shall be no more than a 14-hour span between offering a substantial evening meal and breakfast. (II, III)

2. Unless contraindicated, evening snacks shall be offered routinely to all residents. Special nourishments shall be available when ordered by the primary care provider. (II, III)

(3) Menus shall include a variety of foods prepared in various ways. (III)

(4) Menus shall be written at least one week in advance. The current menu shall be located in an accessible place for easy use by persons purchasing, preparing, and serving food. (III)

(5) Records of menus as served shall be filed and maintained for 30 days and shall be available for review by departmental personnel. When substitutions are necessary or requested, they shall be of similar nutritive value and recorded on the menu or in a notebook. (III)

(6) The facility shall provide an alternative choice at scheduled meal times. (III)

63.18(3) *Dietary storage, food preparation, and service.*

a. All food shall be handled, prepared, served and stored in compliance with the Food Code adopted pursuant to Iowa Code section 137F.2. (I, II, III)

b. Supplies of staple foods for a minimum of a one-week period and of perishable foods for a minimum of a two-day period shall be maintained on the premises. Minimum food portion requirements for a low-cost plan shall conform to information supplied by the bureau of nutrition and health promotion of the department of public health. (II, III)

c. Dishes shall be free of cracks, chips, and stains. (III)

d. If family-style service is used, all leftover prepared food that has been on the table shall be properly handled. (III)

63.18(4) Sanitation in food preparation area. There shall be written procedures established for cleaning all work and serving areas. (III)
[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.19(135C) Orientation and service plan.

63.19(1) Orientation. Within 24 hours of admission, each resident shall receive orientation to the facility. The orientation program shall be documented in the resident's file and shall include, but shall not be limited to, a review of the resident's rights, the daily schedule, house rules and the facility's evacuation plan. (II, III)

63.19(2) Initial service plan. Within 48 hours of admission, the administrator or the administrator's designee shall develop an initial service plan to address any immediate health and safety needs. The plan shall be based on information gathered from the resident, family, referring party, primary care provider, and other significant persons. The plan shall be followed until the service plan required in subrule 63.19(3) is complete. (I, II, III)

63.19(3) Service plan. Within 30 days of admission, the administrator or the administrator's designee, in conjunction with the resident and the resident's interdisciplinary team, shall develop a written, individualized, and integrated service plan for the resident. The service plan shall be developed and implemented to address the resident's priorities and assessed needs, such as activities of daily living, rehabilitation, activity, and social, behavioral, emotional, physical and mental health. (I, II, III)

a. The service plan shall include measurable goals and objectives and the specific service(s) to be provided to achieve the goals. Each goal shall include the date of initiation and anticipated duration of service(s). Any restriction of rights shall be included in the service plan. (I, II, III)

b. The service plan shall include the documentation procedure for each goal and objective. (II, III)

c. The service plan should be modified to add or delete goals and objectives as the resident's needs change. Communications related to service plan changes or changes in the resident's condition shall occur within five working days of the change and shall be conveyed to all individuals inside and outside the residential care facility who work with the resident, as well as to the resident's responsible party. (I, II, III)

d. The service plan shall be reviewed at least quarterly by relevant staff, the resident and appropriate others, such as the resident's family, case manager and responsible party. The review shall include a written report which addresses a summary of the resident's progress toward goals and objectives and the need for continued services. (I, II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.20(135C) Resident activities program.

63.20(1) Activities program. Each residential care facility shall provide suitable group and individual activities for residents. (III)

a. The activities provided shall be designed to meet the needs and interests of each resident and to assist residents in continuing normal activities within limitations set by the resident's primary care provider. This shall include helping residents continue in their individual interests or hobbies. (III)

b. Residents shall be encouraged, but not required, to participate in activities. (III)

63.20(2) Each resident may participate in activities of social, religious, and community groups at the resident's discretion unless contraindicated for reasons documented by the primary care provider or interdisciplinary team as appropriate in the resident's record. (II)

63.20(3) Residents who wish to meet with or participate in activities of social, religious, or other community groups in or outside of the facility shall be informed, encouraged, and assisted to do so. (II)

63.20(4) Supplies, equipment, and storage.

a. Each facility shall provide a variety of supplies and equipment of a nature calculated to fit the needs and interests of the residents. (III)

b. Storage shall be provided for recreational equipment and supplies. (III)
[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.21(135C) Residents' rights.

63.21(1) Each facility shall ensure that policies and procedures are written and implemented which include, at a minimum, the provisions of this rule and which govern all areas of service provided by the facility. These policies and procedures shall be available to staff, residents, residents' families or legal representatives and the public and shall be reviewed annually. (II, III)

63.21(2) Policies and procedures shall include a method for submitting complaints and recommendations by residents or their responsible parties and for ensuring a response and disposition by the facility. (II, III) The written procedures shall:

a. Ensure the provision of assistance to residents as necessary to complete and submit complaints and recommendations; (II, III)

b. Ensure protection of the resident from any form of reprisal or intimidation; (II, III)

c. Include designation of an employee responsible for handling grievances and recommendations; (II, III)

d. Include a method of investigating and assessing the validity of a grievance or recommendation; (II, III) and

e. Include methods of recording grievances and actions taken. (II, III)

63.21(3) Policies and procedures shall include provisions governing access to, duplication of, and dissemination of information from the residents' records. (II, III)

63.21(4) Policies and procedures shall include a provision that each resident shall be fully informed of the resident's rights and responsibilities as a resident and of all rules governing resident conduct and responsibilities. This information must be provided upon the resident's admission or, in the case of residents already in the facility, upon the facility's adoption or amendment of residents' rights policies. (II, III)

a. The facility shall communicate to residents prior to or within five days after admission what residents may expect from the facility and its staff and what is expected from residents. The communication shall be in writing, e.g., in a separate handout or brochure describing the facility, and interpreted verbally, e.g., as part of a preadmission interview, resident counseling, or in individual or group orientation sessions following the resident's admission. (II, III)

b. Residents' rights and responsibilities shall be presented in language understandable to the resident. If the facility serves residents who are non-English-speaking or deaf or hard of hearing, steps shall be taken to translate the information into a foreign or sign language. In the case of blind residents, either Braille or a recording shall be provided. Residents shall be encouraged to ask questions about their rights and responsibilities, and these questions shall be answered. (II, III)

c. A statement shall be signed by the resident, or the resident's responsible party if applicable, indicating an understanding of these rights and responsibilities and shall be maintained in the resident's record. The statement shall be signed no later than five days after admission, and a copy of the signed statement shall be given to the resident or responsible party. (II, III)

d. In order to ensure that residents continue to be aware of these rights and responsibilities during their stay, a written copy shall be prominently posted in a location that is available to all residents. (II, III)

e. All residents shall be advised within 30 days following changes made in the statement of residents' rights and responsibilities. Appropriate means shall be utilized to inform non-English-speaking, deaf or hard-of-hearing, or blind residents of changes. (II, III)

63.21(5) Choice of primary care provider. Each resident shall be permitted free choice of a primary care provider, and pharmacy, if accessible. The facility may require the selected pharmacy to utilize a drug distribution system compatible with the system currently used by the facility. (II)

63.21(6) Each resident shall be afforded the opportunity to participate in the planning of the resident's total care and treatment, which may include, but shall not be limited to, medical care, nutritional needs, activities, and social work services. Each resident has the right to refuse treatment

except as provided by Iowa Code chapter 229. In the case of a resident with a responsible party, the responsible party shall be afforded the opportunity to participate in the planning of the resident's total care and medical treatment and to be informed of the resident's medical condition. (II, III)

63.21(7) Each resident shall be encouraged and assisted throughout the resident's period of stay to exercise the resident's rights as a resident and as a citizen and may voice grievances and recommend changes in policies and services to administrative staff or to outside representatives of the resident's choice, free from interference, coercion, discrimination, or reprisal. (II)

63.21(8) The facility shall provide ongoing opportunities for residents to be aware of and to exercise their rights as residents. Residents shall be kept informed of changes in policies and services that are more restrictive, and their views shall be solicited prior to action. (II)

63.21(9) The facility shall post in a prominent area the text of Iowa Code section 135C.46 (Retaliation by facility prohibited) and the name, telephone number, and address of the long-term care ombudsman, the department, and the local law enforcement agency to provide residents a further course of redress. (II)

63.21(10) All rights and responsibilities of the resident devolve to the resident's responsible party or any legal surrogate designated in accordance with state law, to the extent permitted by state law. This subrule is not intended to limit the authority of any individual acting pursuant to Iowa Code chapter 144A. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18; ARC 5711C, IAB 6/16/21, effective 7/21/21]

481—63.22(135C) Dignity preserved. The resident shall be treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and in care for personal needs. (I, II)

63.22(1) Staff shall display respect for residents when speaking with, caring for, or talking about them, as constant affirmation of their individuality and dignity as human beings. (I, II)

63.22(2) Schedules of daily activities shall allow maximum flexibility for residents to exercise choice about what they will do and when they will do it. Residents' individual preferences regarding such things as menus, clothing, religious activities, friendships, activity programs, entertainment, sleeping and eating, also times to retire at night and arise in the morning shall be elicited and considered by the facility. (II)

63.22(3) Residents shall be examined and treated in a manner that maintains the privacy of their bodies. A closed door or a drawn curtain shall shield the resident from passersby. People not involved in the care of the residents shall not be present without the resident's consent while the resident is being examined or treated. (II)

63.22(4) Privacy of a resident's body also shall be maintained during toileting, bathing, and other activities of personal hygiene, except as needed for resident safety or assistance. (II)

63.22(5) Staff shall knock and be acknowledged before entering a resident's room unless the resident is not capable of a response. This shall not apply under emergency conditions. (II)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.23(135C) Communications. Each resident may communicate, associate, and meet privately with persons of the resident's choice, unless to do so would infringe upon the rights of other residents, and may send and receive personal mail unopened. (II)

63.23(1) Subject to reasonable scheduling restrictions, visiting policies and procedures shall permit residents to receive visits from anyone they wish. Visiting hours shall be posted. (II)

63.23(2) Reasonable, regular visiting hours shall not be less than 12 hours per day and shall take into consideration the special circumstances of each visitor. A particular visitor(s) may be restricted by the facility for one of the following reasons:

- a. The resident refuses to see the visitor(s). (II)
- b. The resident's primary care provider documents specific reasons why such a visit would be harmful to the resident's health. (II)
- c. The visitor's behavior is unreasonably disruptive to the functioning of the facility. This judgment must be made by the administrator, and the reasons shall be documented and kept on file. (II)

63.23(3) Decisions to restrict a visitor are reviewed and reevaluated:

- a. Each time the medical orders are reviewed by the primary care provider;
- b. At least quarterly by the facility's staff; or
- c. At the resident's request. (II)

63.23(4) Space shall be provided for residents to receive visitors in reasonable comfort and privacy. (II)

63.23(5) Telephones shall be available and accessible for residents to make and receive calls with privacy. Residents who need help shall be assisted in using the telephone. (II)

63.23(6) Arrangements shall be made to provide assistance to residents who require help in reading or sending mail. (II)

63.23(7) Residents, including residents court-ordered to the facility, shall be permitted to leave the facility at reasonable times unless there are justifiable reasons established in writing by court order, the primary care provider, the interdisciplinary team, or the facility administrator for refusing permission. (II)

63.23(8) Residents shall not have their personal lives regulated beyond reasonable adherence to meal schedules, bedtime hours, and other written policies which may be necessary for the orderly management of the facility and as required by these rules. However, residents shall be encouraged to participate in recreational programs. (II)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.24(135C) Resident property.

63.24(1) Residents shall be permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility. The facility shall offer the resident the opportunity to have personal property itemized and documented on an inventory sheet upon the resident's admission. The inventory sheet shall be kept in a safe location which is convenient for the resident to review and update. At discharge, residents may sign off on a list of the personal property they are taking with them. (II, III)

63.24(2) The facility shall provide for the safekeeping of personal effects, funds and other property of its residents. The facility may require that items of exceptional value or that would convey unreasonable responsibilities to the licensee be removed from the premises of the facility for safekeeping. (III)

63.24(3) Any funds or other property belonging to or due a resident, or expendable for the resident's account, which is received by the facility shall be trust funds; shall be kept separate from the funds and property of the facility and of its other residents, or specifically credited to such resident; and shall be used or otherwise expended only for the account of the resident. (III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.25(135C) Financial affairs—management. Each resident who has not been assigned a guardian or conservator by the court may manage the resident's own personal financial affairs. To the extent the facility assists in management, under written authorization by the resident, the management shall be carried out in accordance with Iowa Code section 135C.24. (II)

63.25(1) The facility shall maintain a written account of all residents' funds received by or deposited with the facility. (II)

63.25(2) An employee shall be designated in writing to be responsible for resident accounts. (II)

63.25(3) The facility shall keep on deposit personal funds over which the resident has control in accordance with Iowa Code section 135C.24. Should the resident request these funds, they shall be given to the resident on request with receipts maintained by the facility and a copy to the resident. In the case of a resident with impaired decision-making skills, the resident's legal representative shall designate a method of disbursing the resident's funds. (II)

63.25(4) If the facility makes financial transactions on a resident's behalf, the facility must document that it has prepared and sent an itemized accounting of disbursements and current balances at least quarterly. A copy of this statement shall be maintained in the resident's financial or business record. (II)

63.25(5) A resident's personal funds shall not be used without the written consent of the resident or the resident's legal representative. (I, II)

63.25(6) A resident's personal funds shall be returned to the resident when the funds have been used without the written consent of the resident or the resident's legal representative. The department may report findings that resident funds have been used without written consent to the department's investigations division or to the local law enforcement agency, as appropriate. (II)
[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.26(135C) Resident work. No resident may be required to perform services for the facility, except as provided by Iowa Code section 347B.5. (II)

63.26(1) Residents may not be used to provide a source of labor for the facility against their will. Approval by the primary care provider or psychiatrist is required for all work programs. (I, II)

63.26(2) Residents who perform work for the facility must receive compensation unless the work is part of their approved training program. Persons on the resident census who perform work shall not be used to replace paid employees in fulfilling staffing requirements. (II)
[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.27(135C) Resident abuse prohibited. Each resident shall receive kind and considerate care at all times and shall be free from mental, physical, sexual, and verbal abuse, exploitation, neglect, and physical injury. (I, II)

63.27(1) Mental abuse includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation. (I, II)

63.27(2) Physical abuse includes, but is not limited to, corporal punishment and the use of restraints as punishment. (I, II)

63.27(3) Drugs such as tranquilizers shall only be used in accordance with orders of the primary care provider. (I, II)

63.27(4) Allegations of dependent adult abuse. Allegations of dependent adult abuse shall be reported and investigated pursuant to Iowa Code chapter 235E and 481—Chapter 52. (I, II, III)

63.27(5) Staff shall receive training relating to the identification and reporting of dependent adult abuse as required by Iowa Code section 235B.16. (I, II, III)
[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.28(135C) Crisis intervention. If a facility utilizes physical restraints, the facility shall have written policies that define the uses of physical restraints, designate the administrator or designee as the person who may authorize their use, establish a mechanism for monitoring and controlling their use, and provide staff with proper training. (I, II)

63.28(1) Temporary physical restraint of residents shall be used only under the following conditions: (I, II)

a. An emergency to prevent injury to the resident or to others; or (I, II)

b. For crisis intervention, but shall not be used for punishment, for the convenience of staff or as a substitution for supervision or programming; (I, II) and

c. No staff person shall use any restraint that obstructs the airway of the resident. (I, II)

63.28(2) Authorization for the use of physical restraints must be prior to or immediately after application of the restraint. (I, II)

63.28(3) Prone restraint is prohibited. Staff persons who find themselves involved in the use of a prone restraint when responding to an emergency must take immediate steps to end the prone restraint. (I, II)

63.28(4) The rationale and authorization for the use of physical restraint and staff action and procedures carried out to protect the resident's rights and to ensure safety shall be clearly set forth in the resident's record by the responsible staff persons. (I, II)

63.28(5) The primary care provider, the interdisciplinary team and the resident's responsible party shall be notified of any restraints administered. (I, II, III)

63.28(6) The facility shall provide to the staff a department-approved training program by qualified professionals on physical restraint techniques. (I, II)

a. The facility shall keep a record of training for review by the department and shall include attendance. (II, III)

b. Only staff with documented training in physical restraint and techniques shall be authorized to assist with physical restraint of a resident. (I, II)

c. Under no circumstances shall a resident be allowed to actively or passively assist in the restraint of another resident. (I, II)

63.28(7) Residents shall not be kept behind locked doors. (I, II)

63.28(8) Mechanical restraint is prohibited. Staff persons who find themselves involved in the use of a mechanical restraint when responding to an emergency must take immediate steps to end the mechanical restraint. (I, II)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.29(135C) Safety. The licensee of a residential care facility shall be responsible for the provision and maintenance of a safe environment for residents and personnel. (I, II, III)

63.29(1) Fire safety.

a. All residential care facilities shall meet the fire safety rules and regulations as promulgated by the state fire marshal. (I, II)

b. The size of the facility and needs of the residents shall be taken into consideration in evaluating safety precautions and practices.

63.29(2) Safety duties of administrator. The administrator shall have a written emergency plan to be followed in the event of fire, tornado, explosion, or other emergency. (III)

a. The plan shall be prominently posted in a common area of the building. (III)

b. In-service shall be provided to ensure that all employees are knowledgeable of the emergency plan. (II, III)

63.29(3) Resident safety.

a. Smoking shall be prohibited, except as allowed by Iowa Code chapter 142D, the smokefree air Act. (II, III)

b. Whenever full or empty tanks of oxygen are being used or stored, they shall be securely supported in an upright position. (II, III)

c. Residents shall receive adequate supervision to ensure against hazard from themselves, others, or elements in the environment. (I, II, III)

d. Storage areas for cleaning agents, bleaches, insecticides, or any other poisonous, dangerous, or flammable materials shall be locked. Residents permitted to access these materials shall have an order by their primary care provider stating the resident is able to utilize such materials, and staff shall supervise the residents as identified in the resident's service plan. (I, II, III)

e. Sufficient numbers of noncombustible trash containers with covers shall be available. (III)

f. Residents' personal possessions that may constitute a hazard to residents or others shall be removed and stored. (III)

63.29(4) First-aid kit. A first-aid emergency kit shall be available on each floor in every facility. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.30(135C) Housekeeping.

63.30(1) Each resident room shall be cleaned on a routine schedule. (III)

63.30(2) All rooms, corridors, storage areas, linen closets, attics, and basements shall be kept in a clean, orderly condition, free of unserviceable furniture and equipment and accumulations of refuse. (II, III)

63.30(3) A hallway or corridor shall not be used for storage of equipment. (II, III)

63.30(4) All odors shall be kept under control by cleanliness and proper ventilation. (III)

63.30(5) Clothing worn by personnel shall be clean and washable. (III)

63.30(6) All furniture, bedding, linens, and equipment shall be cleaned periodically and before use by another resident. (II, III)

63.30(7) Polishes used on floors shall provide a nonslip finish. (II, III)

63.30(8) Throw or scatter rugs shall have nonskid backing. (II, III)

63.30(9) Entrances, exits, steps, and outside walkways shall be kept free from ice, snow, and other hazards. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.31(135C) Maintenance.

63.31(1) The building, grounds, and other buildings shall be maintained in a clean, orderly condition and in good repair. (II, III)

63.31(2) Window treatments and furniture shall be clean and in good repair. (II, III)

63.31(3) Cracks in plaster, peeling wallpaper or paint, and tears or splits in floor coverings shall be promptly repaired or replaced in a professional manner. (II, III)

63.31(4) The electrical systems, including appliances, cords, and switches, shall be maintained to guarantee safe functioning and comply with the National Electric Code. (II, III)

63.31(5) All plumbing fixtures shall function properly and comply with the state plumbing code. (II, III)

63.31(6) Yearly inspections of the heating and cooling systems shall be made to guarantee safe operation. (II, III)

63.31(7) The building, grounds, and other buildings shall be kept free of breeding areas for flies, other insects, and rodents. (II, III)

63.31(8) The facility shall be kept free of flies, other insects, and rodents. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.32(135C) Laundry.

63.32(1) Residents' personal laundry shall be marked with an identification if commingled with other residents' personal laundry. (III)

63.32(2) Bed linens, towels, and washcloths shall be clean and stain-free. (III)

63.32(3) If laundry is done in the facility, a clean, dry, well-lit area to accommodate a washer and dryer of adequate size to serve the needs of the facility shall be provided. (III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.33(135C) Garbage and waste disposal.

63.33(1) All garbage shall be gathered, stored, and disposed of in a manner that will not permit transmission of disease, create a nuisance, or provide a breeding or feeding place for vermin or insects. (III)

63.33(2) All containers for refuse shall be watertight and rodent-proof and have tight-fitting covers. (III)

63.33(3) All unlined containers inside of the facility shall be thoroughly cleaned each time the containers are emptied. (III)

63.33(4) All waste shall be properly disposed of in compliance with local ordinances and state codes. (III)

(III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.34(135C) Supplies.

63.34(1) Linen supplies.

a. There shall be an adequate supply of linens so that each resident shall have at least three washcloths, hand towels, and bath towels per week. (III)

b. A complete change of bed linens shall be available in the linen storage area for each bed. (III)

c. Sufficient lightweight, clean, serviceable blankets shall be available. All blankets shall be laundered as often as necessary for cleanliness and freedom from odors. (III)

d. Each bed shall be provided with clean, washable bedspreads. There shall be a supply available when changes are necessary. (III)

e. Adequate storage shall be provided for linens, pillows, and bedding. (III)

63.34(2) Supplies, equipment and storage.

- a. All equipment shall be properly cleaned and sanitized before use by another resident. (III)
 - b. Clean and sanitary storage shall be provided for equipment and supplies. (III)
 - c. Locked storage should be available for potentially dangerous items such as scissors, knives, and toxic materials. (III)
- [ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.35(135C) Buildings, furnishings, and equipment.

63.35(1) Buildings—general requirements.

- a. All windows shall be supplied with window treatments that are kept clean and in good repair. (III)
- b. Whenever glass sliding doors or transparent panels are used, they shall be marked conspicuously. (III)
- c. The facility shall meet the equivalent requirements of the appropriate group occupancy of the state building code. (III)
- d. The facility shall be located in an area zoned for single- or multiple-family housing or in an unincorporated area and shall be constructed in compliance with applicable local housing codes and rules adopted for this classification of license by the state fire marshal. (II, III)

63.35(2) Furnishings and equipment.

- a. All furnishings and equipment shall be durable, cleanable, and appropriate to their function. (III)
- b. All resident areas shall be decorated, painted, and furnished to provide a homelike atmosphere. (III)

63.35(3) Dining areas and living rooms.

- a. Living rooms shall be maintained for the use of residents and their visitors and may be used for recreational activities. Living rooms shall be suitably furnished. (III)
- b. Dining areas shall be furnished with dining tables and chairs appropriate to the size and function of the facility. Dining rooms and furnishings shall be kept clean and sanitary. (III)

63.35(4) Bedrooms.

- a. Each resident shall be provided with a twin-sized or larger bed, substantially constructed and in good repair. Rollaway beds, metal cots, or folding beds are not acceptable. (III)
- b. Each bed shall be equipped with the following: casters or glides; clean springs in good repair; a clean, comfortable, well-constructed mattress approximately five inches thick and standard in size for the bed; and clean, comfortable pillows of average bed size. (III)
- c. There shall be a comfortable chair, either a rocking chair or armchair, per resident bed. The resident's personal wishes shall be considered. (III)
- d. There shall be drawer space for each resident's clothing. In a bedroom in which more than one resident resides, drawer space shall be assigned to each resident. (III)
- e. Beds and other furnishings shall not obstruct free passage to and through doorways. (III)
- f. Beds shall not be placed in such a manner that the side of the bed is against the radiator or in close proximity to it unless the radiator is covered so as to protect the resident from contact with it or from excessive heat. (III)
- g. There shall be a wardrobe or closet in each resident's room. Minimum clear dimensions shall be 1 foot 10 inches deep by 1 foot 8 inches wide with full hanging space and provide a clothes rod and shelf. In a multiple bedroom, closet or wardrobe space shall be assigned each resident sufficient for the resident's needs. (III)
- h. Each room shall have sufficient accessible mirrors to serve resident's needs. (III)
- i. Useable floor space of a room shall be no less than 8 feet in any major dimension. (III)
- j. Bedrooms shall have a minimum of 60 square feet of useable floor space per bed for a double room, 80 square feet of useable floor space for a single room. (III)
- k. There shall be no more than two residents per room. (III)

63.35(5) Bath and toilet facilities.

- a. All sinks shall have paper towel dispensers and an available supply of soap. (III)

- b. Toilet paper shall be readily available to residents. (III)
- c. There shall be a minimum of one toilet and bath facility for five residents. (III)

63.35(6) Heating. A centralized heating system shall be maintained in good working order and capable of maintaining a comfortable temperature for residents of the facility. Portable units or space heaters are prohibited from being used in the facility except in an emergency. (II, III)

63.35(7) Water supply.

a. Private sources of water supply shall be tested annually and the report made available for review by the department upon request. (III)

b. A bacterially unsafe source of water supply shall be grounds for denial, suspension, or revocation of license. (III)

c. The department may require testing of private sources of water supply at its discretion in addition to the annual test. The facility shall supply reports of such tests as directed by the department. (III)

d. Hot and cold running water under pressure shall be available in the facility. (II, III)

e. Prior to construction of a new facility or new water source, private sources of water supply shall be surveyed and shall comply with the requirements of the department. (III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18; ARC 4577C, IAB 7/31/19, effective 9/4/19]

481—63.36(135C) Family and employee accommodations. If the family or employees live within the facility, separate living quarters and recreation facilities shall be required for the family or employees distinct from such areas provided for the residents. (III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

481—63.37(135C) Animals. No animals shall be allowed to reside in the facility except with written approval of the department and under controlled conditions. (II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18]

These rules are intended to implement Iowa Code chapter 135C.

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⁰ Two or more ARCs

¹ Effective date of 63.15(2)“a” and “b” delayed 70 days by the Administrative Rules Review Committee, IAB 2/26/86.
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² See IAB, Inspections and Appeals Department.

³ Rule 481—63.49(135C), effective 7/1/92.

⁴ September 7, 2016, effective date of 57.19(3)“d,” 62.15(2)“d,” and 63.18(3)“d” [ARC 2643C] delayed 70 days by the Administrative Rules Review Committee at its meeting held August 5, 2016.

CHAPTER 64
INTERMEDIATE CARE FACILITIES FOR THE
INTELLECTUALLY DISABLED*

481—64.1 Rescinded IAB 7/26/89, effective 7/7/89.

481—64.2(135C) Waivers. Waivers from these rules may be granted by the director of the department of inspections and appeals for good and sufficient reason when the need for a waiver has been established; no danger to the health, safety, or welfare of any resident results; alternate means are employed or compensating circumstances exist and the waiver will apply only to an individual intermediate care facility for the intellectually disabled. Waivers will be reviewed at the discretion of the director of the department of inspections and appeals.

64.2(1) To request a waiver, the licensee must:

- a. Apply for a waiver in writing on a form provided by the department;
- b. Cite the rule or rules from which a waiver is desired;
- c. State why compliance with the rule or rules cannot be accomplished;
- d. Explain alternate arrangements or compensating circumstances which justify the waiver;
- e. Demonstrate that the requested waiver will not endanger the health, safety, or welfare of any resident.

64.2(2) Upon receipt of a request for a waiver, the director of the department of inspections and appeals will:

- a. Examine the rule from which a waiver is requested to determine that the request is necessary and reasonable;
- b. If the request meets the above criteria, evaluate the alternate arrangements or compensating circumstances against the requirement of the rules;
- c. Examine the effect of the requested waiver on the health, safety, or welfare of the residents;
- d. Consult with the applicant if additional information is required.

64.2(3) Based upon these studies, approval of the waiver will be either granted or denied within 120 days of receipt.

[ARC 0764C, IAB 5/29/13, effective 7/3/13; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—64.3(135C) Application for license.

64.3(1) Initial application. In order to obtain an initial intermediate care facility for the intellectually disabled license for an intermediate care facility for the intellectually disabled which is currently licensed, the applicant must:

- a. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;
- b. Make application at least 30 days prior to the change of ownership of the facility on forms provided by the department;
- c. Submit a floor plan of each floor of the intermediate care facility, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which room will be put and window and door location;
- d. Submit a photograph of the front and side elevation of the intermediate care facility for the intellectually disabled;
- e. Submit the statutory fee for an intermediate care facility for the intellectually disabled license;
- f. Meet all of the rules, regulations and standards contained in 481—Chapter 64.
- g. Comply with federal, state, and local laws, codes, and regulations pertaining to health and safety, including procurement, dispensing, administration, safeguarding and disposal of medications and controlled substances; building, construction, maintenance and equipment standards; sanitation; communicable and reportable diseases; and postmortem procedures;

*See Interpretive Guidelines at end hereof

h. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

64.3(2) In order to obtain an initial intermediate care facility for the intellectually disabled license for a facility not currently licensed as an intermediate care facility for the intellectually disabled, the applicant must:

**a.* Meet all of the rules, regulations, and standards contained in 481—Chapters 61 and 64; exceptions noted in 481—subrule 61.1(2) shall not apply;

*Nullified by 1989 Iowa Acts, SJR 10

b. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;

c. Make application at least 30 days prior to the proposed opening date of the facility on forms provided by the department;

d. Submit a floor plan of each floor of the intermediate care facility for the intellectually disabled, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which the rooms will be put and window and door locations;

e. Submit a photograph of the front and side elevation of the intermediate care facility for the intellectually disabled;

f. Submit the statutory fee for an intermediate care facility for the intellectually disabled;

g. Comply with federal, state, and local laws, codes, and regulations pertaining to health and safety, including procurement, dispensing, administration, safeguarding and disposal of medications and controlled substances; building, construction, maintenance and equipment standards; sanitation; communicable and reportable diseases; and postmortem procedures;

h. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

64.3(3) Renewal application. In order to obtain a renewal of the intermediate care facility for the intellectually disabled license, the applicant must:

a. Submit the completed application form 30 days prior to annual license renewal date of intermediate care facility for the intellectually disabled license;

b. Submit the statutory license fee for an intermediate care facility for the intellectually disabled with the application for renewal;

c. Have an approved current certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations;

d. Submit appropriate changes in the résumé to reflect any changes in the resident care program or other services.

64.3(4) Licenses are issued to the person or governmental unit which has responsibility for the operation of the facility and authority to comply with all applicable statutes, rules or regulations.

The person or governmental unit must be the owner of the facility or, if the facility is leased, the lessee.

[ARC 0764C, IAB 5/29/13, effective 7/3/13]

481—64.4(135C) General requirements.

64.4(1) The license shall be displayed in a conspicuous place in the facility which is viewed by the public. (III)

64.4(2) The license shall be valid only in the possession of the licensee to whom it is issued.

64.4(3) The posted license shall accurately reflect the current status of the intermediate care facility for the intellectually disabled. (III)

64.4(4) Licenses expire one year after the date of issuance or as indicated on the license.

64.4(5) Each citation or a copy of each citation issued by the department for a Class I or Class II violation shall be prominently posted by the facility in plain view of the residents, visitors, and persons inquiring about placement in the facility. The citation or copy of the citation shall remain posted until the violation is corrected to the satisfaction of the department. (III)

64.4(6) The facility shall have in effect a transfer agreement with one or more hospitals sufficiently close to the facility to make feasible the transfer between them of residents and their records. (III) Any facility which does not have such an agreement in effect but has attempted in good faith to enter into such an agreement with a hospital shall be considered to have such an agreement so long as it is in the public interest and essential to ensuring intermediate care facility for the intellectually disabled services for eligible persons in the community.

64.4(7) A resident's personal funds and property shall not be used without the written consent of the resident or the resident's guardian. (II)

64.4(8) A resident's personal funds and property shall be returned to the resident when the funds or property have been used without the written consent of the resident or the resident's guardian. The department may report findings that funds or property have been used without written consent to the audits division or the local law enforcement agency, as appropriate. (II)

64.4(9) A properly trained person shall be charged with the responsibility of administering non-parenteral medications.

a. The individual shall have knowledge of the purpose of the drugs, their dangers, and contraindications.

b. This person shall be a licensed nurse or physician or shall have successfully completed a department-approved medication aide course or passed a department-approved medication aide challenge examination administered by an area community college.

c. A person who is a nursing student or a graduate nurse may take the challenge examination in place of taking a medication aide course. This individual shall do all of the following before taking the medication aide challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination;

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination;

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating the individual is competent in medication administration.

(4) Successfully complete a department-approved nurse aide competency evaluation.

d. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination.

[ARC 0764C, IAB 5/29/13, effective 7/3/13]

481—64.5(135C) Notifications required by the department. The department shall be notified:

64.5(1) Within 48 hours, by letter, any reduction or loss of direct care professional or dietary staff lasting more than seven days which places the staffing ratio of the intermediate care facility for the intellectually disabled below that required for licensing. No additional residents shall be admitted until the minimum staffing requirements are achieved; (III)

64.5(2) Of any proposed change in the intermediate care facility for the intellectually disabled's functional operation or addition or deletion of required services; (III)

64.5(3) Thirty days before addition, alteration, or new construction is begun in the intermediate care facility for the intellectually disabled, or on the premises; (III)

64.5(4) Thirty days in advance of closure of the intermediate care facility for the intellectually disabled; (III)

64.5(5) Within two weeks of any change in administrator; (III)

64.5(6) When any change in the category of license is sought; (III)

64.5(7) Prior to the purchase, transfer, assignment, or lease of an intermediate care facility for the intellectually disabled, the licensee shall:

a. Inform the department of the pending sale, transfer, assignment, or lease of the facility; (III)

b. Inform the department of the name and address of the prospective purchaser, transferee, assignee, or lessee at least 30 days before the sale, transfer, assignment, or lease is completed; (III)

c. Submit a written authorization to the department permitting the department to release all information of whatever kind from the department's files concerning the licensee's intermediate care facility for the intellectually disabled to the named prospective purchaser, transferee, assignee, or lessee. (III)

64.5(8) Pursuant to the authorization submitted to the department by the licensee prior to the purchase, transfer, assignment, or lease of an intermediate care facility for the intellectually disabled, the department shall, upon request, send or give copies of all recent licensure surveys and of any other pertinent information relating to the facility's licensure status to the prospective purchaser, transferee, assignee, or lessee; costs for such copies shall be paid by the prospective purchaser.

[ARC 0764C, IAB 5/29/13, effective 7/3/13]

481—64.6(135C) Veteran eligibility.

64.6(1) Within 30 days of a resident's admission to a health care facility receiving reimbursement through the medical assistance program under Iowa Code chapter 249A, the facility shall ask the resident or the resident's personal representative whether the resident is a veteran and shall document the response. If the facility determines that the resident is a potential veteran, the facility shall report the resident's name along with the names of the resident's spouse and any dependent children, as well as the name of the contact person for this information, to the Iowa department of veterans affairs. Where appropriate, the facility may also report such information to the Iowa department of human services.

64.6(2) If a resident is eligible for benefits through the United States Department of Veterans Affairs or other third-party payor, the facility first shall seek reimbursement from the identified payor source before seeking reimbursement from the medical assistance program established under Iowa Code chapter 249A.

64.6(3) The provisions of this rule shall not apply to the admission of an individual as a resident to a state mental health institute for acute psychiatric care. (II, III)

481—64.7(135C) Licenses for distinct parts.

64.7(1) Separate licenses may be issued for distinct parts of a health care facility which are clearly identifiable, containing contiguous rooms in a separate wing or building or on a separate floor of the facility and which provide care and services of separate categories.

64.7(2) The following requirements shall be met for a separate licensing of a distinct part:

- a. The distinct part shall serve only residents who require the category of care and services immediately available to them within that part; (III)
- b. The distinct part shall meet all the standards, rules, and regulations pertaining to the category for which a license is being sought;
- c. The distinct part must be operationally and financially feasible;
- d. A separate staff with qualifications appropriate to the care and services being rendered must be regularly assigned and working in the distinct part under responsible management; (III)
- e. Separately licensed distinct parts may have certain services such as management, building maintenance, laundry, and dietary in common with each other.

481—64.8 to 64.16 Rescinded IAB 7/26/89, effective 7/7/89.

481—64.17(135C) Contracts. Each party shall receive a copy of the signed contract. (III) Each contract for residents shall:

64.17(1) State the rate or scale per day or per month for services included in the rate or scale and method of payment; (III)

64.17(2) Contain a complete schedule of all offered services for which a fee may be charged in addition to the base rate. (III) Furthermore, the contract shall:

- a. Stipulate that no further additional fees shall be charged for items not contained in complete schedule of services as set forth in this subrule; (III)
- b. State the method of payment of additional charges; (III)

c. Contain an explanation of the method of assessment of such additional charges and an explanation of the method of periodic reassessment, if any, resulting in changing such additional charges; (III)

d. State that additional fees may be charged to the resident for nonprescription drugs, other personal supplies, and services by a barber, beautician, etc.; (III)

64.17(3) Contain an itemized list of those services, with the specific fee the resident will be charged and method of payment, as related to the resident's current condition, based on a preadmission evaluation assessment which is determined in consultation with the administrator; (III)

64.17(4) Include the total fee per day to be charged to the resident; (III)

64.17(5) State the conditions whereby the facility may make adjustments to its overall fees for resident care as a result of changing costs. (III) Furthermore, the contract shall provide that the facility shall give:

a. Written notification to the resident, or responsible party when appropriate, of changes in the overall rates of both base and additional charges, at least 30 days prior to effective date of such changes; (III)

b. Notification to the resident, or responsible party when appropriate, of changes in charges, based on a change in the resident's condition. Notification must occur prior to the date such revised charges begin. If notification is given orally, subsequent written notification must also be given within a reasonable time, not to exceed one week, listing specifically the adjustments made; (III)

64.17(6) State the terms of agreement in regard to refund of all advance payments in the event of transfer, death, voluntary or involuntary discharge; (III)

64.17(7) State the terms of agreement concerning the holding and charging for a bed in the event of temporary absence of the resident; such terms shall include, at a minimum, the following provisions:

a. If a resident has a temporary absence from a facility for medical treatment, the facility shall ask the resident or responsible party if they wish the bed held open. This shall be documented in the resident's record including the response. Upon request of the resident/responsible party, the facility shall hold the bed open for at least ten days during the resident's absence and the facility shall receive payment for the absent period in accordance with provisions of the contract. (II)

b. If a resident has a temporary absence from a facility for therapeutic reasons as approved by a physician or qualified intellectual disabilities professional, the facility shall ask if the resident or responsible party wishes that the bed be held open. This request shall be documented in the resident's record, including the response. The bed shall be held open at least 30 days per year, and the facility shall receive payment for the absent periods in accordance with the provisions of the contract. The required holding during temporary absences for therapeutic reasons is limited to 30 days per year. (II)

c. For Title XIX residents the department of social services shall continue funding for the temporary absence as provided under paragraphs "a" and "b" and in accordance with department of social services guidelines.

d. Private pay residents shall have a negotiated rate stated in the signed contract relating to these provisions. (II)

64.17(8) State the conditions under which the involuntary discharge or transfer of a resident would be effected; (III)

64.17(9) State the conditions of voluntary discharge or transfer; (III)

64.17(10) Set forth any other matters deemed appropriate by the parties to the contract. No contract or any provision thereof shall be drawn or construed so as to relieve any facility of any requirement or obligation imposed upon it by this chapter or any standards or rules in force pursuant to this chapter. (III)
[ARC 0764C, IAB 5/29/13, effective 7/3/13]

481—64.18(135C) Records.

64.18(1) *Resident record.* The licensee shall keep a permanent record about each resident, with all entries current, dated, and signed. (II) The record shall include:

a. Name and previous address of resident; (III)

b. Birth date, sex, and marital status of resident; (III)

- c. Church affiliation of resident; (III)
- d. Physician's name, telephone number, and address; (III)
- e. Dentist's name, telephone number, and address; (III)
- f. Name, address, and telephone number of resident's next of kin or legal representative; (III)
- g. Name, address, and telephone number of the person to be notified in case of emergency; (III)
- h. Funeral director's telephone number and address; (III)
- i. Pharmacy's name, telephone number and address; (III)
- j. Certification by the physician that the resident requires no higher level of care than the facility is licensed to provide; (III)
- k. Physician's orders for medication and treatments in writing, which shall be signed by the physician quarterly, and diet orders, which shall be renewed yearly; (III)
- l. A notation of the resident's yearly or other visits to physician or other professionals and all consultation reports and progress notes; (III)
- m. Documentation describing any change in the resident's condition; (II, III)
- n. A notation describing the resident's condition on admission, transfer, and discharge; (III)
- o. In the event of a resident's death, notations in the resident's record shall include the date and time of the resident's death, the circumstances of the resident's death, the disposition of the resident's body, and the date and time that the resident's family and physician were notified of the resident's death; (III)
- p. A copy of instructions given to the resident, the resident's legal representative, or receiving facility in the event of the resident's discharge or transfer; (III) and
- q. Disposition of personal property. (III)

64.18(2) Confidentiality of resident records. The facility shall have policies and procedures providing that each resident shall be ensured confidential treatment of all information, including information contained in an automated data bank. The resident's or the resident's legal guardian's written informed consent shall be required for the release of information to persons not otherwise authorized under law to receive it. (II)

A release of information form shall be used which includes to whom the information shall be released, the reason for the release of the information, how the information is to be used, and the period of time for which the release is in effect. A third party not requesting the release shall witness the signing of the release of information form. (II)

a. The facility shall limit access to any resident records to staff and consultants providing professional service to the resident. Information shall be made available to staff only to the extent that the information is relevant to the staff person's responsibilities and duties. (II)

Only those personnel concerned with financial affairs of the residents may have access to the financial information. This paragraph is not meant to preclude access by representatives of state or federal regulatory agencies. (II)

b. The resident, or the resident's legal guardian, shall be entitled to examine all information and shall have the right to secure full copies of the record at reasonable cost upon request, unless the physician or qualified mental health professional determines the disclosure of the record or certain information contained in the record is contraindicated in which case the information will be deleted before the record is made available to the resident. This determination and the reasons for it must be documented in the resident's record by the physician or qualified mental health professional in collaboration with the resident's interdisciplinary team. (II)

64.18(3) Incident records. Each facility shall maintain an incident record report and shall have available incident report forms. (II, III)

- a. The report of every incident shall be in detail on a printed incident report form. (II, III)
- b. The person in charge at the time of the incident shall oversee the preparation of the report and sign the report. (III)
- c. The facility shall maintain a copy of the incident report as part of the facility's administrative records and shall make the record available for review. (III)

64.18(4) Retention of records. A resident's records shall be retained in the facility for five years following termination of services to the resident even when there is a change of ownership of the facility. (III)

When the facility ceases to operate, the resident's records shall be released to the receiving facility. If no transfer occurs, the records shall be released to the resident's physician. (III)

481—64.19 to 64.32 Reserved.

481—64.33(135C) Allegations of dependent adult abuse.

64.33(1) Allegations of dependent adult abuse. Allegations of dependent adult abuse shall be reported and investigated pursuant to Iowa Code chapter 235E and 481—Chapter 52. (I, II, III)

64.33(2) Separation of accused abuser and victim. Upon a claim of dependent adult abuse of a resident being reported, the administrator of the facility shall separate the victim and accused abuser immediately and maintain the separation until the department's abuse investigation is completed and an abuse determination is made. (I, II)

[ARC 1204C, IAB 12/11/13, effective 1/15/14]

481—64.34(135C) Employee criminal record checks, child abuse checks and dependent adult abuse checks and employment of individuals who have committed a crime or have a founded abuse. The facility shall comply with the requirements found in Iowa Code section 135C.33 as amended by 2013 Iowa Acts, Senate File 347, and rule 481—50.9(135C) related to completion of criminal record checks, child abuse checks, and dependent adult abuse checks and to employment of individuals who have committed a crime or have a founded abuse. (I, II, III)

[ARC 0903C, IAB 8/7/13, effective 9/11/13]

481—64.35(135C) Care review committee. Rescinded ARC 1205C, IAB 12/11/13, effective 1/15/14.

481—64.36(135C) Involuntary discharge or transfer.

64.36(1) Involuntary discharge or transfer permitted. A facility may involuntarily discharge or transfer a resident for only one of the following reasons:

- a. Medical reasons;
- b. The resident's welfare or that of other residents;
- c. Nonpayment for the resident's stay, as described in the contract for the resident's stay;
- d. Due to action pursuant to Iowa Code chapter 229;
- e. By reason of negative action by the Iowa department of human services; or
- f. By reason of negative action by the quality improvement organization (QIO). (I, II, III)

64.36(2) Medical reasons. Medical reasons for transfer or discharge shall be based on the resident's needs and shall be determined and documented in the resident's record by the primary care provider. Transfer or discharge may be required in order to provide a different level of care to the resident. (II)

64.36(3) Welfare of a resident. Welfare of a resident or that of other residents refers to a resident's social, emotional, or physical well-being. A resident may be transferred or discharged because the resident's behavior poses a continuing threat to the resident (e.g., suicidal) or to the well-being of other residents or staff (e.g., the resident's behavior is incompatible with other residents' needs and rights). Written documentation that the resident's continued presence in the facility would adversely affect the resident's own welfare or that of other residents shall be made by the administrator or designee and shall include specific information to support this determination. (II)

64.36(4) Involuntary discharge or transfer prohibited—payment source. A resident shall not be transferred or discharged solely because the cost of the resident's care is being paid under Iowa Code chapter 249A or because the resident's source of payment is changing from private support to payment under Iowa Code chapter 249A. (I, II)

64.36(5) Notice. Involuntary transfer or discharge of a resident from a facility shall be preceded by a written notice to the resident and the responsible party. (II, III)

- a. The notice shall contain all of the following information:

- (1) The stated reason for the proposed transfer or discharge. (II)
- (2) The effective date of the proposed transfer or discharge. (II)
- (3) A statement, in not less than 12-point type, that reads as follows:

You have a right to appeal the facility's decision to transfer or discharge you. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after the department's receipt of your request and you will not be transferred before a final decision is rendered. Extension of the 14-day requirement may be permitted in emergency circumstances upon request to the department's designee. If you lose the hearing, you will not be transferred before the expiration of either (1) 30 days following your receipt of the original notice of the discharge or transfer, or (2) no sooner than 5 days following final decision of such hearing, including the exhaustion of all appeals, whichever occurs later. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. (II)

b. The notice shall be personally delivered to the resident, and a copy shall be placed in the resident's record. A copy shall also be transmitted to the department, the resident's responsible party, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. The notice shall indicate that copies have been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent.

c. The notice required by paragraph 64.36(5) "a" shall be provided at least 30 days in advance of the proposed transfer or discharge unless one of the following occurs:

(1) An emergency transfer or discharge is mandated by the resident's health care needs and is in accordance with the written orders and medical justification of the primary care provider. Emergency transfers or discharges may also be mandated in order to protect the health, safety, or well-being of other residents and staff from the resident being transferred. (II)

(2) The transfer or discharge is subsequently agreed to by the resident or the resident's responsible party, and notification is given to the responsible party, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility.

(3) The discharge or transfer is the result of a final, nonappealable decision by the department of human services or the QIO.

d. A hearing requested pursuant to this subrule shall be held in accordance with subrule 64.36(7).

64.36(6) *Emergency transfer or discharge.* In the case of an emergency transfer or discharge, the resident must be given a written notice prior to or within 48 hours following the transfer or discharge. (II, III)

a. A copy of this notice shall be placed in the resident's file. The notice shall contain all of the following information:

- (1) The stated reason for the transfer or discharge. (II)
- (2) The effective date of the transfer or discharge. (II)
- (3) A statement, in not less than 12-point type, that reads as follows:

You have a right to appeal the facility's decision to transfer or discharge you on an emergency basis. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after the department's receipt of your request. You may be transferred or discharged before the hearing is held or before a final decision is rendered. If you win the hearing, you have the right to be transferred back into the facility. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. (II)

b. The notice shall be personally delivered to the resident, and a copy shall be placed in the resident's record. A copy shall also be transmitted to the department, the resident's responsible party, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. The notice shall indicate that copies have been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent.

c. A hearing requested pursuant to this subrule shall be held in accordance with subrule 64.36(7).
64.36(7) Hearing.

a. Request for hearing.

(1) The resident must request a hearing within 7 days of receipt of written notice.

(2) The request must be made to the department, either in writing or verbally.

b. The hearing shall be held no later than 14 days after the department's receipt of the request unless either party requests an extension due to emergency circumstances.

c. Except in the case of an emergency discharge or transfer, a request for a hearing shall stay a transfer or discharge pending a final decision, including the exhaustion of all appeals. (II)

d. The hearing shall be heard by a department of inspections and appeals administrative law judge pursuant to Iowa Code chapter 17A and 481—Chapter 9. The hearing shall be public unless the resident or representative requests in writing that the hearing be closed. In a determination as to whether a transfer or discharge is authorized, the burden of proof by a preponderance of the evidence rests on the party requesting the transfer or discharge.

e. Notice of the date, time, and place of the hearing shall be sent by certified mail or delivered in person to the facility, the resident, and the responsible party not later than five full business days after the department's receipt of the request. The notice shall also inform the facility and the resident or the responsible party that they have a right to appear at the hearing in person or be represented by an attorney or other individual. The appeal shall be dismissed if neither party is present or represented at the hearing. If only one party appears or is represented, the hearing shall proceed with one party present.

f. The administrative law judge's written decision shall be sent by certified mail to the facility, resident, and responsible party within 10 working days after the hearing has been concluded.

g. If the basis for an involuntary transfer or discharge is the result of a negative action by the Iowa department of human services or the QIO, an appeal shall be filed with those entities as appropriate. Continued payment shall be consistent with rules of those entities.

64.36(8) Nonpayment. If nonpayment is the basis for involuntary transfer or discharge, the resident shall have the right to make full payment up to the date that the discharge or transfer is to be made and then shall have the right to remain in the facility. (II)

64.36(9) Discussion of involuntary transfer or discharge. Within 48 hours after notice of involuntary transfer or discharge has been received by the resident, the facility shall discuss the involuntary transfer or discharge with the resident, the resident's responsible party, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. (II)

a. The facility administrator or other appropriate facility representative serving as the administrator's designee shall provide an explanation and discussion of the reasons for the resident's involuntary transfer or discharge. (II)

b. The content of the explanation and discussion shall be summarized in writing, shall include the names of the individuals involved in the discussion, and shall be made part of the resident's record. (II)

c. The provisions of this subrule do not apply if the involuntary transfer or discharge has already occurred pursuant to subrule 64.36(6) and emergency notice is provided within 48 hours.

64.36(10) *Transfer or discharge planning.*

a. The facility shall develop a plan to provide for the orderly and safe transfer or discharge of each resident to be transferred or discharged. (II)

b. To minimize the possible adverse effects of the involuntary transfer, the resident shall receive counseling services by the sending facility before the involuntary transfer and by the receiving facility after the involuntary transfer. Counseling shall be documented in the resident's record. (II)

c. The counseling requirement in paragraph 64.36(10) "b" does not apply if the discharge has already occurred pursuant to subrule 64.36(6) and emergency notice is provided within 48 hours.

d. Counseling, if required, shall be provided by a licensed mental health professional as defined in Iowa Code section 228.1(6). (II)

e. The health care facility that receives a resident who has been involuntarily transferred shall immediately formulate and implement a plan of care which takes into account possible adverse effects the transfer may cause. (II)

64.36(11) *Transfer upon revocation of license or voluntary closure.* Residents shall not have the right to a hearing to contest an involuntary discharge or transfer resulting from the revocation of the facility's license by the department of inspections and appeals. In the case of the voluntary closure of a facility, a period of 30 days must be allowed for an orderly transfer of residents to other facilities.

64.36(12) *Intrafacility transfer.*

a. Residents shall not be arbitrarily relocated from room to room within a licensed health care facility. (I, II) Involuntary relocation may occur only in the following situations, which shall be documented in the resident's record: (II)

(1) A resident's incompatibility with or disturbance to other roommates.

(2) For the welfare of the resident or other residents of the facility.

(3) For medical, nursing or psychosocial reasons, as judged by the primary care provider, nurse or social worker in the case of a facility which groups residents by medical, nursing or psychosocial needs.

(4) To allow a new admission to the facility that would otherwise not be possible due to separation of roommates by sex.

(5) In the case of a resident whose source of payment was previously private, but who now is eligible for Title XIX (Medicaid) assistance, the resident may be transferred from a private room to a semiprivate room or from one semiprivate room to another.

(6) Reasonable and necessary administrative decisions regarding the use and functioning of the building.

b. Unreasonable and unjustified reasons for changing a resident's room without the concurrence of the resident or responsible party include:

(1) Change from private pay status to Title XIX, except as outlined in subparagraph 64.36(12) "a"(5). (II)

(2) As punishment or behavior modification, except as specified in subparagraph 64.36(12) "a"(1). (II)

(3) Discrimination on the basis of race or religion. (II)

c. If intrafacility relocation is necessary for reasons outlined in paragraph 64.36(12) "a," the resident shall be notified at least 48 hours prior to the transfer and the reason therefor shall be explained. The responsible party shall be notified as soon as possible. The notification shall be documented in the resident's record and signed by the resident or responsible party. (II)

d. If emergency relocation is required in order to protect the safety or health of the resident or other residents, the notification requirements may be waived. The conditions of the emergency shall be

documented. The family or responsible party shall be notified immediately or as soon as possible of the condition that necessitates emergency relocation, and such notification shall be documented. (II)

e. A transfer to a part of a facility that has a different license must be handled the same way as a transfer to another facility and not as an intrafacility transfer. (II, III)

[ARC 1205C, IAB 12/11/13, effective 1/15/14; ARC 1752C, IAB 12/10/14, effective 1/14/15; ARC 3523C, IAB 12/20/17, effective 1/24/18]

481—64.37 to 64.58 Rescinded IAB 7/26/89, effective 7/7/89.

481—64.59(135C) County care facilities. Rescinded ARC 0764C, IAB 5/29/13, effective 7/3/13.

481—64.60(135C) Federal regulations adopted—conditions of participation. Regulations in 42 CFR Part 483, Subpart D, Sections 410 to 480 effective October 3, 1988, are adopted by reference and incorporated as part of these rules. A copy of these regulations is available on request from the Health Facilities Division, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

Classification of violations is I, II, and III, determined by the division using the provisions in 481—Chapter 56, “Fining and Citations,” to enforce a fine to cite a facility.

This rule is intended to implement Iowa Code section 135C.2(3).

481—64.61(135C) Federal regulations adopted—rights. Regulations in 42 CFR Part 483, Subpart B, Sections 10, 12, 13, and 15 effective August 1, 1989, are adopted by reference and incorporated as part of these rules. Section 10 governs resident rights; Section 12, admission, transfer or discharge rights; Section 13, resident behavior and facility practices; and Section 15, quality of life. Classification of violations for all of these regulations is I and II. A copy is available on request from the Health Facilities Division, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

NOTE: The federal interpretive guidelines are printed immediately following 481—Chapter 64.

This rule is intended to implement Iowa Code section 135C.14(8).

481—64.62(135C) Another business or activity in a facility. A facility is allowed to have another business or activity in a health care facility or in the same physical structure of the facility, if the other business or activity is under the control of and is directly related to and incidental to the operation of the health care facility, or the business or activity is approved by the department and the state fire marshal.

To obtain the approval of the department and the state fire marshal, the facility must submit to the department a written request for approval which identifies the service(s) to be offered by the business and addresses the factors outlined in paragraphs “a” through “j” of this rule. (I, II, III)

64.62(1) The following factors will be considered by the department in determining whether a business or activity will interfere with the use of the facility by residents, interfere with services provided to residents, or be disturbing to residents:

- a.* Health and safety risks for residents;
- b.* Compatibility of the proposed business or activity with the facility program;
- c.* Noise created by the proposed business or activity;
- d.* Odors created by the proposed business or activity;
- e.* Use of entrances and exits for the business or activity in regard to safety and disturbance of residents and interference with delivery of services;
- f.* Use of the facility’s corridors or rooms as thoroughfares to the business or activity in regard to safety and disturbance of residents and interference with delivery of services;
- g.* Proposed staffing for the business or activity;
- h.* Sharing of services and staff between the proposed business or activity and the facility;
- i.* Facility layout and design; and
- j.* Parking area utilized by the business or activity.

64.62(2) Approval of the state fire marshal shall be obtained before approval of the department will be considered.

64.62(3) A business or activity conducted in a health care facility or in the same physical structure as a health care facility shall not reduce space, services or staff available to residents below minimums required in these rules. (I, II, III)

481—64.63(135C) Respite care services. Respite care services means an organized program of temporary supportive care provided for 24 hours or more to a person in order to relieve the usual caregiver of the person from providing continual care to the person. A facility which chooses to provide respite care services must meet the following requirements related to respite care services and must be licensed as a health care facility.

64.63(1) A facility which chooses to provide respite care services is not required to obtain a separate license or pay a license fee.

64.63(2) Rules regarding involuntary discharge or transfer rights do not apply to residents who are being cared for under a respite care contract.

64.63(3) The facility shall have a contract with each resident in the facility. When the resident is there for respite care services, the contract shall specify the time period during which the resident will be considered to be receiving respite care services. At the end of that period, the contract may be amended to extend that period of time. The contract shall specifically state the resident may be involuntarily discharged while being considered as a respite care resident. The contract shall meet other requirements for contracts between a health care facility and resident, except the requirements concerning the holding and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons.

64.63(4) Respite care services shall not be provided by a facility to persons requiring a level of care which is higher than the level of care the facility is licensed to provide.

These rules are intended to implement Iowa Code sections 10A.202, 10A.402, 135C.2(6), 135C.6(1), 135C.14, 135C.14(8), 135C.25, 135C.25(3), 135C.32, 135C.36, 227.4, 235B.1(6), and 235B.3(11).

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[Filed ARC 5719C (Notice ARC 5560C, IAB 4/21/21), IAB 6/16/21, effective 7/21/21]

[◇] Two or more ARCs

¹ See IAB, Inspections and Appeals Department.

Interpretive Guidelines****§440.150 Intermediate Care Facility Services, Other Than in Institutions for Mental Diseases****W101**

W101 is reassigned to §483.410(e). Section 442.251, the standard which requires that facilities meet the requirement for a State license, is redesignated to §483.410(e) and W101 is reassigned as well to afford a sense of continuity.

W102

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410 Condition of participation: Governing body and management (a) Standard: Governing body

W103

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(a) The facility must identify an individual or individuals to constitute the governing body of the facility.

Guidance §483.410(a)

If concerns are noted regarding the governing body, written documentation verifies that the facility has designated the individual or individuals to constitute the governing body and their titles.

W104

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(a)(1) The governing body must exercise general policy, budget, and operating direction over the facility.

Guidance §483.410(a)(1)

The governing body develops, monitors, and revises, as necessary, policies and operating directions which ensure the necessary staffing, training resources, equipment and environment to provide clients with active treatment and to provide for their health and safety.

Direction by the Governing Body includes areas such as health, safety, sanitation, maintenance and repair, and utilization and management of staff.

Condition level operational deficiencies may be associated with a failure by the Governing Body to exercise general direction of the facility.

W105

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(a)(2) The governing body must set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility.

Guidance §483.410(a)(2)

The policies of the facility must include the qualifications of the administrator, and the qualifications are stated in the job description of the administrator.

W106

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(a)(3) The governing body must appoint the administrator of the facility.

Guidance §483.410(a)(3)

This appointment must be in writing.

(b) Standard: Compliance with Federal, State and local laws

§483.410(b) The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to:

Guidance §483.410(b)

The facility has no final adverse action by a Federal, State, or local authority. Such adverse actions include, but are not limited to fines, limitation on services that may be provided, or loss of licensure.

**Editor's Note: Verbatim from federal regulations. Neither the Department nor the Iowa Administrative Code editors have changed the content of the guidelines.

The facility must be able to provide for review, current licenses and permits as well as applicable reports of inspections by State or local health authorities.

If a situation is identified indicating the provider may not be in compliance with Federal, State, or local law, refer that information to the authority having jurisdiction (AHJ) for follow-up actions. See W107, W108, or W109.

W107

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(b) health,

Guidance §483.410(b)

Reference the specific law, regulation, or code not met.

W108

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(b) safety, and

Guidance §483.410(b)

Reference the specific law, regulation, or code not met.

W109

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(b) sanitation.

Guidance §483.410(b)

Reference the specific law, regulation, or code not met.

(c) Standard: Client Records

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

W110

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(c)(1) The facility must develop and maintain a record keeping system that includes a separate record for each client and;

W111

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(c)(1) that documents the client's health care, active treatment, social information, and protection of the client's rights.

Guidance §483.410(c)(1)

The structure and content of a client's record must be an accurate, functional representation of the actual experience of the client in the facility.

The record should contain an accurate account of all information relevant to the client's health care, active treatment, social information and protection of the client's rights, such as communications, correspondence, program plans (to include both in-house and outside service programs), progress summaries, activity plans and activity participation, incidents, consent forms and all medical information.

If the records are maintained electronically, the facility staff should be able to access various parts of the record without difficulty. If they are unable to access components of the record upon request, then this may indicate a lack of training by the facility.

W112

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(c)(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

Guidance §483.410(c)(2)

"Keep confidential" means safeguarding the content of information including video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the client, parent of a minor child, or legal guardian, and consistent with the advocate's right of access. Facility staff and consultants, hired to provide services to the client, sign confidentiality agreements before having access to client records and should have access to only that portion of information that is necessary to provide effective responsive services to the client.

These agreements should be renewed according to the policies of the facility. The agreement may stipulate that the agreements are in place until either the facility or member terminates the agreement. The facility has in place safeguards to ensure that access to all information regarding clients is limited to those clients designated by Health Insurance Portability and Accountability Act (HIPAA) requirements, the Developmental Disabilities Act, State law and facility policy.

The facility should prevent any instances of unauthorized access or dissemination. For example, the staff is observed to leave the client record (hard copy or electronic version) in the living room of the house when visitors or persons not authorized to access client records are present. Client records must be secured when staff is not present.

The facility must develop and follow procedures for maintaining the confidentiality of client information during transport to medical appointments or to other locations outside the facility.

Confidentiality applies to both central records and information kept at dispersed locations. If there is information considered too confidential to place in the record used by all staff (e.g., identification of the family's financial assets, sensitive medical data), it may be retained in a companion record located in a secure location in the facility with a notation made in the primary record as to the location of confidential information. The facility must ensure that any client information provided to day services programs is maintained confidential.

The sharing of client specific information with members of the "specially constituted committee" required by §483.440(f)(3), who are not affiliated with the agency, does not violate a client's right to have information about him or her kept confidential. The committee must have relevant information to function properly.

Facility confidentiality safeguards include the development and implementation of written policies to assure that members of the specially constituted team maintain confidentiality. Such processes may include signed confidentiality agreements. These agreements should be renewed according to the policies of the facility. The agreement may stipulate that the agreements are in place until either the facility or member terminates the agreement.

W113

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(c)(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

Guidance §483.410(c)(3)

The facility develops and follows written policies governing the release of client information.

Release of any personally identifiable information does not occur unless consent(s) is obtained prior to the release.

These policies must address at a minimum who must give consent for the release of information from records. The policy and procedures should account for other situations involving the release of client information, such as:

- who should be notified when records have been released;
- procedures to be followed with subpoenas;
- time frames for providing requested information; and
- information regarding a client's HIV status may not be released without specific consent and may not be in the record if that consent has not been given.

W114

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(c)(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

Guidance §483.410(c)(4)

Illegible writing in hard copy records can contribute to communication deficits among staff. Illegible writing which cannot be easily interpreted by facility staff upon surveyor request may constitute a safety issue.

Electronic signatures are acceptable in the electronic record system.

W115

§483.410(c)(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

W116

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(c)(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

Guidance §483.410(c)(6)

“Appropriate” means those parts of each client's record are most likely (or known) to be needed by the residential staff to carry out the client's active treatment program in the unit; to alert staff to health risks and other aspects of medical treatment; to support the psychosocial needs of the client; to contact family or emergency contacts, and to provide anything else necessary to the staff's ability to work on behalf of the client.

The staff of the residential living unit has, and can access, all information which is relevant to implementing client program plans, appropriate care of, interaction with, and provision of services for the client.

(d) Standard: Services provided under agreements with outside sources**W117**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(d)(1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

Guidance §483.410(d)(1)

If a service is not provided directly, there must be a written agreement for such services.

Written agreements are required for emergency services such as dentists and pharmacies. For those services that require a visit to a hospital, the Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) typically utilizes services from an emergency department of the hospital, thus no written contract is required.

Federal statute (P.L. 94-142) requires all school-aged children to receive a free and appropriate school education. Therefore, a written agreement between ICF/IIDs and public schools is not necessary.

W118

(d)(2)(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

W119

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(d)(2)(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.

W120

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(d)(3) The facility must assure that outside services meet the needs of each client.

Guidance §483.410(d)(3)

Outside services are any services needed by the clients and not provided directly by the facility (hospital visits, dental visits, day program services, etc.).

Programs and services must be coordinated between the facility and the outside service, and foster consistency of implementation across settings of teaching strategies and behavior management.

The facility monitors outside services on an ongoing basis to ensure that services provided are consistent with the needs of each client as identified in the Individual Program Plan (IPP). For example, if the facility is implementing a behavior management or a communication program for the client, it is shared with the outside program and implemented by the outside program (workshop, day program, etc.) and the outside program agrees to incorporate it into their day program. At periodic intervals, the facility staff visit or communicate with the outside program to verify consistency across the two settings.

With outside resources, it is the responsibility of the facility to assure that the services are provided in a safe clean environment, by appropriately qualified professions, and any untoward outcome of services are promptly addressed. If, in spite of attempts by the facility to assure compliance, the outside program does not implement the program for the client, then the facility remains responsible for the lack of active treatment.

W121

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(d)(4) If living quarters are not provided in a facility owned by the ICF/IID, the ICF/IID remains directly responsible for the standards relating to physical environment that are specified in §483.470(a) through (g), (j) and (k).

Guidance §483.410(d)(4)

Even though the facility's premises may be rented from a landlord, the facility must ensure that the requirements for physical environment are met, either through arrangement with the landlord or through the facility's own services.

(e) Standard: Licensure

§483.420(a) Standard: Protection of Clients' Rights

The facility must ensure the rights of all clients. Therefore, the facility must

Guidelines §483.420(a)

"Ensure" means that the facility actively asserts the individual's rights and does not wait for him or her to claim a right. This obligation exists even when the individual is less than fully competent and requires that the facility is actively engaged in activities which result in the pro-active assertion of the individual's rights, e.g., guardianship, advocacy, training programs, use of specially constituted committee, etc.

§483.410(e) Standard: Licensure

W101

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.410(e) The facility must be licensed under applicable State and local law.

Guidance §483.410(e)

The facility has a current, valid State license when required under State law.

W122

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420 Condition of participation: Client protections

(a) Standard: Protection of clients' rights

§483.420(a) The facility must ensure the rights of all clients. Therefore the facility must

Guidance §483.420(a)

The facility must ensure the client's rights and does not wait for him or her to claim a right. This obligation exists even when the client is less than fully competent and requires that the facility is actively engaged in activities which result in the protection of the client's rights, advocacy for individual clients who have no family or an inactive family, and training programs for clients and staff on the understanding and protection of client rights.

W123

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;

Guidance §483.420(a)(1)

The obligation to inform requires that the facility presents information on rights to the client, his or her family or his or her legal guardian in a manner and form which they can understand. In most instances, family means parent. However, in those instances where parents are deceased or choose not to be active in the client's life and there is another family member who does wish to be active, but is not the legal guardian, this family member should be informed of the client's rights. Printed materials should be provided in understandable terms and provided in the language necessary to ensure understanding. Specialized methods, as indicated, should be provided for communication with clients, families or legal guardians with hearing or vision impairment.

Pro-active assertion of client rights includes, but is not limited to:

- Signed evidence that the client, his or her family and/or his or her legal guardian have been informed of the client's rights, and
- Evidence that the communication of these rights were provided at the client's level of comprehension, and in the language understandable to the client.

The obligation to inform also requires that the facility make some determination of whether the client and his or her family, or legal guardian understood the rights presented and made additional efforts to communicate the rights if the rights were not understood.

If the facility has written "rules of the facility", these rules must be communicated to the client, their family and or legal guardians at the time of admission and must not be in conflict with any of the rights listed in 42 CFR 483.420 (a) (1-13).

W124

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

Guidance §483.420(a)(2)

Clients, their families or legal guardians are promptly informed of any change in the client's medical or behavioral needs that requires immediate alteration to programmatic or medical intervention. Promptly is defined by the level of severity of the alteration. In each case, they must also be informed of the attendant risks of any recommended treatments or interventions and of their right to refuse treatment, training or services.

If parents or legal guardians wish for other members of the client's family to be informed of such changes, they must put this permission in writing.

The communication of this information must be provided in the manner and language understood by the client or their family or legal guardian (language boards, sign language, etc.).

The term "attendant risks of treatment" describes the risk vs. risk and risk vs. benefit associated with the treatment. These risks include possible side effects, other complications from treatments including medical and drug therapy, unintended consequences of treatment, other behavioral or psychological ramifications arising from treatment, etc.

The facility actively attempts to engage clients who refuse to participate in active treatment. While the regulation recognizes the client's right to refuse treatment, persistent refusal that impacts the health and safety of the client and/or others, or the ability to provide overall active treatment, may result in facility's consideration of alternative placements for the client. It is expected, however, that the facility has assessed the reason for refusal, and developed and implemented all possible interventions to engage the client in active treatment programs prior to referring the client to another therapeutic setting.

A client, his or her family member, or legal guardian who refuses a particular treatment (e.g., a behavior control, seizure control medication or a particular intervention strategy) must be offered information about acceptable alternatives to the treatment, if acceptable alternatives are available. The client's preference about alternatives should be elicited and considered in deciding on the course of treatment. If the client, family member, or legal guardian also refuses the alternative treatment, or if no alternative exists to the treatment refused, the facility must consider the effect this refusal may have on other clients, the client himself or herself, and if they can continue to provide services to the client consistent with these regulations.

If the facility is unable to provide services to a client due to consistent refusal to participate, they must weigh all options including an involuntary discharge. Involuntary discharge must be for good cause (see 483.440(b)(4)(i)).

When a client is considered for participation in experimental research the client, his/her family and/or legal guardian must be fully informed of the nature of the experiment (e.g., what medications or physical interventions will be utilized, the length of the research, any possible side effects and how the information from the research will be utilized). Information regarding the possible consequences of participating or not participating must be provided to the client, family member or legal guardian. The written consent

of the client, his/her family or legal guardian must be received prior to participation. For a client who is a minor or who has been adjudicated as incompetent, the written informed consent of the parents of the minor or the legal guardian is required. The signed, informed consent documentation must be in compliance with HHS Guidelines for Research Involving Human Subjects. The signed consent must also include a clear discussion of what treatments will be included in the research, the time limits for the research and should clearly inform the client, family member or legal guardian that the client may end participation at any time without fear of recrimination. If the research protocol indicates that clients receive compensation, then clients are compensated per the protocol.

Any research must be reviewed and approved by the Specially Constituted Committee. See W263.

W125

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process;

Guidance §483.420(a)(3)

To the extent that a client is able, choices are made on his/her own. Each client has autonomy of decision making and choice.

They are free to move about without limitations imposed due to staff preferences or staff convenience.

Clients are not restricted without due cause or due process.

To the extent that the client is able to make decisions for him or herself, it is inappropriate to delegate the person's right to others (e.g. parents, family members, etc.).

The facility has an obligation to assure client health and safety and must balance that obligation with the rights of clients.

If the facility has implemented a restriction, the following should be in place:

- An assessment supporting the need for the restriction;
- An individualized behavior plan to reduce the need for the restriction has been developed and implemented;
- A written informed consent for the behavior plan which includes the restriction;
- Approval of the Specially Constituted Committee; and
- Monitoring by the Committee of the progress of the training program, designed to reduce and eventually eliminate the restriction.

Clients, families, and legal guardians have the right to register a complaint with the facility and the State Survey Agency. If so, the facility must respond promptly and appropriately. The facility must ensure protection of the client from any form of reprisal or intimidation as a result of a complaint or grievance reported by the client, family, or legal guardian.

Issues involving the exercise of constitutional rights such as voting should be addressed as a component of the IPP when the Interdisciplinary Team (IDT) determines a need for training. Clients who have been adjudged to need guardianship or have been assessed as needing assistance to advocate for themselves should receive assistance or support so they may exercise their rights as citizens of the United States.

W126

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

Guidance §483.420(a)(4)

The regulation is clear that in those cases where a client already possesses the skills necessary to independently manage their own financial affairs, the facility will allow the client to continue to do so. Formal training in financial management must be provided for all other clients in the facility to the extent of their capabilities. The regulation places the responsibility for determining the extent of the client's capabilities in this matter upon an assessment and interdisciplinary process within the facility.

To reach a determination as to whether a money management program is appropriate, the facility IDT uses the comprehensive functional assessment (CFA) to evaluate the ability of each client to participate in such a program. Under 42 C.F.R. 483.440(c)(3), the team evaluation must establish, through

documentation, that the IDT considers all of the objective data within the assessment in reaching their determination, especially the identification of client skills which can be used across training programs. Examples of assessment findings that may be considered by the IDT include skills that can be cross-utilized in training programs such as:

1. Fine motor coordination;
2. The ability to make choices;
3. The ability to identify preferences; and
4. Cognitive abilities including tracking, attention span, communication, and the client's ability to understand the cause and effect. (The client understands of cause and effect is significant in the determination.)

Money management includes a broad spectrum of programs with varying levels of participation by the client ranging from the use of choice in money expenditures, to an understanding of the concept of money, and ultimately to actual money handling and budgeting. The IDT must not conclude that a money management program is inappropriate based solely upon the level of intellectual or physical disability of the client.

The CFA must be reviewed at least annually per 42 C.F.R.483.440(f)(2). As a part of this annual review, a client's ability to participate in money management will also be reviewed. The annual review should always include an update to the CFA and take into consideration any changes in the client's circumstances since the last IPP. The need for a formal money management program must be addressed in every client's IPP by the IDT on an annual basis.

The determination of the appropriateness of a formal money management program is made by the IDT and must be based upon a CFA. The IDT discussions resulting in that determination must be established through documentation in the client's IPP.

W127

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

Guidance §483.420(a)(5)

Identification of patterns or isolated instances of physical, verbal, sexual or psychological abuse or punishment without prompt identification and corrective action by the facility would result in a non-compliance determination for this Standard and Condition level non-compliance.

The facility must develop and implement systems that protect clients from all forms of abuse, neglect, or mistreatment, including client to client abuse, neglect, or mistreatment.

a. The facility is expected to ensure that staff possess and demonstrate needed competencies to effectively and appropriately interact with clients.

b. The facility must monitor to assure that systems are effectively implemented and the facility takes immediate actions to address circumstances where abuse, neglect, or mistreatment have occurred and prevent reoccurrence.

c. The facility must be organized in such a manner as to proactively assure clients are free from any threat to their physical and psychological health and safety.

d. The facility must act to prevent physical, verbal, sexual or psychological abuse. If the facility fails to implement appropriate corrective action, the potential of additional threats to the clients remain at the facility.

“Threat”, for the purposes of this guideline, is considered any condition/situation which could cause or result in severe, temporary or permanent injury or harm to the mental or physical condition of clients, or in their death.

“Abuse”, for the purposes of this guideline, is the willful infliction of injury, unreasonable confinement, intimidation or punishment with the resulting physical harm, pain or personal anguish.

Physical abuse refers to any action intended to cause physical harm or pain, trauma or bodily harm (e.g., hitting, slapping, punching, kicking, pinching, etc.). It includes the use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment.

Verbal abuse refers to any use of insulting, demeaning, disrespectful, oral, written or gestured language directed towards and in the presence of the client. Psychological abuse includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation, sexual coercion and intimidation (e.g. living in fear in one's own home). Since many clients residing in ICF/IIDs are unable to communicate feelings of fear, humiliation, etc. associated with abusive episodes, the assumption is made that any actions that would usually be viewed as psychologically or verbally abusive by a member of the general public, would also be viewed as abusive by the client residing in the ICF/IID, regardless of that client's perceived ability to comprehend the nature of the incident.

Sexual abuse includes any incident where a client is coerced or manipulated to participate in any form of sexual activity for which the client did not give affirmative permission (or gave affirmative permission without the attendant understanding required to give permission) or sexual assault against a client who is unable to defend him/herself.

The facility must implement, through policies, oversight and training, safeguards to ensure that clients are not subjected to abuse by anyone including, but not limited to, facility staff, consultants or volunteers, staff of other agencies serving the client, family members or legal guardians, friends, other clients, or the general public.

The facility must take whatever action is necessary to protect the clients residing there. For example, if a facility is forced by court order or arbitration rulings to retain or reinstate an employee found to be abusive, the facility must take measures to protect the clients of the facility (such as assigning the employee to an area where there is no contact with clients).

W128

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

Guidance §483.420(a)(6)

The facility must implement an aggressive active treatment program, which includes appropriate replacement behaviors, to address the reduction/elimination of physical restraints and drugs to manage behaviors.

For purposes of this Guideline drugs to manage behavior are "unnecessary" if there is evidence the drugs are being used:

- In excessive dose (duplicate therapy);
- For excessive duration;
- Not monitored adequately;
- Without adequate indications for its use;
- With adverse consequences which indicate the dose should be reduced or discontinued; or
- Any combination of the reasons listed above.

The long term use of a drug/physical restraint to manage behavior combined with one or more of the following may indicate unnecessary use:

- The client's developmental and/or behavioral needs are not being met and the appropriateness of less restrictive approaches to manage inappropriate behaviors should be questioned;
- Staff behavior may be prompting behaviors in clients which result in the chronic use of physical restraints and drugs to control behavior;
- Staff may have inadequate training and/or experience to provide active treatment and employ preventive measures;

Restraints applied for behaviors when less restrictive measures have not been tried or have been tried and found to be just as effective.

W129

(Rev. 144, Issued: 08-14-15, Effective: 08-14-15, Implementation: 08-14-15)

§483.420(a)(7) Provide each client with the opportunity for personal privacy and

Guidance §483.420(a)(7)

The facility must provide areas within the living area in which the client can have time to be alone, when appropriate, and to have privacy (their conversations cannot be overheard) for personal

interactions/activities. There should be a location where the client can meet privately with family and/or friends and a telephone available where he/she can hold private telephone conversations.

Personal privacy for clients also includes the right to have certain personal information about them kept confidential. Staff should not discuss one client in front of others (clients, parents, legal guardians, visitors, etc.) and should not post personal information about clients in areas where other clients, families and the public can read the information.

Video/audio taping or live feed must not be used in place of or for the convenience of staff. The facility may install video/audio equipment for purposes of observing client/staff interactions. Video/audio equipment may only be installed in common areas (in no case may videotaping or live feed be done in bathrooms or areas where private visits are conducted). The clients, families and/or legal guardians of the clients residing in the areas where videotaping or live feed will occur must give informed consent for the installation and must be assured that no personal privacy will be jeopardized. The use of the equipment must be presented at and approved by the specially constituted committee for the facility prior to the installation of video or audio devices.

Motion sensors should not be considered cameras.

W130

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(7) ensure privacy during treatment and care of personal needs;

Guidance §483.420(a)(7)

Clients must be provided privacy during personal hygiene activities (e.g., toileting, bathing, dressing) and during medical/nursing treatments that require exposure of one's body.

People not involved in the care of the client should not be present without their consent while they are being examined or treated.

Whenever possible, the facility should be sensitive to clients' preferences for same sex care in private situations.

W131

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(8) Ensure that clients are not compelled to perform services for the facility and

Guidance §483.420(a)(8)

Clients are not required or expected to be a source of labor for a facility. The client must not be required or expected to do productive work for the facility, other than appropriate care of one's own personal space or shared responsibilities for common areas.

W132

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(8) ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

Guidance §483.420(a)(8)

"Work", as used in the regulation, means any directed activity, or series of related activities which results in a benefit to the economy of the facility or in a contribution to its maintenance, or in the production of a salable product. In deciding whether a particular activity constitutes "work" as defined above, the key determinant is whether the facility would be required to hire additional full or part-time staff (or pay overtime to existing staff) to perform the service the client is asked to perform.

Clients volunteering to do real work that benefits the facility should give informed consent for such practices and understand that by providing employable services they are able to be compensated. This does not preclude a client from helping out a friend or being kind to others. Self-care activities related to the care of one's own person or property are not considered "work" for purposes of compensation.

In general, participation in any household task which promotes greater independent functioning and assists the client to prepare for less restrictive setting (and which the client has not yet learned) is permitted as long as tasks are included in the IPP in written behavioral and measurable terms. This participation must be supervised, and indices of performance should be available. No task may be performed for the convenience of staff (e.g., supervising clients, running personal errands).

“Compensated” means the client is provided with money or other forms of negotiable compensation for work (including work performed in an occupational training program) and such compensation is to be used at the client’s discretion.

Prevailing wage refers to the wage paid to non-disabled workers in nearby industry or the surrounding community for essentially the same type, quality and quantity of work or work requiring comparable skills. A client who works in the facility must be paid at least the prevailing minimum wage, unless an appropriate certificate has been obtained by the facility in accordance with current regulations and guidelines issued under the Fair Labor Standards Act, as amended.

Any client performing “work”, as defined above, must be compensated in direct proportion to his or her output. The facility should utilize Department of Labor and/or Department of Vocational Rehabilitation formulas and techniques for determining rate of pay. A client’s pay is not dependent on the production of other clients when he or she works in a group.

When the client’s active treatment program includes assignment to occupational or vocational training or work, specific work objectives of anticipated progress should be included in the IPP along with reasons for the assignments. If the training of clients on particular occupational activities or functions involves “real work” to be accomplished for the facility, the clients must be compensated based on ability. For example, if in the process of work training activities which involve learning to clean a floor, the floor for a particular building is cleaned and does not require further janitorial cleanup, then the client must be compensated for this activity at the prevailing wage.

W133

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice,

Guidance §483.420(a)(9)

Privacy must be provided for both face-to-face interactions and electronic interactions.

The facility must provide opportunities for the client to communicate, through regular mail, telephone and/or electronic mail and meet in private with persons of their choice (e.g., friends from the community, family members, and advocates). There may be instances where legal guardians override the wishes of the client. In these instances, the facility should be actively working with the legal guardian and the client to reach the maximum agreeable level of interaction for the client.

Space must be provided for clients to receive visitors in reasonable comfort and privacy.

W134

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(9) and to send and receive unopened mail;

Guidance §483.420(a)(9)

Clients must be provided the opportunity to send/receive all types of mail unopened and read the contents themselves if able. If the staff has to open and read mail to the client, this should be done in a private place allowing the client as much participation as possible.

Clients who have their own electronic equipment must be provided the opportunity to send, receive, and read electronic mail with privacy.

W135

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

Guidance §483.420(a)(10)

Any restriction of telephone access must be explained in the IPP with a plan to advance the client’s access. For persons with hearing loss who could benefit, Text Telephone (TTY) services or other accommodations should be provided.

As with any other rights restriction, the restriction must be addressed in the IPP, written informed consent obtained, and the plan must be reviewed and approved by the specially constituted committee.

W136

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

Guidance §483.420(a)(11)

Clients should be offered the opportunity to participate in various types of activities in the community (e.g., going to grocery stores, hair salons, restaurants, places of worship, pharmacies, community meetings and events) based on their interests and choices. The facility must make accommodations for physical issues such as hearing impairment and mobility limitations. In addition, clients should be taught the applicable skills to participate in their choice of activities to the fullest extent of their abilities. It is not acceptable for all client activities to be provided in the facility.

When a client is identified to be on restriction from community integration opportunities, interview clients, families, legal guardians and staff to determine if due process was afforded for this restriction and whether the restriction is included in the IPP.

In the event of a court placement that restricts community access, due process does not apply.

There should be evidence that the facility assists and encourages all clients, regardless of functioning levels, to have input into the decisions on community integration activities.

It is not acceptable to require clients to attend unwanted activities due to staffing considerations.

W137

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and

Guidance §483.420(a)(12)

Clients should have personal possessions and clothing which meet their needs, interests and choices.

Clients should have free access to their own possessions and clothing. When considering whether a client has free access to their personal possessions and clothing, ensure that physical limitations have been addressed.

Clients who are unable to access and use personal possessions and clothing appropriately are involved in programs to learn the necessary skills to do so.

In situations where the behavior of one or more clients in a living area prevents free access to personal possessions for each client, the facility must develop IPPs for the client with disruptive behavior. The facility must also ensure that during the implementation of this program plan that none of the other clients have their rights infringed upon. Clients should not be without personal possessions because of the behavior of others with whom they live.

All client possessions, regardless of their apparent value to others are treated with respect for what they may represent to the client. Where those choices include socially stigmatizing materials, the facility should provide learning opportunities to make more socially appropriate choices. The facility should encourage clients to use or display possessions of his or her choice in a culturally normative manner.

If a method for identifying personal effects is used, it should be inconspicuous and in a manner that will assist the client to identify them.

“Appropriate” clothing means a supply of clothing that is sufficient, in good repair, accounts for a variety of occasions and seasons, and appropriate to age, size, gender, and level of activity. Modification or adaptation of clothing fasteners should be considered based on the needs of a client with a physical disability to become more independent.

As appropriate, each client’s active treatment program maximizes opportunities for choice and self-direction with regard to choosing and shopping for clothing which enhances his or her appearance, and selecting daily clothing in accordance with age, sex and cultural norms.

Clients are permitted to keep personal clothing and possessions for their use while in the facility. Determine how the facility both ensures the safety of personal possessions while at the same time providing client access to them when the client chooses.

Clients are provided the opportunity, encouraged, and trained to use age-appropriate materials. The term “age-appropriate” refers to anything that reinforces recognition of the client as a person of a certain chronological age. Clients who choose to keep items traditionally used by children such as dolls or

model cars are not an automatic citation. There must be evidence the facility is encouraging the client to use these possessions in a socially appropriate, non-stigmatizing manner. The facility's environment must be furnished with materials and activities that will enhance opportunities for growth.

W138

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(12) ensure that each client is dressed in his or her own clothing each day; and

Guidance §483.420(a)(12)

Clothing such as pajamas, underwear, socks, hats, mittens/gloves, and coats should be the personal property of the client and not considered "*stock*" items. There should be no communal clothes. If clients are unable to do their own personal laundry the facility must ensure that clothing is properly laundered and returned to the appropriate client.

The staff of the facility should ensure that clients dress appropriately for the season and the occasion by implementing training programs or guidance for the client as indicated.

W139

§483.420(a)(13) Permit a husband and wife who both reside in the facility to share a room.

§483.420(b) Standard: Client Finances

(b)(1) The facility must establish and maintain a system that

W140

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(b)(1)(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and

Guidance §483.420(b)(1)(i)

All purchases made using client personal funds must be itemized in the accounting record with the exception of pocket money. Pocket money given to the client does not need to be itemized. Pocket money should be considered a nominal amount of five dollars or less at a time. Funds provided by the facility and dispensed to a client as part of a program to train the client in money management, and funds that are not entrusted to the facility (e.g., funds paid directly to the client's representative payee) do not require accounting.

In those instances where a legal guardian or the individual client is in control of their personal funds, no accounting is necessary by the facility.

W141

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(b)(1)(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

Guidance §483.420(b)(1)(ii)

If the facility elects to pool clients' funds in an interest-bearing account, including common trust accounts, it is expected to know the interest separately accrued by each client, as part of its required accounting of funds. Interest accumulated to a client's account belongs to the client, not the facility.

W142

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(b)(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

Guidance §483.420(b)(2)

Those persons having legal authority to access the accounting records for personal funds such as the client, parent, or legal guardians should be afforded access upon request unless there is documented rationale for withholding the information.

It is not necessary that a facility furnish an annual financial statement to the client, or the client's parent or legal guardian, since the facility is already required to make the financial record available at any time upon request. The client, parent, and/or legal guardian, in turn, is free to choose to make the financial record available to anyone else.

(c) Standard: Communication with clients, parents, and guardians.

§483.420(c)

**The Facility must –
W143**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(c)(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

Guidance §483.420(c)(1)

The facility must maintain an on-going effort to communicate with parents, family members and/or legal guardians regarding the implementation of active treatment programs for the client. The facility encourages and engages parents, family members and legal guardians in the continued implementation of active treatment programs even while spending time outside of the facility setting.

“Unobtainable”, for the purposes of this guideline, means that the facility has made a good faith effort to seek parental or legal guardian participation in the process, even though the effort may ultimately be unsuccessful (for example, the parent may be impossible to locate or may prove unwilling or unable to participate).

“Inappropriate”, for the purposes of this guideline, means that behavior of the parent or legal guardian could be disruptive or detrimental to the client’s program outcome. In this case, determine what the facility has done to bring effective resolution to the problem.

W144

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(c)(2) Answer communications from clients’ families and friends promptly and appropriately;

Guidance §483.420(c)(2)

It is reasonable to expect that the facility will provide at least an interim response to inquiries from the client’s families and friends within 48 hours.

W145

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(c)(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client’s and other clients’ privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

Guidance §483.420(c)(3)

Any limitations on visitors must be implemented as a result of IDT evaluation and discussion and be documented. This documentation should include evidence of approval from the specially constituted committee. Decisions to restrict a visitor for an individual client must be reviewed and re-evaluated each time the IPP is reviewed or at the client’s request. Broad restrictions on visitors such as times of the day or certain days of the week are a violation of this requirement.

W146

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(c)(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client’s and other clients’ privacy;

W147

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(c)(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

Guidance §483.420(c)(5)

The facility should assist and encourage the client to communicate with their families or legal guardians concerning possible outside visits and vacations as frequently as possible. When the client does schedule a trip or vacation, the facility must ensure that all necessary preparation is completed to facilitate the departure.

The facility should not sponsor or allow clients to take a particular type of trip that would jeopardize their safety or health without consultation with parents/legal guardians and/or the IDT.

W148

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(c)(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.

Guidance §483.420(c)(6)

“Significant” incidents or changes in the client's condition include serious injury, unusual seizure activity, hospitalization, serious illness, accident, death, allegations of abuse, neglect, or mistreatment, unauthorized absence, or any notifications the parent or legal guardian's requests.

It is reasonable to expect the facility to contact the family or legal guardian of a client as soon as possible after an incident occurs, but no later than 24 hours after the incident. If notification is done via electronic mail, the facility must request a response from the e-mail recipient to confirm notification. Telephone notification must be accomplished by talking to the person directly. If a message is left, the facility must request a call back to confirm receipt of the notification.

Contact by letter may be utilized as follow up confirmation, but not be the initial, primary or sole mode of communication with the family or legal guardian.

If unable to contact the family or legal guardian, there should be evidence that the facility attempted to reach alternate emergency contacts.

Requests from clients who are their own guardian to limit notifications to their families must be honored.

(d) Standard: Staff treatment of clients.

W149

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.

Guidance §483.420(d)(1)

The facility, through implementation of its policies, must set up a structure that screens and trains employees, protects clients and prevents, identifies, investigates and reports abuse, neglect and mistreatment of clients.

The policies must designate who (either by name or title) has the authority to act in the Administrator's absence and take any immediate corrective actions necessary to assure a client's safety such as removing a staff person from direct client contact.

“Mistreatment”, for the purposes of this guideline, includes behavior or facility practices that result in any type of client exploitation such as financial, physical, sexual, or criminal. Mistreatment also refers to the use of behavioral management techniques outside of their use as approved by the specially constituted committee and facility policies and procedures.

“Neglect” means failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness. Staff failure to intervene appropriately to prevent self- injurious behavior may constitute neglect. Staff failure to implement facility safeguards, once client to client aggression is identified, may also constitute neglect.

Refer to W127 for definitions of abuse.

W150

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(1)(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.

W151

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(1)(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.

W152

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(1)(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.

Guidance §483.420(d)(1)(iii)

The facility is required to screen potential employees for a prior employment history of child or client abuse, neglect or mistreatment, as well as for any conviction based on those offenses. The abuse, neglect or mistreatment must have been directed toward a child or a client/resident/patient of a health care facility in order for the prohibition of employment to apply.

No one with a conviction or substantiated allegation of child or client abuse, neglect or mistreatment regardless of employment date, is employed by the facility. This requirement also applies to acts of abuse, neglect or mistreatment committed by a current ICF/IID employee outside the jurisdiction of the ICF/IID (e.g., in the community or in another health care facility). The facility must follow state guidelines or requirements for background checks to assure that they make every effort to check new employee's background.

Where the facility has terminated an employee based upon confirmation that abuse, neglect or mistreatment occurred during the employee's performance, and the termination decision was overturned by either arbitration finding or a court finding, the employee must be returned to a position which does not involve direct contact between that employee and clients of the facility.

A person who abused a resident in a nursing facility, and as a result, is barred from employment in the nursing home setting would also be prohibited from employment in the ICF/IID. While facilities are not required to periodically screen existing employees, if the facility becomes aware that such action has been taken against an employee, the facility is required to prohibit continued employment. This is also true of any conviction in a court of law for child, elder, or client (resident, patient) abuse, neglect or mistreatment. Therefore, conviction for abusing one's own child is also a reason employment would be prohibited.

W153

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.

Guidance §483.420(d)(2)

Injuries of unknown source that give rise to a suspicion that they may be the result of abuse or neglect, should be reported immediately.

An injury should be reported as an "injury of unknown source" when:

- The source of the injury was not witnessed by any person and the source of the injury could not be explained by the client; and
- The injury raises suspicions of possible abuse or neglect because of the extent of the injury or the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) or the number of injuries observed at one particular point in time or the incidence of injuries over time.

It is important to note that members of the ICF/IID population are a mobile population and lead active lives. Therefore, they experience normal day-to-day bumps and minor abrasions as they go about their lives. These minor occurrences which are not of serious consequence to the individual and do not present as a suspicious or repetitive injury (as discussed above) should be recorded by the facility staff once they are aware of them and follow-up should be conducted as indicated. For injuries that do not rise to the level of reportable "injuries of unknown source", the facility should follow its policies and procedures for incident recording, investigation, and tracking.

The facility must immediately report any suspicious injuries of unknown source and all allegations of mistreatment, neglect or abuse to a client residing in the facility regardless of who is the alleged perpetrator (e.g., facility staff, parents, legal guardians, volunteer staff from outside agencies serving the client, neighbors, or other clients, etc.).

If state law requires reporting to an agency or entity other than the administrator, the Centers for Medicare & Medicaid Services (CMS) expects the administrator to be notified as well, in order to ensure facility response to promptly safeguard the client(s).

For the purposes of this regulation "immediately" means there should be no delay between staff awareness of the occurrence and reporting to the administrator or other officials in accordance with

State law unless the situation is unstable in which case reporting should occur as soon as the safety of all clients is assured.

W154

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(3) The facility must have evidence that all alleged violations are thoroughly investigated and

Guidance §483.420(d)(3)

In the absence of any pre-survey information that would indicate the need for a more thorough review of reports of investigation, review 5 percent of the total client investigations for the last three (3) months (but no less than 10).

A thorough investigation includes at a minimum:

- The collection of all interviews, statements, physical evidence and any pertinent maps, pictures or diagrams;
- Review of all information;
- Resolution of any discrepancies;
- Summary of conclusions; and
- Recommendations for action both to safeguard all the clients during the investigation and after the completion of the report.

If patterns of possible abuse, mistreatment or neglect are identified, or the incident report logs for the past three (3) months indicate an extremely high incident rate, then a full review of the incidents for the past three (3) months should be completed.

W155

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(3) must prevent further potential abuse while the investigation is in progress.

Guidance §483.420(d)(3)

The facility must take all measures necessary to protect the client, including removal of the staff from working with the client if indicated. See W154.

W156

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and,

Guidance §483.420(d)(4)

Some states require that allegations of abuse must be reported to the police. A police investigation may take longer than five (5) working days. Their investigation does not change the requirement that the facility must complete an internal investigation report of findings within the five day timeframe. When outside authorities are involved, the facility will still be required to complete their investigation within five days to the extent authorized by such entities. "Working days" means Monday through Friday, excluding state and Federal holidays.

W157

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(d)(4) if the alleged violation is verified, appropriate corrective action must be taken.

Guidance §483.420(d)(4)

The facility is required to ensure that clients residing in the facility are not subjected to physical, verbal, sexual or psychological abuse or punishment.

Appropriate corrective action is required for findings of abuse, neglect or mistreatment by other clients residing in the facility, staff of outside agencies, parents or any other person, and for injuries to clients resulting from controllable environmental factors.

If the facility receives allegations of abuse, neglect, or mistreatment of a client during out of facility visits with their family, they must report these allegations to the appropriate state authority for investigation. The facility does not have to conduct an internal investigation regarding the alleged violation.

Appropriate corrective action is defined as that action which is reasonably likely to prevent the abuse, neglect, mistreatment or injury from recurring.

This regulation does not require staff termination as the only appropriate corrective action.

The corrective action imposed by the facility is commensurate with the violation.

When a facility is forced to re-hire a staff person, determined by the facility investigation to have been responsible for abuse, neglect, or mistreatment, the facility continues to be responsible for ensuring the health and safety of the clients, and ensures that those staff members do not work directly with clients.

W158

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430 Condition of participation: Facility staffing.

(a) Standard: Qualified intellectual disability professional

W159

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(a) Each client's active treatment program must be integrated, coordinated and monitored by a qualified intellectual disability professional who –

Guidance §483.430(a)

The position of qualified intellectual disability professional (QIDP) is unique to the ICF/IID program. This position can be central to the overall responsiveness and effectiveness of an active treatment program. Whether a supervisory or non-supervisory position, the QIDP is responsible to:

- Orchestrate all facets of the active treatment effort, including the IDT creation of relevant IPPs tailored to meet individual client needs;
- Effectively coordinate internal and external program services and supports to facilitate the acquisition of client skills and adaptive behaviors; and
- Promote competent interactions of residential staff with clients in program implementation and behavior management.

Breakdowns in the provision of needed services does not automatically equate with deficient practice with QIDP regulations. Non-compliance with QIDP regulations exist where the facility has failed to provide a QIDP or sufficient numbers of QIDPs to effectively perform these required functions or the QIDP(s) has failed to assertively attempt to integrate, coordinate and/or monitor each client's active treatment program.

Elements of integrating, coordinating and monitoring active treatment programs include:

- Routinely observing clients across settings in program areas to assess effectiveness of program implementation and consistency of training effort to determine effectiveness of IPPs and making timely modifications to facilitate achieving desired skills or goals.
- Routinely interacting with program staff across settings to assist in determining the effectiveness and continued relevance of program plans in meeting identified client needs.
- Determining the need for program revision based on client performance.
- Identifying inconsistencies in training approaches or programs not being implemented as written and facilitating the resolution of these inconsistencies.
- Assures follow-up occurs for any recommendation for services, equipment or programs so that needed services and supplies are provided in a timely manner to meet the client's needs.

The number of QIDPs will vary depending on such factors as the number of clients the facility serves, the complexity of needs manifested by these clients, the number, qualifications and competencies of additional professional staff members, and whether or not other duties are assigned to the QIDP function. The QIDP function may not be delegated to other employees even though the QIDP co-signs their work.

W160

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(a)(1) Has at least one year of experience working directly with persons with intellectual disability or other developmental disabilities; and

Guidance §483.430(a)(1)

“Experience” means providing professional or direct services, either paid or volunteer, in a setting that serves persons with intellectual disabilities. The experience working directly with persons with

intellectual or other developmental disabilities can be obtained prior to or after obtaining the qualifying degree or credentials.

§483.430(a)(2) Is one of the following:

W161

(a)(2)(i) A doctor of medicine osteopathy.

W162

(a)(2)(ii) A registered nurse.

W163

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(a)(2)(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section

Guidance §483.430(a)(2)(iii)

The individual must have at least a bachelor's degree in one of the professions listed in §483.430(b)(5)(i-xi)

(b) Standard: Professional program services

W164

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430 (b)(1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan.

Guidance §483.430 (b)(1)

The effectiveness of the active treatment effort is dependent on a facility's assembly of a competent team of professional program staff, with knowledge of contemporary care practices in intellectual disabilities specific to their field of expertise, that work cooperatively as members of an IDT. The facility is responsible for the acquisition of professional staff necessary to provide direct and indirect professional services to meet client needs.

Professional program services are those services that meet the needs identified by a client's CFA that must be provided by a member of a vocation founded upon specialized education/training.

Professional staff services also include on-going monitoring of the effectiveness of programs and plans developed by professional staff but implemented by non -professional staff.

Indirect professional staff services also include on-going, technical support to staff implementing these programs as well as timely assessment of the need for modification of the program with appropriate communication to the QIDP and IDT.

The needs identified in the initial CFA, as required in §483.440(c)(3)(v), should guide the team in deciding if a particular professional's involvement is necessary and, if so, to what extent professional involvement must continue on a direct or indirect basis.

Since such needed professional expertise may fall within the purview of multiple professional disciplines, based on overlapping training and experience, determine if the facility's delivery of professional services is adequate by the extent to which clients' needs are aggressively and competently addressed. Some examples in which professional expertise may overlap include, but are not limited to:

- Physical development and health: nurse, dietitian, pharmacist.
- Nutritional status: nurse, nutritionist or dietitian.
- Sensorimotor development: educators, recreation therapists, and occupational therapist, physical therapist.
- Affective (emotional) development: special educators, social workers, psychologists, psychiatrists, mental health counselors, rehabilitation counselors, behavior therapists, behavior management specialists, behavior analyst, and medical staff.
- Speech and language (communication) development: speech-language pathologists, special educators for people who are deaf or hearing impaired, and medical staff.
- Auditory functioning: audiologists (basic or comprehensive audiologic assessment and use of amplification equipment); speech-language pathologists (like audiologists, may perform aural rehabilitation); special educators for clients who are hearing impaired and medical staff.

- Cognitive development: teachers (if required by law, e.g., school aged children, or if pursuit of GED is indicated), behavior analysts, psychologists, speech-language pathologists.
- Vocational development: occupational therapists, vocational rehabilitation counselors, or other work specialists (if development of specific vocational skills or work placement is indicated).
- Social Development: teachers, professional recreation staff, social workers, behavior analysts, psychologists (specialized training needs for social skill development).
- Adaptive behaviors or independent living skills: special educators, occupational therapists, behavior analysts, and medical staff.

W165

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(1) Professional program staff must work directly with clients

Guidance §483.430(b)(1)

Examples of professional staff working directly with clients include: performing professional assessments of clients, provision of direct support and services and periodic monitoring by the professional of the client working on the program. The amount and degree of direct care that professionals must provide will depend on the needs of the client and the ability of other staff to effectively work with clients on a day-to-day basis.

For those services that must be provided by a professional due to either law, licensure or registration, the client receives the services directly from the professional. Professionals may deliver services through the supervision and direction of subordinates where provided by law.

W166

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(1) and with paraprofessional, nonprofessional and other professional program staff who work with clients.

Guidance §483.430(b)(1)

Paraprofessionals are persons in various occupational fields who are trained to assist professionals but are themselves not licensed at the professional level.

Examples of “working with” these other staff may include, but not be limited to:

- Modeling the correct technique for interacting with clients or implementing a specific program objective.
- Designing residential activity programs and teaching staff how to implement them.
- Conducting classes on discipline specific topics.
- Answering questions of staff related to program implementation or specific behavioral management issues.
- Monitoring active treatment areas to identify program implementation or staff-client interaction issues.

W167

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.

Guidance §483.430(b)(2)

There should be sufficient professional staff in the facility to ensure that:

- needed assessments by professionals are completed timely;
- direct professional services are provided when indicated;
- clients are receiving interventions as specified in the IPP;
- client outcomes are being monitored by the professional;
- assessments and outcomes are being communicated to the IDT; and
- professional staff are available to consult with team members when needed.

W168

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

Guidance §483.430(b)(3)

When a professional does an assessment and determines there are client needs which become incorporated into the IPP, with a current prioritized objective, the professional should actively participate on the IDT. This participation may be through written reports or verbally while attending the IPP meeting or participating via telephone or other electronic means, to provide team members with the opportunity to review and discuss information and recommendations relevant to the client's needs, and to reach decisions as a team, rather than individually, on how best to address those needs.

W169

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.

Guidance §483.430(b)(4)

Professional program staff provides various types of training to staff as indicated by the IPP and IDT. Formal training: a specific training done at the time a program is implemented or updated by the professional, with all staff who works with the client.

Informal training: when the professional observes the staff not correctly implementing a program, the professional provides informal guidance on correct implementation.

Training on programs that apply to multiple clients: when a particular program applies to several clients in a facility, a professional may provide training to several staff on a particular topic that applies to multiple clients (such as safe transfer techniques).

Professional staff of the facility should participate in ongoing training such as conferences and workshops to maintain current standards of practice in the field of intellectual and developmental disabilities as required by their professional licensure or certification.

W170

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in §483.410(b), must meet the following qualifications:

W171

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5)(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.

Guidance §483.430(b)(5)(i)

If a professional is not nationally certified, they would have to show evidence they completed the degree and field work in their designated field and are eligible to sit for the national exam.

The American Occupational Therapy Association is now known as the National Board for Certified Occupational Therapists (NBCOT). There is no "other comparable body."

Eligibility means the professional must have completed a degree in their designated field, completed all field work required for a license, must meet licensure requirements in the state they are practicing in, and are registered or certified nationally as applicable.

W172

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5)(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.

Guidance §483.430(b)(5)(ii)

If a professional is not nationally certified, they would have to show evidence they completed the degree and field work in their designated field and are eligible to sit for the national exam.

The American Occupational Therapy Association is now known as the National Board for Certified Occupational Therapists (NBCOT). There is no “other comparable body.”

Eligibility means the professional must have completed a degree in their designated field, completed all field work required for a license, must meet licensure requirements in state they are practicing in, and are registered or certified nationally as applicable.

W173

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5)(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.

Guidance §483.430(b)(5)(iii)

If a professional is not nationally certified, they would have to show evidence they completed the degree and field work in their designated field and are eligible to sit for the national exam.

Eligibility means the professional must have completed a degree in their designated field, completed all field work required for a license, must meet licensure requirements in state they are practicing in, and are registered or certified nationally as applicable.

W174

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5)(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.

Guidance §483.430(b)(5)(iv)

If a professional is not nationally certified, they would have to show evidence they completed the degree and field work in their designated field and are eligible to sit for the national exam.

Eligibility means the professional must have completed a degree in their designated field, completed all field work required for a license, must meet licensure requirements in State they are practicing in, and are registered or certified nationally as applicable.

W175

§483.430(b)(5)(v) To be designated as a psychologist, an individual must have at least a master’s degree in psychology from an accredited school.

§483.430(b)(5)(vi) To be designated as a social worker, an individual must—

W176

§483.430(b)(5)(vi)(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or

§483.430(b)(5)(vi)(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.

§483.430(b)(5)(vii) To be designated as a speech-language pathologist or audiologist, an individual must—

W177

§483.430(b)(5)(vii)(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

§483.430(b)(5)(vii)(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

W178

§483.430(b)(5)(viii) To be designated as a professional recreation staff member an individual must have a bachelor’s degree in recreation or in a specialty area such as art, dance, music or physical education.

W179

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5)(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

Guidance §483.430(b)(5)(ix)

If a professional is not nationally registered as a dietitian, they would have to show evidence they completed the degree and field work in their designated field and are eligible to sit for the national exam.

W180

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5)(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

Guidance §483.430(b)(5)(x)

Human Services is a diverse field focused on improving the quality of life of clients in communities in which the professional serves. A human services professional works directly with the population being served. Surveyors should see evidence that a human service professional has a bachelor's degree at a minimum.

W181

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(b)(5)(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5)(i) through (x) of this section are not required-

(A) Except for qualified intellectual disability professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

Guidance §483.430(b)(5)(xi)

An individual client program may not require that professional staff perform all of the services as outlined by the IPP (e.g. the direct support staff may be trained by the professional to safely and effectively carry out the designed program), however, any specialized therapy must involve evaluation, program development, and re-assessment by the appropriate professional at periodic intervals.

(c) Standard: Facility staffing

W182

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(c)(1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.

Guidance §483.430(c)(1)

The facility must have sufficient staff to provide needed care and services without the use of volunteers or enlisting the help of clients residing in the facility to perform the duties normally performed by facility staff.

The facility may not rely on volunteers in lieu of paid staff to fill required staff positions and perform direct care services. Volunteers are permissible, but must be in addition to the number of paid staff required to carry out a function. Volunteers should have an orientation to the policies and procedures of the facility and oversight is required by facility staff.

W183

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(c)(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing- -

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

Guidance §483.430(c)(2)

Indicators of staff not being awake in relation to the occurrence of incidents, accidents, and injuries may include, but are not limited to:

- incidents of unplanned client absences;
- untimely reaction to a medical emergency;
- injuries from client to client aggression; or
- a pattern of injuries of unknown origin.

If even one client meets 483.430(c)(2)(i-ii) then staff must be awake on a 24-hour basis.

A client has a medical care plan when an acute or chronic occurrence requires clinical assessment and monitoring on a scheduled basis.

W184

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(c)(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing- -

(i) Clients for whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients.

Guidance §483.430(c)(3)

At all times, there must be at least one staff person on-duty in the facility if even one client is present. For purposes of this provision, “on duty” staff need not be awake during normal sleeping hours, but do need to respond to injuries, illness, and emergencies promptly.

W185

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(c)(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

Guidance §483.430(c)(4)

Direct care staff should not be performing support services (e.g., making beds, cooking, cleaning, etc.) independently which takes them away from client interaction and teaching. If support services in the house cannot be done jointly as chores between clients, as part of their training program, and the support staff, additional staff should be added to perform the chores. This does not include any staff chores done during client’s sleeping hours.

“Support staff” include all personnel hired by the facility that are not either direct care staff or professional staff. For example, support staff includes, but are not limited to, secretaries, clerks, housekeepers, maintenance and laundry personnel.

(d) Standard: Direct care residential living unit staff

W186

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(d)(1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

Guidance §483.430(d)(1)

“Sufficient” means enough direct care staff to effectively implement the active treatment programs as defined in the IPP, to meet client needs, and to respond to emergencies, illness, or injuries.

Even though minimum ratios are defined at §483.430(d)(3), active treatment may require more staff than the minimums required ratios, therefore compliance should not be based on staffing ratios alone.

§483.430(d)(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

Guidance §483.430(d)(2)

“Direct care staff” are those personnel who are assigned to work directly with the clients providing support during activities of daily living and active treatment programs.

Professional staff who work with clients in a living unit on a periodic basis are not included in direct care staff ratios.

Supervisors of direct care staff can be counted only if they share in the actual work of the direct care of clients on a continuous basis (e.g. take client assignment).

Direct care supervisors whose principle assigned function is to supervise direct care staff may not be included in direct care staff ratios although they may occasionally provide direct services to clients.

Non-direct care staff supervisors whose principle assigned function is to supervise non- direct care staff may not be included in direct care staff ratios.

W187

(Rev. 144, Issued: 08-14-15, Effective: 08-14-15, Implementation: 08-14-15)

§483.430(d)(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

Guidance §483.430(d)(3)

*The minimum ratios in this standard indicate the **minimum** number of direct-care staff that must be present and on duty, 24 hours a day, 365 days a year, for each discrete living unit. For example, to calculate the minimum number of living unit staff that must be present and on duty in a discrete living unit serving 16 individuals with multiple disabilities: divide the number of individuals "16," by the number corresponding to the regulation "3.2," the result equals "5." Therefore, the facility must determine how many staff it must hire to ensure that at least 5 staff will be able to be present and on duty during the 24 hour period in which those individuals are present.*

Using the living unit described above, "calculated over all shifts in a 24-hour period" means that there are present and on duty every day of the year: one direct care staff for each eight individuals on the first shift (1:8), one direct care staff for each eight individuals on the second shift (1:8), and one direct care staff for each 16 individuals on the third shift (1:16). Therefore, there are five (5) direct care staff present and on duty for each twenty-four hour day, for 16 individuals. The same calculations are made for the other ratios, whichever applies. Determine if absences of staff for breaks and meals results in a pattern of prolonged periods in which present and on-duty staff do not meet the ratios.

W188

§483.420(d)(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.

§483.430(e) Standard: Staff Training Program

W189

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(e)(1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

Guidance §483.430(e)(1)

Newly employed staff receive a supported orientation program (mentor or ongoing supervision) during their early employment. All staff receive continuing education on such issues as abuse and neglect, handling emergency situations, behavior management, and treating people with respect and dignity, etc. The primary evidence of an effective staff training program is the observed competent interaction between staff and clients.

§483.430(e)(2) For employees who work with clients, training must focus on skills and competencies directed toward clients'

W190

(Rev. 144, Issued: 08-14-15, Effective: 08-14-15, Implementation: 08-14-15)

§483.430(e)(2) developmental,

Guidance §483.430(e)(2)

Staff receive training in the following areas:

- developmental programming principles and techniques (e.g. techniques to involve clients in their programs to their highest capability, use of positive reinforcement, use of assistive technology, use of appropriate materials and providing informal opportunities to practice skills);
- use of adaptive equipment and augmentative communication devices and systems;
- and
- effective recordkeeping procedures.

W191

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(e)(2) behavioral,

Guidance §483.430(e)(2)

Staff receive training in the following areas:

- use of behavioral principles during interactions between staff and clients;
- use of accurate procedures regarding abuse detection and prevention, restraints, drugs to manage behaviors, client safety, emergencies, etc.;
- use of least restrictive interventions;
- use of positive behavior intervention programming; and
- training clients in appropriate replacement behaviors.

W192

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(e)(2) and health needs

Guidance §483.430(e)(2)

Staff receive training in the following areas:

- signs and symptoms of the client's changing health (e.g. constipation, urinary tract infections, adverse drug reactions, as indicated);
- exercise and diet;
- first aid;
- infection control;
- reporting to appropriate healthcare professionals; and
- for those staff who can administer medications, how to include clients in their medication administration by recognizing and encouraging the use of applicable skills.

W193

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(e)(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.

Guidance §483.430(e)(3)

Staff correctly and consistently implement the interventions specified in the behavior plans of clients with whom they are working.

Inadequate training is evident when staff do not correctly implement behavioral programs, use inappropriate management techniques, cannot explain what intervention is to be used and how it is to be implemented.

W194

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.430(e)(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.

Guidance §483.430(e)(4)

Staff are observed in various settings during the day correctly and consistently implementing the specific IPPs of the clients with whom they are working.

W195

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440 Condition of participation: Active treatment services

(a) Standard: Active treatment

W196

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(a)(1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward-

(i) The acquisition of the behaviors necessary for the client to function with as much self-determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

Active treatment embodies an individually- tailored series of daily life and living experiences that serve as the primary opportunity for the acquisition, development and expression of functional skills and adaptive behaviors necessary for the client to experience optimal independence and promote purposeful “self-expression”.

The uniqueness of each client is a core consideration in the design of active treatment programs. It is expected that individual clients are given the opportunity to provide input into the content of their day-to-day living experiences.

An active treatment program includes the following elements as substantiated through observation, interview and record review:

a) Each client’s needs and strengths have been accurately assessed and relevant input has been obtained from team members; (Observations and interviews with the client by the surveyor should be consistent with the current assessment information. Interview the QIDP regarding any needs observed but not addressed through assessment/programming by the facility).

b) Each client’s IPP is based on assessed needs and strengths, and addresses major life areas such as personal skills, home living skills, community living skills, employment skills, etc., essential to increasing independence and ensuring rights;

c) Needs identified as a priority are addressed formally and through activities which are relevant and responsive to client need, interest and choice;

d) Active treatment is consistently implemented in all relevant settings both formally and informally as the need arises or opportunities present themselves. It should not be limited to specific periods of time during the day or environments. Each client should receive aggressive and consistent training, treatments and supports in accordance with their needs and IPP. New skills and appropriate behaviors are encouraged and reinforced across environments and times of day. Each client has the adaptive equipment and environmental adaptations necessary for him/her to progress toward heightened independence as recommended and contained in their IPP. Active treatment means taking advantage of opportunities for the practice of new skills and the use of other skills during the normal rhythm of each client’s day.

e) Each client’s performance related to IPP objectives is accurately and consistently measured and documented and programs are modified on an ongoing basis based on data and major life changes; and

i. Clients with degenerative conditions receive training, treatment and services designed to retain skills and functioning and to prevent further regression to the extent possible.

ii. Clients may need adjustments to their active treatment programs as functional or endurance limitations are identified associated with the aging process. In such cases, there may be more of an emphasis on the retention of skills already attained and reducing the rate of loss of skills, than on the acquisition of new skills.

In large part, it is this pervasive and continuous reinforcement of “formal” training through “informal” routine daily living experiences and interactions with staff and others that makes active treatment programs effective. Formal settings are those that are planned and specifically structured for training on objectives and interventions. Informal settings are times that are not anticipated or planned but that offer the opportunity for training.

Active treatment programs mirror normal living experiences such as leisure activities and social conversation at the dinner table. It must be clear that active treatment programs are far more than

implementation of discreet formal training sessions or programs that are conducted at prescribed times by defined personnel. Learning occurs in the process of the normal rhythm of life and life experiences.

W197

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(a)(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

Guidance §483.440(a)(2)

All active treatment programs must be based upon assessed developmental needs which are prohibiting the client from living in a more independent setting.

Active treatment moves clients to a more independent setting.

- When a client is in the facility simply for protective oversight and is not in need of training for developmental deficits, this does not constitute active treatment (e.g. a court placement to protect the community or the client from the client's behavior).

- Programs that are simply being provided to maintain a client's independence would not be considered active treatment since the client is not actively being trained to live in a more independent setting. If a client already possesses the skills that enables them to live in a less restrictive environment, and does not require the structure, support and resources that services that only an ICF/IID can provide, they can be considered generally independent.

For example, a client is admitted to the ICF/IID for the primary purpose of competency determination for a court hearing. This client lived independently prior to admission. The active treatment programs they are receiving are focused on maintaining that independence and do not address specific developmental deficits that inhibit independent living. This would not be considered active treatment.

(b) Standard: Admissions, transfers, and discharge

W198

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(1) Clients who are admitted by the facility must be in need of and receiving active treatment services.

Guidance §483.440(b)(1)

All client admissions must be based upon assessed developmental deficits which are prohibiting the client from living in a more independent setting and which require those intensive specialized supports, services, and supervision that only an ICF/IID can provide.

The individual components of the provision of active treatment include CFA, IPP, program implementation, program documentation, and program monitoring and change. When any of these individual components of active treatment are not in place, resulting in the clients not receiving active treatment, this regulation this not met.

W199

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

Guidance §483.440(b)(2)

Preliminary evaluations should support the need for an admission to an ICF/IID (e.g., deficits in functional skills or adaptive behaviors). The information from the preliminary evaluation must be used by the facility to make an admission decision.

Occasionally, emergency admissions of clients may occur without benefit of a preliminary evaluation having been conducted prior to admission. When situational emergencies necessitate admission before a preliminary evaluation can be conducted, or when pre-admission information is incomplete, the completion of the preliminary admission evaluation within seven (7) calendar days after admission will satisfy compliance with this requirement.

W200

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

Guidance §483.440(b)(3)

The preliminary evaluation contains specific information useful to determine if the facility can meet the client's needs and if the client can benefit from placement.

The facility makes every reasonable effort to gather all available data to assist in their determination.

Background information would include information that gives insight into the clients' previous living environments and programming efforts.

The assessment must include a consideration as to whether reasonable accommodation as required by the Americans with Disabilities Act would enable the client to benefit from placement in facility.

§483.440(b)(4) If a client is to be either transferred or discharged, the facility must –
W201

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(4)(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and

Guidance §483.440(b)(4)(i)

Transfer or discharge occurs only when the facility cannot meet the client's needs, the client no longer requires an active treatment program in an ICF/IID setting; the individual/guardian chooses to reside elsewhere, or when a determination is made that another level of service or living situation would be more beneficial to the client.

"Transfer" means the temporary movement of a client to another facility (e.g. another ICF/IID, psychiatric hospital, medical hospital) with the intention of return to the original site.

"Discharge" means the permanent movement of a client to another facility or setting which operates independently from the ICF/IID (e.g. the facility is not under the jurisdiction of the facility's governing body).

Documentation includes evidence of an assessment that evaluated the pros and cons of the transfer or discharge and the rationale for the final decision.

W202

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(4)(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

Guidance §483.440(b)(4)(ii)

The client and their family or the client and their legal guardian are involved in planning for any transfer or discharge and receive the services necessary to assist in preparing for movement, unless an emergency (medical) situation prevents that involvement. If the client has an advocate, the advocate should participate in the decision-making process.

Orderly, planned transfers and discharges usually take place over an extended period of time. The IPP should reflect objectives or interventions which prepare the client for transfer or discharge. Transfers or discharges executed on short timeframes (e.g. less than 30 days) without "good cause" would not comply with the "reasonable" intent of the regulations.

"Reasonable" time is the time required to provide clients and their families with planned steps and established timeframes to facilitate the successful transition. Time frames are modified based on client needs and emergent situations.

Preparation of the client for transfer may include orientation or trial visits to the new location. Staff should take steps to minimize potential anxiety or any behavioral reactions which could result from the client's transfer.

§483.440(b)(5) At the time of the discharge, the facility must-

W203

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(5)(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status**Guidance §483.440(b)(5)(i)**

The final summary should be useful for continued services in the client's new setting. The final discharge summary should be entered into the client's record, provide a summary of the client's course of stay in the ICF/IID, provide a final summary of the client's developmental, behavioral, social, health and nutritional status, and include the current status of the objectives listed in the client's IPP.

The status should address whether or not a clients' skills have been maintained, deteriorated, or improved during their stay.

W204

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(5)(i) and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and**Guidance §483.440(b)(5)(i)**

When the client is discharged, the receiving entity (another ICF/IID, waiver home, family home, nursing home, etc.) is provided a copy of the discharge summary. The ICF/IID should obtain written consent to share this information with the persons who will be providing services to the client in the future and their parents/or legal guardians. Sharing the discharge summary with State Agencies as applicable is determined by state requirements.

W205

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(b)(5)(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.**Guidance §483.440(b)(5)(ii)**

The post discharge plan of care is a component of the discharge summary.

The facility utilizes the information from the discharge summary to prepare the discharge plan of care. The post-discharge plan of care identifies the essential supports and services necessary for the client to successfully adjust to the new living environment and describe necessary coordination of services. It should incorporate the client's preferences. It should identify specific client needs after discharge such as personal care, physical therapy, client/caregiver education needs, and the ability of the client or caregiver to meet those needs after discharge.

(c) Standard: Individual program plan**W206**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to- -

i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

ii) Designing programs that meet the client's needs.

Guidance §483.440(c)(1)

If a need is identified in the CFA, the professional associated with that need will conduct an initial evaluation for the development of the IPP.

The needs identified in the CFA determine the professional, paraprofessional, direct support staff, disciplines or service areas that must participate in the development of the IPP.

W207

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(2) Appropriate facility staff must participate in interdisciplinary team meetings.**Guidance §483.440(c)(2)**

While there is no correct number of individuals that comprise the IDT, the team should include appropriate facility staff (professional and paraprofessional staff), that are responsible for designing, developing, and/or implementing the client's IPP and direct support staff who work closely with the clients.

For any prioritized objective, the paraprofessional or professional personnel responsible for the development and monitoring of that program should participate on the team, either through actual attendance or written or verbal input.

Members of the IDT may change as the assessed needs of the client change (e.g. medical issues, nutritional issues, communication needs, fine motor skill needs, gross motor skill needs, social issues or behavioral concerns).

W208

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(2) Participation by other agencies serving the client is encouraged.

Guidance §483.440(c)(2)

The facility must make every effort to coordinate the Individual Education Plan (IEP) from the school or the client's program plan from outside program, work site or workshop with the IPP. This may result in a single document, but there is no requirement for a single combined document. There must be evidence that all applicable plans were coordinated (evidence of discussion across the plans and observation would confirm integration of the IPP across the various settings). The QIDP is responsible for the coordination of the plans.

The facility should communicate changes in the IPP or in the clients' life situation with teachers and workplace representatives either directly or through written communication.

W209

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(2) Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless the participation is unobtainable or inappropriate.

Guidance §483.440(c)(2)

The facility should make every effort to schedule team meetings at a time that enables the client parent or legal guardian, to attend without having to forfeit work time or pay.

The facility should make every effort to schedule team meetings at a time that enables the client parent or legal guardian, to attend without having to forfeit work time or pay.

It is expected that the client will routinely attend team meetings unless their participation is unobtainable. Examples of when client participation is not available include, but are not limited to: 1) the client is away from the facility for medical reasons or hospitalization; or 2) although the facility has documented repeated attempts to engage the client, the client refuses to participate.

If families/legal guardians are unable to attend a program planning meeting, the facility provides them information regarding the meeting outcome and gives them an opportunity to discuss the plan with the facility staff.

“Unobtainable”, for the purposes of this guideline, means that the facility has made a good faith effort to seek parental or legal guardian participation in the process, even though the effort may ultimately be unsuccessful (for example, the parent may be impossible to locate or may prove unwilling or unable to participate).

“Inappropriate”, for the purposes of this guideline, means that the parent or legal guardian's behavior is so disruptive or uncooperative that others cannot effectively participate; the client does not wish his or her parent to participate, and the client is competent to make this decision; or there is strong and documented evidence that the parent or legal guardian is not acting on the client's behalf or in the client's best interest. In the case of the latter, determine what the facility has done to bring effective resolution to the problem.

Instances when it is not appropriate for the client, parent or legal guardian, to attend the team discussion are rare. If the client does not attend the meeting, the facility must document the reason for his/her non-participation.

There may also be instances where a parent or legal guardian is considered unobtainable for a team meeting, such as being out of the country. In these instances, the parent or legal guardian should still be notified of the meeting, provided with information concerning the outcome of the meeting and documentation in the client record should describe why the parent or legal guardian could not attend and what information was provided to them.

If the client is an adult who is competent to make decisions and who is not adjudicated, parents may not participate in the process if their participation is opposed by the client.

In the event that a non-adjudicated adult chooses not to have their family involved in the active treatment process, the surveyor should see evidence in the record of efforts made by the facility to understand why the client has declined family participation. If the client continues to decline family involvement after the facility has held discussions with him/her about the importance of this issue, the facility should honor the wishes of the client.

In general, the more involvement and communication among the team members, the client and the parent or legal guardian the more likely the plan will be successful. The facility goal should be to routinely include these parties unless rare circumstances exist.

W210

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission.

Guidance §483.440(c)(3)

For new admissions, the CFA is completed within 30 days after admission and is utilized as the basis for the IPP.

New, revised or updated assessments completed within the first 30 days of admission, accurately identify the functional abilities of the client.

“Accurate” assessments refer to assessment data that are current, relevant and valid, and the skills, abilities, and training needs identified by the assessment correspond to the client’s actual, observed status. Assessments must be administered with appropriate adaptations such as specialized equipment, use of an interpreter, use of manual communication and tests designed to measure performance in the presence of visual disability.

The content of or format of the assessments or the particular assessment tools which are to be used for the CFA are not specified. Assessments must include identification of those functional life skills in which the client needs to be more independent and those services needed for the client to become more community integrated.

W211

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3) The comprehensive functional assessment must take into consideration the client’s age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must -

Guidance §483.440(c)(3)

During assessment, the client is given opportunities to participate in age-appropriate activities to assess the person’s functioning in those activities or settings. For example, the use of baby toys during the assessment of an adult would not be appropriate.

W212

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(i) Identify the presenting problems and disabilities and where possible, their causes;

Guidance §483.440(c)(3)(i)

The CFA includes:

- all diagnoses and developmental deficits for the client;
- the supporting information for each; and
- each evaluation should include conclusions and recommendations which go into the development of an active treatment program for the client.

W213

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(ii) Identify the client’s specific developmental strengths;

Guidance §483.440(c)(3)(ii)

The client's identified developmental strengths, preferences, methods of coping/compensation, community use and awareness, friendships and positive attributes and capabilities are clearly described in functional terms in the assessments.

Identified strengths are consistent with the client's observed functional status.

W214

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(iii) Identify the client's specific developmental and behavioral management needs; Guidance §483.440(c)(3)(iii)

The CFA must address and identify those skill deficits/needed supports that may be amenable to training, those that must be treated by therapy and/or provision of assistive technology, and those that require adapting the environment and/or providing personal support. Assessment of needed supports should be done within the context of the client's age, gender, and culture.

"Behavioral management needs" include those behaviors that interfere with progress, prevent assimilation into the community, decrease freedom or increase the need for restriction of activities (e.g. spitting, pica, self-injurious behavior, aggressive behavior toward others or self-injurious behavior).

A functional behavioral assessment is a problem-solving process for evaluating client inappropriate behavior. It relies on a variety of techniques and strategies to identify the purpose of the specific behavior(s) and to help the IDT select interventions to directly address the behavior(s). A functional behavior assessment looks beyond the behavior itself. The focus when conducting a functional behavioral assessment is on identifying significant client-specific social, affective, cognitive, and/or environmental factors associated with the occurrence (and non-occurrence) of specific behaviors.

The CFA must identify the specific accommodations that address the client's needs to ensure better opportunity for the client's success. The identified accommodations may be assistive technology which can help a person learn, play, complete tasks, get around, communicate, hear or see better, control their own environment and take care of their personal needs (e.g. door levers instead of knobs, plate switches, audio books, etc.).

W215

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(iv) Identify the client's needs for services without regard to the actual availability of the services needed; and

Guidance §483.440(c)(3)(iv)

Identification of needed services is based on the CFA.

In the presence of significant developmental deficits, it is not acceptable for the facility to say that a particular professional therapy or treatment is not needed or not available if the CFA identifies a deficit. The assessment must identify the course of specific interventions recommended to meet the client's needs, both through direct professional services and non-professional services. For example, a client's communication skill development may not require the intensive services of a speech-language pathologist however, the direct care staff will need to work with the client and use a pre-determined communication system.

§483.440(c)(3)(v) Include

Guidance §483.440(c)(3)(v)

The CFA should include an assessment of each of the areas listed below. Assessments should include specific information about the person's ability to function in different environments, specific skills or lack of skills, and how function can be improved, either through training, environmental adaptations, or provision of adaptive, assistive, supportive, orthotic, or prosthetic equipment.

If assessments are done separately by professional disciplines, there should be evidence that the assessments are brought together in an interdisciplinary approach to address the client's various developmental areas.

The CFA must be completed upon admission and annually as indicated. While the assessment may not have the specific titles of the areas listed below, the surveyor must be able to identify information within assessments from each of the areas below.

W216

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) physical development and health,

Guidance §483.440(c)(3)(v)

Physical development and health: This portion of the CFA includes the client's developmental history, results of the physical examination conducted by a licensed physician, physician assistant, or nurse practitioner, health assessment data (including a medication and immunization history); a review and summary of all laboratory reports since the last comprehensive evaluation, a summary of all required medical interventions since the last CFA; skills of the client normally associated with the monitoring and supervision of one's own health status, and administration and/or scheduling of one's own medical treatments. Reports of all specialist consultations should be included in the assessment as indicated by physical examination results.

IDT reviews any current advanced directives that the client may have in place as part of the CFA.

W217

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) nutritional status,

Guidance §483.440(c)(3)(v)

Nutritional status: Nutritional status includes height and weight, the client's eating habits and preferences, favorite foods, determination of appropriateness of diet, adequacy of total food intake, bowel habits, means through which the client receives nutrition (e.g. feeding tube) and the skills associated with eating (including chewing, sucking and swallowing disorders).

W218

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) sensorimotor development,

Guidance §483.440(c)(3)(v)

Sensorimotor development: Sensorimotor development includes the development of perceptual skills that are involved in observing the environment and making sense of it. Identified sensory deficits should be evaluated in conjunction with the impact they will have on the client's life. A sensory deficit in eye contact may not have a detrimental effect on the client's life if it will not hold the client back from further accomplishments or skill acquisitions. Motor development includes those behaviors that primarily involve: muscular, neuromuscular, or physical skills and varying degrees of physical dexterity. Because sensory and motor development are intimately related and because activities in these areas are functionally inseparable, attention to these two aspects of bodily activity is often combined in the concept of sensorimotor development. For those motor areas that are identified by the assessment as limited, the assessment should specify the extent to which corrective, orthotic, prosthetic, or support devices would impact on functional status and the extent of time the device is to be used throughout the day.

W219

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) affective development,

Guidance §483.440(c)(3)(v)

Affective (Emotional) development: Affective or emotional development includes the development of behaviors that relate to one's interests, attitudes, values, morals, emotional feelings and emotional expressions.

W220

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) speech and language development

Guidance §483.440(c)(3)(v)

Speech and language (communication) development: One of the most contributable causes of behaviors, frustration by the clients, etc. is lack of effective communication. It is imperative that the CFA identifies how the client communicates, what barriers are present, what services are available and what programs and services will be provided to assist the client to go out into and participate fully in the world. Observed client communication skills match the evaluation results and that training programs are in place to address needs.

Communication development refers to the development of both verbal and nonverbal and receptive and expressive communication skills. Assessment data identify the appropriate intervention strategy to be applied, and which, if any, augmentative or assistive devices will improve communication and functional status. These intervention strategies should provide the client with a viable means of communication which is appropriate to their sensory, cognitive and physical abilities.

W221

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) and auditory functioning,**Guidance §483.440(c)(3)(v)**

Auditory functioning: Auditory functioning refers to the extent to which a person can hear, to the maximum use of residual hearing if a hearing loss exists, and whether or not the client will benefit from the use of amplification, including a hearing aid or a program of amplification.

W222

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) cognitive development,**Guidance §483.440(c)(3)(v)**

Cognitive development: Cognitive development refers to the development of those processes by which information received by the senses is stored, recovered, and used. It includes the development of the processes and abilities involved in memory, reasoning and problem solving. It is also the identification of different learning styles the client has and those best used by the trainers. It is critical that the CFA address the individual learning style of the client in order to best direct the way the trainers will teach formal and informal programs.

W223

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) social development,**Guidance §483.440(c)(3)(v)**

Social Development: Social development refers to the formation of those self-help, recreation and leisure, and interpersonal skills that enable a client to establish and maintain appropriate roles and fulfilling relationships with others. Assessments may address family supports and relationships, sexual awareness and sexuality, friendships, social awareness, social skills and social interests.

W224

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) adaptive behaviors or independent living skills necessary for the client to be able to function in the community,**Guidance §483.440(c)(3)(v)**

Adaptive behaviors or independent living skills: Adaptive behavior refers to the effectiveness or degree with which clients meet the standards of personal independence and social responsibility and community orientation and integration expected of their age and cultural group. Adaptive behaviors are those behaviors that are developed to cope with deficits in order to be able to perform every day skills as independently as possible. Independent living skills include, but are not limited to, such things as food shopping, meal preparation, housekeeping and kitchen chores, laundry, bed making, and budgeting. Assessment may be performed by anyone trained to do so. Standardized tests are not required. Standardized adaptive behavior scales which identify all or predominantly all “developmental needs” are not sufficient to meet this requirement, but can serve as a basis for screening.

W225

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(3)(v) and as applicable, vocational skills.**Guidance §483.440(c)(3)(v)**

Vocational development, “as applicable”: Vocational development refers to work interests, work skills, work attitudes, work-related behaviors, and present and future employment options. The determination of whether or not a vocational assessment is “applicable” is typically based on age (adolescents or adults more than likely require this type of assessment). The vocational assessment for each client may address

job sampling, job development, on-site job training and long term follow-up, as appropriate to the client and determined by the IDT.

Vocational assessments should describe, for all domains, what clients can and cannot do in terms of skills needed within the context of their daily lives and jobs.

Assessments should be individualized and based on:

- Actual performance of the client against objective criteria;
- Reports by staff/parents/legal guardians; and
- Observed performance in a variety of settings.

W226

§483.440(c)(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan

W227

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(4) that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section,

Guidance §483.440(c)(4)

Objectives are developed for those needs that are identified by the CFA and which are considered to be most likely to improve the client's ability to independently function in his/her daily life, as determined by the IDT.

There is a clear link between the specific objectives and the functional assessment data and recommendations.

Objectives are developed for those needs that are observed to most likely impact the client's ability to function in daily life. Training objectives should be developed to address client needs rather than staff oriented objectives.

Clients are expected to have training objectives in the areas of activities of daily living, based on the client's assessed needs and as prioritized by the IDT. If clients have eyeglasses, dentures and/or other assistive devices it is expected that the team considers objectives, based upon the assessment of client needs, addressing the care and use of such devices. However, in the area of programs to teach the clients' money management it is not expected that every client will automatically have a formal training objective to participate in such a program. The decision to prioritize such a program and to what level the program is developed is decided by the IDT based upon the results of the CFA and in consideration of such factors as, transferable skills, the ability to make choices, the ability to identify preferences and cognitive abilities such as attention span and an understanding of the principle of cause and effect.

Similarly, the decision to prioritize and develop a training objective for a client to participate in a self-administration program for medications must be made by the IDT and be based upon information from the CFA. Formal self administration programs should not be confused with informal efforts to include the client in the administration process such as allowing them to hold a glass of water, identify the box where his/her medications are stored or put a pill into their own mouth themselves under the supervision of a person who is qualified to administer medications.

W228

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(4) and the planned sequence for dealing with those objectives.

Guidance §483.440(c)(4)

The objectives identified in W227 are organized in a logical sequence, determined by the team that will assist the client toward the attainment of skills resulting in greater self- choice, independence, and community integration. The logical sequencing of objectives means there is a completion of one objective that serves as the building block for the next with relevance to the client's functional status. Where objectives are logically ordered but do not have relevance to the client's functional status, refer to 483.440(c)(4).

If the IPP is organized in a logical sequence, this requirement is met. For example, if the long term goal is to travel independently in the community, the objective sequencing may involve training the client to

recognize traffic signs, cross the street safely, and to obtain help when needed if lost or an emergency arises.

**These objectives must –
W229**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(4)(i) Be stated separately, in terms of a single behavioral outcome;

Guidance §483.440(c)(4)(i)

Each objective clearly states one expected learning result.

“Single” behavioral outcome means that there is a separate objective assigned for each discrete behavior that the team intends the client to learn. For example, “Mary will bake a cake and clean the oven” are two separate behaviors and, therefore, should be stated in two separate objectives. Completion of the morning hygiene routine includes programs for performance of face washing, tooth brushing and hair combing which are three separate objectives; however, the behavioral outcome for each would be the same (e.g. completion of the morning hygiene routine).

W230

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(4)(ii) Be assigned projected completion dates;

Guidance §483.440(c)(4)(ii)

Completion dates are based on the client’s rate of learning.

Completion dates are assigned to each objective on which the client is currently working. Completion dates are individualized (e.g. not all the same for all clients and all objectives).

The “projected date of completion” for an IPP objective is not the same as a “review” date. For each objective assigned a priority, the team should assign a projected date (month and year) by which it believes the client will have learned the new skill, based on all of the assessment data. This date triggers the team to evaluate continuously whether or not the client’s progress or learning curve is sufficient to warrant a revision to the training program.

W231

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(4)(iii) Be expressed in behavioral terms that provide measurable indices of performance;

Guidance §483.440(c)(4)(iii)

The desired learning outcome is stated in a manner which enables all staff working with the client to consistently identify the target behavior and to clearly identify when it is being displayed.

The objective is stated in a manner which permits it to be measured with quantifiable data.

“Behavioral” terms include only those behaviors which are “client” rather than staff oriented and those that any person would agree can be seen or heard. Determine if all staff who work with the client can define the exact same outcome on which to measure the client’s performance.

“Measurable indices of performance” are the quantifiable criteria to use in determining successful achievement of the objective. Quantifiable criteria include various measurements of intensity and duration. For example, “Client X will walk ten feet, with the use of her tripod walker, on each of five (5) consecutive days.”

W232

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(4)(iv) Be organized to reflect a developmental progression appropriate to the individual; and

Guidance §483.440(c)(4)(iv)

Objectives must be relevant to the client’s current skill sets and abilities as identified in the CFA.

The ICF/IID must consider the person’s current functional abilities and project what steps, methods, and strategies are likely to be effective in achieving the objective.

W233

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(4)(v) Be assigned priorities.

Guidance §483.440(c)(4)(v)

Priorities are established based on the needs and in consideration of the desires of the client and emphasize the development of greater independence, self-choice, and community integration.

The team determines which objectives are the highest priority to be addressed, either because the client has an immediate need or the priority objectives must be accomplished before other priorities are addressed.

§483.440(c)(5) Each written training program designed to implement the objectives in the individual program plan must specify:**Guidance §483.440(c)(5)**

The following regulations (5) (i-iv) apply to formal training programs developed for current implementation.

W234

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(5)(i) The methods to be used;**Guidance §483.440(c)(5)(i)**

The training program provides clear directions to any staff person working with the client on how to implement the teaching strategies. To comply with this requirement the methodologies must be written in a clear enough manner that a substitute staff person will be able to read the methodologies and implement them without substantial differences from a regularly assigned staff person. Methodologies should be consistent across settings, such as when the client is in the day program.

W235

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(5)(ii) The schedule for use of the method;**Guidance §483.440(c)(5)(ii)**

Active treatment (the implementation of training programs pursuant to objectives) should be provided in formal and informal settings throughout the rhythm of the client's day. While there may be structured episodes when the client works intensively and singularly on one or more objectives (schedule), the provision of active treatment is not adequate when confined solely to these types of formal settings but should be incorporated into all activities when appropriate (client's routine). For example, objectives on grasping may be as effectively carried out during the client's use of a toothbrush and a spoon as in an isolated session.

W236

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(5)(iii) The person responsible for the program;**Guidance §483.440(c)(4)(v)**

The IPP should include the actual name of the staff person who is responsible for the ongoing monitoring of the client's program to ensure it is being implemented appropriately, as well as the designated position which will implement the program.

The QIDP should be familiar with the assessment and recording requirements for each client for each formal objective, including who is responsible for making these observations and completing the recording, and demonstrate a familiarity with the current data recorded for each client.

W237

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(5)(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;**Guidance §483.440(c)(5)(iv)**

The IDT must determine the type of data necessary to judge a client's progress on an objective, and describe the data collection method in the written training program. The facility determines what data to collect, but whatever system is chosen for collection must yield accurate measurement of the criteria stated in the client's IPP objectives. For example, if the criteria in the client's IPP objective specified a behavior to be measured by "accuracy," or "successes out of opportunities," then it would not be acceptable for the prescribed data collection method to record "level of prompt".

Examples of a few data collection systems include, but are not limited to:

- level of prompt;
- successful trials completed out of opportunities given;
- frequency counts; and
- frequency sampling.

The IDT must consider and select the type and frequency of data collection for each objective based upon the need to measure appropriately the client's performance toward the targeted IPP skill development. The facility should collect data with enough frequency and content to be able to appropriately measure the client's performance toward the targeted IPP skill development. The frequency of data collection may vary with the objective but must be made at sufficient intervals to allow analysis of the progress of the client.

W238

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(5)(v) The inappropriate client behavior(s), if applicable; and The inappropriate client behavior(s), if applicable; and

Guidance §483.440(c)(5)(v)

Any specific behaviors which would interfere with the client's ability to function in, or benefit from the training program are identified (e.g. a fear of water could interfere with the client's bathing program).

W239

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(5)(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

Guidance §483.440(c)(5)(vi)

The training program provides specific information as to how to elicit or strengthen appropriate behavior and what behaviors to teach reinforce or encourage which would reduce or replace the inappropriate behavior.

If a client is exhibiting an inappropriate behavior, the CFA should discover why the behavior is occurring and the team should develop associated training objectives to help the client develop more appropriate behaviors. The objective for decelerating targeted inappropriate behaviors is not solely the reduction of these behaviors. The objective should also include the positive functional replacement behavior (adaptive behavior).

A replacement behavior allows a client to substitute an unconstructive or disruptive behavior with something more constructive and functionally equivalent. For example, instead of throwing work materials as a way to get a break from vocational task demands, teach the client to say or sign for 'break'.

§483.440(c)(6) The individual program plan must also:

W240

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(i) Describe relevant interventions to support the individual toward independence.

Guidance §483.440(c)(6)(i)

Appropriate materials, adaptations and modifications to equipment and the environment are available in order to promote and support individual training programs. Examples may include, but are not limited, to built-up toilet seats, adaptive eating utensils, extended reach devices, and modification to the facility van to accommodate a wheelchair.

The IPP describes supports and services, in addition to the individual goals and objectives that will be provided by the facility to assist the client to function with greater independence.

W241

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.

Guidance §483.440(c)(6)(ii)

This requirement refers to the training program plans, objectives, descriptions of staff interventions and data collection tools which must be readily accessible to any staff in order for the programs to be consistently and effectively carried out and data collected.

W242

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.

Guidance §483.440(c)(6)(iii)

All clients who lack the skills listed within this standard have associated training programs developed to meet their needs according to prioritization. These programs are consistently implemented in both formal and informal settings.

“Developmentally incapable” is a decision made by the IDT that means a client does not have the capacity to acquire certain skill sets. The decision must be based on an assessment of the client’s strengths, needs, and functional limitations.

The determination of developmental incapability must be accompanied by written evidence supporting this determination.

Such evidence may include training programs which failed after many different strategies were tried, or physical limitations that preclude the acquisition of the skill. Examples are:

- 1) Eye contact program was attempted using seven different methods over a two year period;
- 2) An client has two frozen elbow joints which do not allow her to get her hands to her mouth and consequently she will not be trained on any hand to mouth skills; and
- 3) Some clients may have insufficient neuromuscular and sensory control to ever be totally independent in toileting skills.

Toilet scheduling alone without any plan to progress would not be considered a toilet training program. The components of functional skills “training” as used in this regulation means aggressive implementation of a systematic program of formal and informal techniques, which are:

- targeted toward assisting the client achieving the measurable behavioral level of skill competency specified in IPP objectives;
- implemented at natural occurrences of activity and training programs; (e.g.: an objective for a client to increase grasping may be implemented as easily in the workshop with a built up tool as in the bathroom with a toothbrush);
- conducted by all personnel involved with the client including those outside the home such as in day programs; and
- carried out in conversation and interaction with the client appropriate to the situation.

§483.440(c)(6)(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify

Guidance §483.440(c)(6)(iv)

The use of mechanical supports are based upon an individual assessment and fitting. Mechanical devices are used to support a client’s proper body position or alignment and may be essential to prevent contractures or deformities. However, mechanical supports restrict movement and the client should be released from the support periodically for exercise and free movement. Mechanical supports may not be used as a substitute for programs or therapy. For example, the use of a bolster to position a client upright in a sitting position without any indication there has been an assessment for the need for muscle re-training may be an indication of a mechanical device in lieu of programming. Some supports allow movement and provide opportunity for more increased functioning. Some examples of devices used as mechanical supports include splints, wedges, bolsters, lap trays, etc.

Wheelchairs are not generally used to position or align the body and would not alone constitute a mechanical support. However, adaptations to a wheelchair which facilitate correct body alignment by inhibiting reflexive, involuntary motor activity are mechanical supports and should be included in the plan for the client.

W243

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(iv) the reason for each support,

W244

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(iv) the situations in which each is to be applied,

W245

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(iv) and a schedule for the use of each support.

W246

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.

Guidance §483.440(c)(6)(v)

Clients with sensory or physical difficulties should be given the same opportunities to move around in their environments as clients who do not have those difficulties. Even clients who use specialized wheelchairs should be given the opportunity to utilize other devices such as walkers, wagons and scooters to move about and/or change their positions.

With the exception of those clients who are acutely ill (such as those who are hospitalized or incapacitated by a “short term” illness), all clients should be out of bed and outside their bedroom area as long as possible each day, and in proper body alignment at all times. This is a necessity in order to prevent regression, contractures, and deformities and to provide sensory stimulation.

Bed rest is a temporary situation associated most usually with a medical condition and must be ordered by the medical staff of the facility. The term implies that the client will remain in his/her bed for most of any 24-hour period. Although active treatment programs may be carried out to some extent while the client is on bed rest, the client’s program cannot be completed in its entirety. While there may be situations where continuous bed rest may be necessary, these situations are rare.

For those rare instances where out-of-bed activity is a threat to a client’s health and safety (e.g., blood clot in the leg), active treatment adapted to the medical capacity of the client must be continued.

W247

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(6)(vi) Include opportunities for client choice and self-management.

Guidance §483.440(c)(6)(vi)

Choice and self-management are integral components of becoming independent. Clients should be given opportunities for choice and self-management in both formal and informal settings through the IPP process, leisure activities, and other life choices.

The ICF/IID must incorporate opportunities into daily life experiences that promote choice making and decision making by clients. Examples of some activities leading toward responsibility for one’s own self-management include, but are not limited to:

- 1) choosing housing or roommates;
- 2) choosing clothing to purchase or wear;
- 3) choosing what, where, and how to eat (e.g., the use of family style dining, access to condiments and second helpings).

Choices can be made by all clients. The type of choices the person makes may vary from simple to complex, dependent upon client abilities.

Clients are provided opportunities for choice and self-management and the facility does not limit choices by making decisions for the people being served without their input. Clients are provided the opportunity to demonstrate skills to the degree they are capable and only assisted by staff as indicated in their IPP. A lack of facility staffing or staff convenience must not result in a limitation of choices of self-management for the clients.

W248

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(c)(7) A copy of each client's individual plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.

Guidance §483.440(c)(7)

The client or legal representative, as well as the facility staff, and staff from outside agencies, with appropriate consent, have, or can access, a copy of the IPP.

(d) Standard: Program implementation

W249

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(d)(1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.

Guidance §483.440(d)(1)

There should be no delay in the development and implementation of the IPP. To promote a team process and meaningful discussion, IPP development should take place during IDT meetings. Any IPP objective or modification that is critical to the health and safety of any client should be implemented immediately following IDT discussion.”

Each individual receives training and services consistent with the current IPP.

The time period between admission and the 30 day IDT meeting is primarily to assist the client to become adjusted and acclimated to his or her new living environment and to enable the facility to complete the CFA. During this time period the facility should also be providing those services and activities determined during the pre-admission assessment as essential to the client's daily functioning.

The active treatment program for the client is consistently implemented in all relevant settings both formally and informally as opportunities present themselves. It should not be limited to specific periods of time during the day or specific environments.

Each client should receive aggressive and continuous training, treatments and supports in accordance with their needs and IPP. New skills and appropriate behaviors are encouraged and reinforced across environments and times of day.

- During observations confirm that the client activities relate directly to the strengths, needs and objectives in the IPP for each client and are not “busy work,” generalized or non-developmental time fillers. For example, screwing nuts on bolts and then unscrewing them repeatedly with no goal or transferable skills is “busy work.” Screwing nuts on bolts that will be part of a product is functional reinforcement of skill acquisition.

- Clients use adaptive equipment, assistive devices, environmental supports, materials, supplies, etc., as specified in each client's IPP to assist the client to accomplish stated objectives.

There is no specific number or frequency of interventions that meets this requirement. The surveyors should see that the facility capitalizes on all opportunities throughout the course of the day that promote progress toward the achievement of goals and objectives.

Informal opportunities (“teachable moments”) should be utilized to reinforce learning or appropriate skill development and needs are addressed as they present.

Although a client may not be able to reach complete independence in a functional skill, it is crucial that retention of their current skills be supported.

Clients may have defined periods of time where they may engage in leisure activities of their choice which are not necessarily directly associated with their IPP goals and objectives.

W250

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(d)(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.

Guidance §483.440(d)(2)

The schedule is individualized, consistent with the client's objectives, and reflects normal daily routines.

The staff working with individual clients are familiar with their daily schedules and can produce the schedule upon request.

The active treatment schedule allows flexibility and is adjusted to the needs and preferences of the client, as necessary. It's a schedule of the client's general daily plans, but can be changed.

The active treatment schedule is a functional schedule which enables client and staff to be in the right location in order to participate in the training as scheduled by the IPP.

W251

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(d)(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.

Guidance §483.440(d)(3)

All disciplines, including direct care staff, interacting with the client work together to provide a uniform, consistent approach to implementation of the IPP.

(e) Standard: Program documentation

W252

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(e)(1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measurable terms.

Guidance §483.440(e)(1)

"Data" are defined to be performance information collected and reported in numerical or quantifiable form for each training objective assigned priority in the IPP.

Data are those performance measurements collected at the time the treatment, procedure, intervention or interaction occurs with the client and recorded as soon as possible. The data should be located in a place accessible to staff who conduct training.

Data should be collected in a form and frequency as required by the plan to enable quantitative (frequency or numbers) analysis of the client's progress.

Data are accurate (e.g., reflective of actual client performance.)

§483.440(e)(2) The facility must document significant events that

W253

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(e)(2) are related to the client's individual program plan and assessments and

Guidance §483.440(e)(2)

Significant events are those events which would cause a reasonable person to be affected and which impact a normal routine. Such events include changes in the client's functional status, emotional health, physical health, accomplishments, activities or needs which impact the CFA and IPP, as well as instances of abuse, neglect or mistreatment.

The client record should contain documentation that such events are evaluated and monitored.

W254

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(e)(2) that contribute to an overall understanding of the client's ongoing level and quality of functioning.

(f) Standard: Program monitoring and change

§483.440(f)(1) The individual program plan must be reviewed at least by the qualified intellectual disability professional and revised as necessary, including, but not limited to situations in which the client-

Guidance §483.440(f)(1)

Program implementation is a critical piece of each client's active treatment program. The QIDP must review or revise client programs according to 483.440(f)(1)(i-iv) and at such an interval that any of the requirements are promptly identified and addressed.

W255

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(f)(1)(i) Has successfully completed an objective or objectives identified in the individual program plan;

Guidance §483.440(f)(1)(i)

The QIDP ensures the program has been modified or changed in response to the client's specific accomplishments or need for new program.

W256

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(f)(1)(ii) Is regressing or losing skills already gained;

W257

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(f)(1)(iii) Is failing to progress toward identified objectives after reasonable efforts have been made; or

Guidance §483.440(f)(1)(iii)

There should be evidence that the QIDP has reviewed and revised the IPP in those situations when the client's IPP has been consistently implemented yet the client fails to achieve their objectives.

W258

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(f)(1)(iv) Is being considered for training towards new objectives.

§483.440(f)(2) At least annually,

Guidance §483.440(f)(2)

For the "annual" review to meet this requirement, it must be completed by at least the 365th day following the previous review, unless in an isolated or rare instance a client or the client's family is not available for a projected period of time and the subsequent delay is a minimal number of days.

W259

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(f)(2) the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed;

Guidance §483.440(f)(2)

The CFA is reviewed at least annually.

The review of the CFA occurs sooner than annually if:

- indicated by the needs of the client;
- reflects any changes in the client since their last evaluation; and
- incorporates information about the client's progress or regression with objectives.

The review of the CFA applies to all evaluations conducted for a client. It is not required that each assessment be completely redone each year, except the physical examination. It is required that at least annually the assessment(s) be updated when changes occur so as to accurately reflect the client's current status.

W260

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(f)(2) and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.

Guidance §483.440(f)(2)

The IPP reflects the functional changes for the client which occurred since the last IPP. It is unlikely that an active treatment program will have no changes from year to year without documentation to support not changing the plan. Question an IPP that is a duplication of the prior year's plan without explanation.

W261

(Rev. 144, Issued: 08-14-15, Effective: 08-14-15, Implementation: 08-14-15)

§483.440(f)(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to-

Guidance §483.440(f)(3)

The facility must have a specially constituted committee whose primary function is to proactively protect client rights by monitoring facility practices and programs. The purpose of the committee is to assure that each client's rights are protected utilizing a group of both internal staff and *external participants who have no vested interest in the facility as well as clients as appropriate*. There should be evidence that the committee members have been trained annually on the rights of the clients, what constitutes a restriction of a right and the difference between punishment and training.

Depending on size, complexity and available resources, the ICF/IID may establish more than one specially constituted committee. However, each committee must contain the required membership and participate regularly and perform the functions of the committee according to the requirements. Participation on the specially constituted committee(s) must be in real time allowing all membership to speak and discuss in an interactive mode.

The regulation does not specify the professional credentials of the "qualified persons" (who have either experience or training in contemporary practices to change inappropriate client behavior). There is no requirement that any specific discipline, such as nurse, physician or pharmacist be a member of the committee.

The intent of including "persons with no ownership or controlling interest" on the committee is to assure that, in addition to having no financial interest in the facility, at least one member of each constituted committee is an impartial outsider in that he/she would not have an "interest" represented by any other of the required members or the facility itself. Staff and consultants employed by the facility or at another facility under the same governing body, cannot fulfill the role of person with no ownership or controlling interest.

Although occasional absences from committee meetings are understandable, patterns of absence by the required membership of the committee is not acceptable. At least a quorum of committee members (as defined by the facility) must review, approve and monitor the programs which involve risk to client rights and protections and that quorum must include one person from each of the required categories.

W262

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.440(f)(3)(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

Guidance §483.440(f)(3)(i)

Any program that utilizes restrictive or intrusive techniques must be reviewed and approved by the specially constituted committee prior to implementation. This includes, but is not limited to:

- restraints;
- drugs to manage behavior;
- restrictions on community access;
- contingent denial of any right; or
- restrictions of materials or locations in the home.

The committee should ensure that consequences within a written behavior management program do not violate the client's rights.

There is no requirement for the committee to evaluate whether the proposed program is consistent with current practices in the field. Documentation should verify that the specially constituted committee considered factors, such as whether less intrusive methods have been attempted, whether the severity of behavior outweighs the risks of the proposed program and whether replacement behaviors are included within the plan.

Any revision to a behavior plan that increases the level of intrusiveness must be re-reviewed by the specially constituted committee. The committee need not reapprove a program when revisions are made in accordance with the approved plan. For example, if the physician changes the dosage of a medication in accordance with the drug treatment component of the active treatment plan to which the legally authorized person has given consent and which has already been approved by the committee, then there is no need for the committee or the legally authorized person to reapprove the plan. Generally, this would also apply if the medication was changed to another within the same therapeutic class or family.

W263**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.440(f)(3)(ii) Insure that these programs are conducted only with the written informed consent of the client, parents (if the client is a minor) or legal guardian; and****Guidance §483.440(f)(3)(ii)**

The committee must ensure that written informed consent must be obtained prior to implementation of any restrictive or intrusive program. In the event of an emergency, the facility may obtain a verbal consent, which must be authenticated in writing as soon as possible and subsequently submitted to the committee as verification.

The consent is required for the entire behavior management program not just the specific restrictive technique.

Consent is informed when the person giving consent is fully aware of the:

- specific treatment;
- reason for treatment or procedure;;
- the attendant risks vs. benefits;
- alternatives;
- right to refuse; and
- the consequences associated with consent or refusal of the program.

Informed consent must be in writing and must be specific to the program and restrictive practice and reflect a specific time frame. Blanket consents are not allowed. In the case of unplanned events such as assault and property destruction requiring immediate action, verbal consent may be obtained. However, it should be authenticated in writing as soon as reasonably possible (within 30 days).

For clients up to the age of 18, their parent or legally appointed guardian must give consent for him or her. At the age of 18, however, clients become adults and are assumed to be competent unless otherwise determined by a court.

For clients who are adults and have not been adjudicated incompetent and have not been assigned a legal guardian who may not fully understand the consequences of the program, informed consent for use of restrictive programs, practices or procedures should be obtained from a person or an entity in accordance with state law, to act as the representative or advocate of the client's interests.

The specially constituted committee must ensure that the informed and voluntary consent of the client, parent of a minor, legal guardian, or the person or organization designated by the state is obtained prior to each of the following circumstances:

- The involvement of the client in research activities; or
- Implementation of programs or practices that could abridge or involve risks to client protections or rights.

W264**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.440(f)(3)(iii) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other areas that the committee believes need to be addressed.****Guidance §483.440(f)(3)(iii)**

The committee has been made aware of and reviewed:

- facility policies and procedures;
- facility services;
- programs; and
- practices which may restrict or violate the rights of client.

The committee has established and uses a mechanism for monitoring clients' rights issues and informs the governing body of any issues of concern in a timely manner. This process is at the discretion of the committee. There is no requirement for periodic review of the policies by the committee.

The function of the committee is not limited to the review, approval and monitoring of restrictive behavior management practices. Examples of issues involving client rights that might be reviewed by the committee, in addition to behavior management, include, but are not limited to:

- 1) Research proposals involving clients;
- 2) Abuse, neglect and mistreatment of clients;
- 3) Allegations dealing with theft of a client's personal property or funds;
- 4) Damage to a client's goods or denial of other client rights;
- 5) Client grievances;
- 6) Visitation procedures;
- 7) Guardianship/advocacy issues;
- 8) Rights training programs;
- 9) Confidentiality issues;
- 10) Advance directives/DNR orders;
- 11) Practices which restrict clients (e.g., locked doors, fenced in yards); and
- 12) Video monitoring.

W265

§483.440(f)(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

W266

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450 Condition of participation: Client behavior and facility practices

(a) Standard: Facility practices– Conduct toward clients

W267

(Rev.135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(a)(1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients.

Guidance §483.450(a)(1)

The primary survey emphasis is on the implementation of the policies and procedures developed by the facility.

Conduct between staff and clients refers to language, actions, discipline, rules, order and other types of interactions exchanged between staff and clients or imposed upon clients by the staff during a client's daily experiences that affect the quality of a client's life.

§483.450(a)(1) These policies and procedures must –

W268

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(a)(1)(i) Promote the growth, development and independence of the client;

Guidance §483.450(a)(1)(i)

Consistent with facility policies, staff is observed to be engaged in activities which promote the client's growth, development and independence.

1) IPPs and data support the fact that from the time of admission, clients are learning new adaptive and functional skills while becoming more independent.

2) Interactions between clients and staff are consistent and positive.

3) Staff teach and encourage clients to interact with each other in a manner that promotes social integration both in the facility and out in the community.

4) All opportunities to teach and reinforce skill acquisition are utilized.

5) Staff identify and remove impediments in the learning environment (e.g. client is unable to concentrate in a room with a television because when they see the television, they want to watch their favorite show. Staff must identify this learning impediment and train in an environment without a television).

6) Staff encourage clients to complete tasks with as much independence as possible.

7) Staff encourage clients to take risks while providing reasonable safeguards to prevent injury.

8) Encourage clients to make choices during their daily activities.

W269

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(a)(1)(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;

Guidance §483.450(a)(1)(ii)

Written facility policies describe how the facility will offer choice to the clients during the course of their day.

Written policies describe how self-determination, as defined by free choice of one's own acts and decisions without external coercion or direction, to the extent possible and self-management, as defined by control of one's own routine and daily responsibilities, to the extent possible, are incorporated into the development of program plans and daily routines.

W270

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(a)(1)(iii) Specify client conduct to be allowed or not allowed; and

Guidance §483.450(a)(1)(iii)

"Client conduct" refers to any behavior, choice, action, or activity in which a client may choose to engage alone or with others.

Written policies and procedures which may be in the form of "house rules", must not impinge on individual client rights and must not be used as a substitute for the development of individualized programs and plans.

W271

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(a)(1)(iv) Be available to all staff, clients, parents of minor children, and legal guardians.

Guidance §483.450(a)(1)(iv)

Policies and procedures for management of conduct between staff and clients (483.450(a)(1)) should be provided to clients, parents of minor children, and legal guardians at admission and upon request. Policies and procedures are available on the residential and program areas if these are in separate buildings.

W272

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(a)(2) To the extent possible, clients must participate in the formulation of these policies and procedures.

Guidance §483.450(a)(2)

"To the extent possible" does not mean that the clients are excluded due to the clients' schedule or intellectual or developmental level. Facilities should be able to provide documentation that substantiates that clients were offered the opportunity and participated in the development of the policies. This could be accomplished through client committees or in house meetings. There should be documentation of these discussions between the client representatives and the facility.

W273

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(a)(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.

Guidance §483.450(a)(3)

Staff will promptly intervene when any clients tries to independently impose discipline upon another client. For example, a client who is serving dessert to the group withholds dessert from another client based upon their own evaluation of that client's behavior.

(b) Standard: Management of inappropriate client behavior

W274

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior

Guidance §483.450(b)(1)

At a minimum, the facility must have written policies and procedures regarding the management of maladaptive behaviors addressing the following:

483.450(b)(1) (W 275 – W284).

- the use of a functional behavior assessment in the development of behavior management programs;
- a hierarchy of least to most intrusive measures; and
- incorporation of behavior management programs into the IPP.

§483.450(b)(1) These policies and procedures must be

W275

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1) consistent with the provisions of paragraph (a) of this section.

§483.450(b)(1) These procedures must

W276

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(i) Specify all facility approved interventions to manage inappropriate client behavior;

Guidance §483.450(b)(1)(i)

All interventions for the management of inappropriate client behaviors which are approved for use in the facility are clearly stated and described in its policy. Examples of positive interventions include, but are not limited to, verbal praise reward systems, and prompting. Examples of negative interventions include, but are not limited to, removal of a privilege, implementation of restraint, and/or the use of exclusionary time out.

W277

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

Guidance §483.450(b)(1)(ii)

Policies and procedures must include a clear progression as to how staff implement interventions to manage inappropriate client behavior.

Facility policy and procedures must define the entire hierarchy of possible interventions from the most positive, functionally appropriate approaches to most intrusive approaches authorized. The facility determines at what level in the hierarchy the IPP will begin for each client based on their individual assessment. The plan must still begin at the least intrusive technique shown effective for that client. Individual plans should specify the specific techniques that have been determined through assessment to be least restrictive for each client.

The facility policy for unexpected behavioral incidents must provide direction for the staff in the utilization of the hierarchy. For clients not on a behavior plan, staff must apply the appropriate level of intervention per the established hierarchy, including emergency measures to prevent harm to self or others.

W278

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(iii) Insure prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

Guidance §483.450(b)(1)(iii)

Policies must be implemented to ensure that all restrictive procedures begin at the lowest level of the hierarchy unless there is documented evidence that less intrusive interventions have been tried and have been found to be ineffective.

The facility is not required to justify discontinuing the use of a more restrictive technique before initiating a less restrictive technique, since the intent of the regulation is to use the most positive, least intrusive technique possible.

In emergency situations where an unanticipated behavior requires immediate protection of the client or others, the technique chosen is the least restrictive appropriate technique possible.

§483.450(b)(1)(iv) Address the following:

W279

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(iv)(A) The use of time-out rooms;

Guidance §483.450(b)(1)(iv)(A)

“Time-out room” is defined as a separate room that is used to remove a client from stimulation that may be triggering and reinforcing maladaptive behavior. The facility must have written policies and procedures for the use of time out rooms which address all the requirements of 483.450 (c) (1-4) standard: time out room.

W280

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(iv)(B) The use of physical restraints;

Guidance §483.450(b)(1)(iv)(B)

“Physical restraint” is defined as any manual hold or mechanical device that the client cannot remove easily, and which restricts the free movement of, normal functioning of, or normal access to a portion or portions of a client’s body. Examples of mechanical devices may include arm splints and mittens.

Policies and Procedures must address:

- the types of physical restraint that are allowed in the facility;
- the persons who apply such restraints;
- the parameters for duration of application;
- the methods that assure the health and safety of clients while in restraints; and
- the specific training required for staff allowed to apply such restraints.

W281

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(iv)(C) The use of drugs to manage inappropriate behavior;

Guidance §483.450(b)(1)(iv)(C)

Applicable policies may include a discussion of:

- When a drug can be used to manage inappropriate behavior;
- Consistency with diagnosis;
- Alternatives tried before a drug is used;
- Precautions that must be followed prior to and during the use (lab values, monitoring of side effects);
- Implementation of a plan to address the behaviors for which the drug was prescribed; and
- Plan to reduce the medication as appropriate.

Drugs to manage inappropriate behavior are defined as any medication prescribed and administered for purposes of modifying the maladaptive behavior of a client.

W282

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(iv)(D) The application of painful or noxious stimuli;

Guidance §483.450(b)(1)(iv)(D)

“Application of painful or noxious stimuli” is defined as any procedure by which staff apply, contingent upon the exhibition of maladaptive behavior, startling, unpleasant, or painful stimuli, or stimuli that have a potentially noxious effect.

While the regulation permits the use of painful or noxious stimuli these techniques are the last resort and can only be utilized for behaviors that are causing significant harm and have not responded to competently administered interventions of less intrusive nature.

Facility policies must state that:

- The use of noxious stimuli is only permitted when the client exhibits behaviors so severe that they present a potential risk for significant or even life-threatening circumstances;
- the IDT and facility must weigh the potential risk of the behavior against the risk involved in the use of the painful or noxious techniques to manage behavior;

- that safeguards and strict oversight must be in place for consideration to use techniques that may be painful or even unpleasant;
- techniques that may be painful or noxious must be time limited;
- the proposed use of these techniques requires scrutiny of clinical effectiveness and specially constituted committee review; and
- on-going monitoring and safeguards must be in place during implementation of the technique.

W283

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(iv)(E) The staff members who may authorize the use of specified interventions;

Guidance §483.450(b)(1)(iv)(E)

W284

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(1)(iv)(F) A mechanism for monitoring and controlling the use of interventions.

Guidance §483.450(b)(1)(iv)(F)

Facility policies must address what supervisory oversight is provided during the application of the intervention in order to ensure that procedures were followed correctly. Procedures should also address what retrospective analysis is done on each intervention to ensure that procedures are being consistently followed.

W285

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

§483.450(b)(3) Techniques to manage inappropriate client behavior must never be used

W286

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(3) for disciplinary purposes,

Guidance §483.450(b)(3)

No intervention, whether as a part of a formal program or in emergency situations (see W289) may be used as punishment, retaliation or retribution. A staff member cannot employ a behavior management technique simply because a client refuses to follow a staff request.

The implementation of all interventions, except in emergency situations, must be administered consistent with the IPP and the specific behaviors identified in the IPP requiring the intervention. Instances where an intervention is done as a punishment because the client did not comply with staff instructions and not associated with the IPP include:

- Personal property confiscated for behavior at staff discretion;
- Rights restricted without approved plans; and
- Punitive house rules, such as prohibiting reentry into the kitchen for snacks if a meal is not eaten completely.

W287

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(3) for the convenience of staff

Guidance §483.450(b)(3)

Inadequate numbers of staff, inefficient deployment of staff, and insufficient training of staff can lead to restrictive practices used for staff convenience.

Examples of techniques used to manage client behavior for staff convenience including, but are not limited to:

- Clients allowed to discipline other clients;
- Clients restricted to one area of the home; and
- Unauthorized use of restraints (e.g., lap trays, bean bags, gait belt, and merry walkers for the purpose of restricting movement)

W288

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(3) or as a substitute for an active treatment program.

Guidance §483.450(b)(3)

Substitutions for active treatment programming occur when the staff utilizes interventions and restrictive techniques on their own, either because there is not a formal behavioral program to address the client's behaviors or because the staff do not follow the plan as written.

W289

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with §483.440(c)(4) and (5) of this subpart.

Guidance §483.450(b)(4)

The use of behavior interventions are expected to be incorporated into the IPP and be based upon the results of the functional behavioral assessment.

However, there may be isolated and rare instances when a client exhibits unexpected behavior that requires immediate intervention on the part of the staff. In these instances, the least restrictive intervention must be employed and removed as soon as the client is no longer an immediate threat to self or others. The IPP team must then discuss the need for adding a behavioral plan into the clients program.

W290

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(b)(5) Standing or as needed programs to control inappropriate behavior are not permitted.

Guidance §483.450(b)(5)

The staff of the facility may not maintain or use, outside of the IPPs, any list of "as needed" interventions that can be used with any client at any time. With the exception of isolated and rare emergency situations, all restrictive behavior interventions must be incorporated into the formal IPP and individualized for the client.

(c) Standard: Time-out rooms

W291

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(c)(1) A client may be placed in a room from which egress is prevented only if the following conditions are met:

(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)

(ii) The client is under the direct constant visual supervision of designated staff.

(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

Guidance §483.450(c)(1)

Seclusion, defined as the placement of a client alone in a locked room, is never allowed.

Time out procedures allows a client to be alone in a room, but do not allow that room to be locked. During a time out procedure, egress can only be prevented by a person standing in the door way, or holding the door closed, but as soon as the staff move from the door way or let go of the door the client can come out.

Use of the timeout room or procedure must be part of an approved behavioral plan and may involve the separation of a client from a group or a particular situation, in a non- locked setting for the purpose of calming or removing the client from the reinforcing stimuli that are sustaining an identified maladaptive behavior.

Designated time out rooms must be set up so that the staff has continuous, direct observation of the client at all times. Because of the danger that staff can get distracted by other events or duties, this cannot be accomplished by a camera in lieu of the staff having direct visual of the client.

Key locks, latch locks, and doors that open inward without an inside doorknob are not permitted by the regulations for use in time out rooms as they do not require constant physical pressure from a staff member to keep the door shut. In each instance where a time out room is used, the client's IPP must include:

- The functional behavioral assessment which resulted in a recommendation for the use of time out procedures; and
- Instructions on how often data is to be collected during the time out period and the criteria for release from time out.

The use of a time out room must be approved by the Specially constituted committee as part of an approved program.

W292

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(c)(2) Placement of a client in a time-out room must not exceed one hour.

W293

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(c)(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.

Guidance §483.450(c)(3)

Because placement in the time out room is typically secondary to extreme behaviors, it is acceptable that there be no furniture in this room.

A door that opens inward can potentially be held closed, either intentionally or inadvertently, by the client in the room, thereby denying staff immediate access to the room.

W294

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(c)(4) A record of time-out activities must be kept.

Guidance §483.450(c)(4)

The documentation in the client's record accurately reflects planned (e.g. part of the IPP) usage and presents a picture of events prior to, during, and following the use of time-out. The IPP should include direction as to how often data must be collected during each use of time out for each individual client.

(d) Standard: Physical restraints

§483.450(d)(1) The facility may employ physical restraint only- -

W295

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(1)(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;

Guidance §483.450(d)(1)(i)

The use of physical restraint is specified within the IPP. The plan must address:

- 1) The specific type of client behavior to be managed by this plan;
- 2) The less restrictive behavioral approaches which were previously used, but were unsuccessful;
- 3) The hierarchy of measures that must be utilized prior to the application of physical restraint;
- 4) The type of physical restraint;
- 5) The type of client behavior that would indicate that the patient is calm and can be released from the restraint; and
- 6) The replacement behavior being taught to the client to reduce the need for future restraints.

W296

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(1)(ii) As an emergency measure, but only if absolutely necessary to protect client or others from injury; or

Guidance §483.450(d)(1)(ii)

Physical restraint may be used as an emergency intervention only in situations where the client is exhibiting behaviors which:

- 1) the client has not exhibited before;
- 2) were not identified in the functional analysis of behavior; or
- 3) are harming other people or themselves.

When there are repeated episodes of the use of physical restraint as an emergency safety measure, these episodes should be assessed for their predictability by the IDT, and revisions to the IPP considered addressing the behaviors through a formal behavior plan in order to reduce/eliminate the use of physical restraint.

W297

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(1)(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

Guidance §483.450(d)(1)(iii)

Physical restraint during medical procedures must be utilized only when absolutely necessary and be used as a last resort in order for the facility or practitioners to deliver needed medical care to the client. The restraint must be released as soon as the medical procedure is completed unless it is necessary to continue restraint for a longer period of time to continue to deliver care or to prevent the client from displacing tubes or dressings. These restraints may only be used as long as the physician indicates them to be necessary.

For instances where physical restraint are used by the facility or a practitioner during a medical procedure, the client record and interviews should verify that less restrictive measures were attempted before using physical restraint and verify whether any injuries occurred during the use of the physical restraint. Written orders by medical personnel for the application of a physical restraint should include the reason that the restraint is necessary, the type of restraint to be used and the length of time the restraint will be applied.

A restraint device used to prevent a client engaging in self-injurious behavior is not considered a restraint for medical condition.

§483.450(d)(2) Authorizations to use or extend restraints as an emergency measure must be:

Guidance §483.450(d)(2)

Facility policies should list who in the facility is allowed to authorize the emergency use of restraints or to extend the use of an emergency restraint, and the training that is required for those persons who may authorize. Documentation in the client record in those instances should confirm that the facility follows that policy.

W298

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(2)(i) In effect no longer than 12 consecutive hours; and

Guidance §483.450(d)(2)(i)

This regulation does not mean that restraints may be authorized to be applied for up to a 12 hour period. The client must be released from the physical restraint as soon as the client is no longer a risk to self or others. Once the behavior has ceased, the emergency has ended, and the client has been released, another authorization would be required for any new emergency situation.

The 12 consecutive hour period is the absolute maximum period of time that emergency physical restraint may be utilized for a client during an individual behavioral incident. It is reasonable to expect that the facility will reassess the emergency situation for any client who remains in physical restraint for longer than one hour and reassess the situation at least every 30 minutes thereafter up to 12 hours when the physical restraint must be removed.

W299

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(2)(ii) Obtained as soon as the client is restrained or stable.

Guidance §483.450(d)(2)(ii)

There may be instances where the maladaptive behaviors of a client or clients escalate into a serious and immediate event that must be de-escalated quickly in order to prevent harm to clients, staff, other

clients, or by standers when incidents occur in the community. In these instances, the staff should contact the appropriate person to obtain authorization for the use of physical restraint as soon as the situation is stable. Retrospective documentation of the incident should confirm the need for authorization after application.

W300

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(3) The facility must not issue orders for restraint on a standing or as needed basis.

Guidance §483.450(d)(3)

All instances of physical restraint must be ordered on a case by case basis with individual assessment of the situation and authorization based upon the individual client. Authorizations should include the rationale for the use of the physical restraint versus other less restrictive measures.

W301

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints,

Guidance §483.450(d)(4)

The frequency of monitoring will vary according to the type and design of the device and the psychological and physical well-being of the client. The facility should be checking the client often enough to adequately assess the physical status of the client (e.g., circulation, respiration and vital signs) of the client and the need to continued restraint. The more restrictive the intervention, the greater the risk to the client and the more often the client must be assessed. Frequent assessment will assure that the client will be released as soon as possible, however, in no instance may the staff go longer than 30 minutes without checking the client.

W302

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(4) released from the restraint as quickly as possible, and

Guidance §483.450(d)(4)

“As quickly as possible” means as soon as the client is no longer a danger to self or others. Documentation should support that the client was released from restraint as soon as they became calm.

W303

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(4) a record of these checks and usage must be kept.

§483.450(d)(5) Restraints must be designed and used

W304

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(5) so as not to cause physical injury to the client

Guidance §483.450(d)(5)

Physical restraints to include mechanical devices must be the correct size for the client and be applied with the correct amount of pressure according to manufacturer’s directions. In addition to observation of any physical mechanical restraint in use at the time of the survey, review incident reports for any injuries as a result of restraint use.

W305

§483.450(d)(5) and so as to cause the least possible discomfort.

§483.450(d)(6) Opportunity for motion and exercise must be provided

W306

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(6) for a period of not less than 10 minutes during each two hour period in which restraint is employed,

Guidance §483.450(d)(6)

This requirement does not apply to cases of medical restraints that are specifically ordered for the immobilization of bones and joints during the physical healing process involved with fractures, sprains, etc. (e.g. a broken bone immobilized by a cast or splint).

See 331 483.460(c) regarding surveillance of skin integrity during the use of medical restraints. However, if a mechanical physical restraint is applied to an extremity to prevent a client from removing post-operative sutures, the restraint must be released every two (2) hours for a period of not less than ten (10) minutes in order to maintain adequate circulation.

Mechanical restraints placed on the client during sleeping hours must be medically based and specifically ordered by a physician. There should be evidence in the client's record why the mechanical physical restraint is necessary during sleeping hours. While it is not necessary to wake the client every two (2) hours to release the restraint and provide opportunity for exercise, the staff must check the restraint frequently during the night to ensure that the restraint is still properly applied and the client appears comfortable.

W307

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(6) and a record of such activity must be kept.

§483.450(d)(7) Barred enclosures

Guidance §483.450(d)(7)

A bed or play equipment with bars that prevent the client from leaving the bed or voluntarily climbing out of the bed are barred enclosures. The use of such enclosures must be a part of the written IPP and behavioral assessments must clearly state why such an enclosure is necessary, the risks of using the enclosure versus not using it and what less restrictive measures have been tried prior to the implementation of the barred enclosures.

Such devices may not be used in lieu of adequate staffing.

W308

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(7) must not be more than three feet in height and

W309

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(d)(7) must not have tops.

(e) Standard: Drug usage

§483.450(e) Standard: Drug Usage

W310

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

Guidance §483.450(e)(1)

Clients are alert and available for participation in daily living activities.

Some medications administered for medical reasons or to manage behavior may cause drowsiness as a side effect or due to an accumulation of the drug in the client's system. For clients who are observed to be sleeping in chairs during their work day, their programs or recreational times, there should be evidence that the facility staff notified the medical staff and an assessment was performed of the client including their medication regimen. Medical staff should make adjustments to address the issue if indicated.

§483.450(e)(2) Drugs used for control of inappropriate behavior must

W311

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(2) be approved by the interdisciplinary team and

Guidance §483.450(e)(2)

The physician and other team members discuss the risks and benefits of the medication to address the target behavior/symptoms, and approve the use of the drug as being consistent with the active treatment program. Decisions about the necessity of the use of drugs to manage inappropriate behavior should be made by the IDT. It is the responsibility of the IDT members to provide the physician with sufficient information regarding the need for a client to receive a drug for inappropriate behavior. The physician will make the ultimate decision to order the use of the drug. The IDT should document any disagreement with the physician's order.

In those instances where a client returns from a physician's visit with an order for an unsolicited drug to manage client's inappropriate behaviors, there must be evidence (e.g. IDT meeting notes or clients record) that the team concurred with the necessity for the order without trying less restrictive measures first and discussed any concerns with the physician.

W312

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(2) be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

Guidance §483.450(e)(2)

All medications to manage behavior must be integrated into the IPP and the IPP must specify how the specific target behavior for which the medication is prescribed will be reduced or eliminated. This includes medications which are typically used for medical conditions that may be used to manage behavior (e.g. 1. propranolol (Inderal), an antihypertensive used for self-injurious behavior, and 2. carbamazepine (Tegretol), an anticonvulsant, used for aggression).

Drugs for behavior management must not be ordered on a PRN basis for a client. The facility staff must contact the physician to obtain a one-time order if the situation necessitates the use of medication. The facility policy must address the maximum number of times a medication can be used as an emergency prior to being incorporated in the IPP, side effects of such medications, and the frequency of re-evaluation of ongoing behavior and its treatment.

Clients or their legal guardian have the right to choose sedation for medical and dental procedures. However, the facility cannot do routine administration of medication for sedation for medical and dental procedures without the agreement/consent of the client or their parent/legal guardian and they must follow the specific orders of the healthcare practitioner who will be providing services to the client. Decisions to order medications prior to medical and dental procedures must be made on an individual basis. Clients who demonstrate severe anxiety around these procedures should be considered for desensitization programs.

W313

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

Guidance §483.450(e)(3)

The risk(s) associated with the drug being used is consistent with the type and severity of the behavior/symptoms it is intended to affect.

At the time the drug was started and incorporated into the IPP, the behaviors were discussed and presented to team members. It was the documented decision of the team that the behaviors were of such a severity that pharmacological intervention was required and the physician was provided with the team information to assist him in his decision to prescribe the medication.

§483.450(e)(4) Drugs used for control of inappropriate behavior must be - -

§483.450(e)(4)(i) Monitored closely,

W314

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(4) in conjunction with the physician and the drug regimen review requirement at §483.460(j),

Guidance §483.450(e)(4)

The physician and pharmacist must regularly review use of drugs for control of inappropriate behavior for their effectiveness in changing the targeted behavior/symptoms, untoward side effects, contraindications for continued use, and communicate this information to relevant staff.

W315

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(4) for desired responses and adverse consequences by facility staff; and

Guidance §483.450(e)(4)

Direct support staff members are the people who most closely and most frequently observe and record client behaviors. There should be evidence that the direct support staff receive information via the IPP as to the behaviors to be observed, the side effects associated with the medication, the amount and types of documentation required and the communication with clinical staff which is indicated. See 483.430 (e)(1) for training on observations, documentation and communication related to behavior management.

§483.450(e)(4)(ii) Gradually withdrawn**W316**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(4) at least annually**Guidance §483.450(e)(4)**

Clients receiving medications to control behavior must be evaluated at least annually for a possible reduction of the medication progressing the client toward final elimination of the drug or lowest possible therapeutic level of the drug. However, evaluation should be done earlier than annually if observations indicate that the client's behavior has improved to the point that reduction may be considered as determined by the IPP, unless otherwise ordered by the client's physician.

W317

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.450(e)(4) in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.**Guidance §483.450(e)(4)**

The IDT is aware of and involved in planning the drug reduction program and participates in its implementation and monitoring.

Progress or regression of the client is monitored and taken into consideration in determining the rate of withdrawal and whether to continue withdrawal.

In determining whether there is clinical contraindication to the annual drug withdrawal, the physician and IDT should consider the client's clinical history, diagnostic/behavioral status, previous reduction/discontinuation attempts, and current regimen effectiveness.

If a client also has a diagnosis of a psychiatric condition that requires a stable level of a psychiatric medication in order to control the symptoms associated with the psychiatric diagnosis, the annual evaluation for reduction of that particular medication for the symptoms of the psychiatric diagnosis would not apply. Documentation in the client's record from their psychiatrist or physician that medication reduction would be contraindicated or that the current level of medications is therapeutic meets the intent of this regulation.

W318

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460 Condition of participation: Health care services**(a) Standard: Physician services****W319**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(a)(1) The facility must ensure the availability of physician services 24 hours a day.**Guidance §483.460(a)(1)**

A designated physician must be available via telephone, pager, e-mail or on-site in the facility on a 24 hour per day basis for consultation regarding both emergency and non-emergency medical issues. If the facility employs a fulltime physician, there must be procedures in place for coverage in the absence of the physician from the facility.

If the facility contracts with a community-based physician for 24 hour per day coverage, there must be written arrangements in place to detail the responsibilities of the contract physician regarding direct services to the clients, interactions with the direct support staff and the interactions between the nursing staff of the facility and the contract physician. The contract with the contract physician must delineate the process for coverage when he/she is not available.

Upon interview, the staff should be aware of the procedures they are to follow to contact a physician in the event of an illness or injury. Routinely sending clients to emergent care or the emergency room of a hospital because there are no facility physicians available for consultation is not consistent with the regulations.

Interview and record review verify that the physician is available and responsive 24 hours a day.

W320

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(a)(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care.

Guidance §483.460(a)(2)

A medical care plan of treatment is developed for those clients who are either acutely ill and require licensed nursing care and monitoring temporarily on a 24 hour basis or clients whose chronic medical conditions require or indicate 24 hour licensed nursing care and monitoring. The physician determines when 24 hour nursing care is required.

The medical care plan is based upon the orders from the physician for treatments and care and nursing standards of practice. There is evidence in the client's record that the physician and the nursing staff at the facility work together to ensure that the medical care plan is current and appropriate (e.g. changes in physician written orders for care pursuant to observations from the nursing staff and/or direct observations and interactions with the client, and nursing documentation of care).

The fact that a client has a medical care plan in place should not preclude him/her from an active treatment program, except in instances of acute illness where the active treatment program is temporarily suspended. For clients with chronic medical conditions, it may be necessary for their active treatment program to be modified due to the tolerance level of the client or adapted to accommodate medical limitations. However, active treatment must be provided on a continuous basis.

W321

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(a)(2) This plan must be integrated in the individual program plan.

Guidance §483.460(a)(2)

Although the medical care plan can be a separate document, it is always an integral part of the IPP process. There should be evidence that the plans are shared and discussed at the time of all interdisciplinary discussions and the information from the medical care plan is utilized in the development of the IPP objectives.

§483.460(a)(3) The facility must provide or obtain

W322

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(a)(3) preventive and general care

Guidance §483.460(a)(3)

The facility has procedures in place to ensure that the clients receive general health care services to assure optimal levels of wellness. General health care services include assessment and treatment of acute and chronic complaints or situations; teaching relevant health care principles to staff and clients; and periodic surveillance of the health status of the clients.

As a result of clinical assessment, referrals are made for specialized assessment and tests. Facility health care staff follow-up to ensure the assessments are done and the findings incorporated into the medical care plan and/or the IPP.

The facility must have arrangements in place to provide routine or episodic laboratory, and radiology services for the clients if not provided in-house or through the clients physician. There must be a written agreement that specifies the responsibilities of the facility and outside provider. (See §483.410(a)).

Preventive health care services include screening procedures designed to identify health concerns and initiate treatment as early as possible. The facility should have a health prevention program in place and follow the plan to address those screenings that the facility will perform periodically that are relevant to all clients, and those screenings associated with a particular gender or age or vulnerability.

Physician refusal to perform a test, such as a pap smear, must be consistent with guidelines for clients, per the local standard in the community.

If the facility has a physician that refuses to provide preventative healthcare based on the client's level of functioning, medical staff at the facility should meet with and consult with this physician in order to ensure that clients receive the same health services as persons living in the local community.

Refer to these websites for current recommended screenings: Agency for Healthcare Research and Quality (AHRQ)

For men: <http://www.ahrq.gov/ppip/healthymen.htm>
Centers for Disease Control (CDC)

For women: <http://www.cdc.gov/women/pubs/cancer.htm>

§483.460(a)(3) as well as annual physical examinations of each client that at a minimum include the following:

W323

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(a)(3)(i) Evaluation of vision and hearing;

Guidance §483.460(a)(3)(i)

Information relevant to the client's ability to see and hear is a critical component in the development of appropriate active treatment strategies.

All clients, including clients who are non-verbal, should have evidence in his/her record that they receive an annual evaluation of their vision and hearing which includes a screening as a minimum, follow-up examination as indicated by the screen and timely referrals as indicated by the examination. Screening is a gross assessment of the client's vision and hearing and usually does not include a measurement of acuity. Examinations are conducted to follow-up on issues noted in the screening and are conducted by qualified professionals.

Clients who appear to have vision or hearing problems or the staff indicate that they have vision or hearing problems and no accommodations have been made. The annual vision and hearing evaluation verifies that clients appearing to have vision/hearing issues or if staff indicate that a client has vision/hearing issues that these issues have been/are being addressed.

If a client's vision or hearing can only be assessed through examinations conducted by specialists (e.g., comprehensive ophthalmological examinations and evoked response audiometry (ERA)), these tests need not be conducted yearly, but rather upon the specialist's expressed recommendations. During discussions at the annual IPP review the team reviews information from the health professional, speech and hearing professional, and direct support staff and makes referrals back to the specialist if indicated.

W324

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(a)(3)(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics;

Guidance §483.460(a)(3)(ii)

These immunization guides may be obtained from: American Academy of Pediatrics
www.aap.org/healthtopics/immunizations.cfm

Centers for Disease Control (CDC)
www.cdc.gov/vaccines/recs/schedule/default.htm.

W325

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(a)(3)(iii) Routine screening laboratory examinations as determined necessary by the physician,

Guidance §483.460(a)(3)(iii)

The facility may have a set of routine laboratory tests which are to be done on every client annually which is developed and approved by the facility physician. However, such a list is not required. The physician may write orders individually for the clients based upon their medical history, age, gender or medical vulnerabilities.

W326**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(a)(3)(iii) and special studies when needed;****W327****(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(a)(3)(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section on diseases of the chest of the American Academy of Pediatrics, or both.****Guidance §483.460(a)(3)(iv)**

The facility should have in place a system for the identification, reporting, investigation, and control of Tuberculosis (TB) in order to prevent its transmission within the facility. This system should include:

1) Policies and procedures for screening new employees, new clients, and other people who interact on a consistent basis with clients residing in the facility when those persons are volunteers or professional staff hired or utilized directly by the facility (such as volunteers and contract professional staff);

2) Policies and procedures for subsequent screening for clients and for employees, and other people (such as volunteers and contract professional staff) who interact on a consistent basis with clients residing in the facility when those persons are volunteers or professional staff hired or utilized directly by the facility per State Health Department requirements;

3) Policies and procedures for reporting positive TB test results to the appropriate State authorities;

4) Policies for the investigative procedures, per the local health department, that would be put in place should a client or staff person test positive for TB;

5) Policies and procedures for treatment and precautions to be used with clients who display TB symptoms, as substantiated by positive skin testing or x-ray results; and

6) Policies and procedures for the evaluation of the effectiveness of the surveillance system.

When one or more clients or staff display TB symptoms, as substantiated by positive skin testing or x-ray results, they do not return to work until a physician has cleared them to return to work.

W328**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(a)(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.****Guidance §483.460(a)(4)**

Refer to the applicable State Nurse Practice Act or applicable Board of Medicine Practice Act to determine the extent that the nurse practitioner or physician assistant may provide physician services.

(b) Standard: Physician participation in the individual program plan**§483.460(b) A physician must participate in-****W329****(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(b)(1) The establishment of each newly admitted client's initial individual program plan as required by §456.380 of this chapter that specifies plan of care requirements for ICFs; and****Guidance §483.460(b)(1)**

During the admission process, which takes place from the time the client is admitted to the facility to the time the initial IPP is completed, a physician is required to ensure that an assessment of the client's medical status is thoroughly considered and incorporated into the IPP planning process by the team as it develops the IPP. The physician's input may be by means of written reports, evaluations, and recommendations.

The physician (consistent with Medicaid Utilization Control regulations at §456.380) must evaluate the client at the time of admission to identify all diagnoses and complaints, provide orders for all medications and treatments and provide recommendations for restorative and rehabilitative services.

§456.380 requires that a physician conduct this initial assessment therefore, it may not be done by a physician extender (e.g., Physician assistant or Advanced Practice Registered Nurse).

W330**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)**

§483.460(b)(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

Guidance §483.460(b)(2)

The need for physician participation on an individual client's IPP team is determined by the medical needs of the client. How the physician participates (whether through written report, telephone consultation, attendance at the meeting, etc.) is to be left to the discretion of the facility. In instances where a client has no overriding medical issues, the nurse of the facility can represent the medical component on the IDT process or consult with the appropriate physician and share the information with the team. However, in situations where a client's medical condition is unstable/fragile to the extent that it impacts the training/work that may be planned, the physician must participate in providing guidance on the types and extent of programs that would be appropriate considering the client's physical/medical limitations. If a client is noted to be having difficulty participating in the objectives set forth in his/her IPP due to serious medical concerns, review the input that was provided by the physician into the development of the plan and whether the IPP team requested such input.

(c) Standard: Nursing services

W331

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c) The facility must provide clients with nursing services in accordance with their needs.

Guidance §483.460(c)

The nurse responds in a timely manner to all medical concerns reported, conducts assessments as indicated, effects timely and appropriate interventions, communicates with the client's physicians and other health care professionals as indicated, provides treatments as ordered, monitors client progress following illness or injury and provides training to clients and/or staff as indicated.

§483.460(c) These services must include

W332

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

Guidance §483.460(c)(1)

For those clients who have had an uneventful year medically and have no medical/health concerns at the time of the IPP meeting the facility nurse may submit a summary report to the IDT unless the IDT determines that his/her attendance is necessary. An eventful year medically would include a year which required unplanned hospital admissions or in which medical issues necessitated treatment for a prolonged or continuing period. However when a client has had an eventful year medically or current medical/health concerns, this could have an impact on their objectives and accordingly the nurse should participate in the IDT discussion directly.

W333

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;

Guidance §483.460(c)(2)

A medical care plan addresses those clinical treatments and observations that are to be done for the client by the medical staff and other staff of the facility in order to either improve an acute medical condition or to maintain a medically fragile client as clinically stable as possible. The medical care plan is an adjunct to the IPP and is not considered a substitution for the IPP.

§483.460(c)(3) For those clients certified as not needing a medical care plan, a review of their health status which must-

W334

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(3)(i) Be by a direct physical examination;

Guidance §483.460(c)(3)(i)

A direct physical examination means a visual review of the body as well as examination/assessment of body systems. This includes observations made through non-verbal communication (including visual, tactile, nonverbal gestures, grimaces, etc.) which may be an indication that there is a potential for further assessment and/or monitoring. A paper review of the client's medical record and health statistics does not meet the intent of the regulation for a direct physical examination.

W335

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(3)(ii) Be by a licensed nurse;

Guidance §483.460(c)(3)(ii)

The term "licensed nurse", for purposes of these guidelines, means a registered nurse, a licensed practical nurse or a licensed vocational nurse currently licensed by the State in which the facility is located. The nurse must operate consistent with the requirements of the applicable Nurse Practice Act. If this direct physical examination is done by a physician, it is not necessary for the nurse to repeat the exam.

W336

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(3)(iii) Be on a quarterly or more frequent basis depending on client need;

Guidance §483.460(c)(3)(iii)

"On a quarterly basis" means that the examinations are conducted approximately 90 days apart (e.g. scheduled to be conducted approximately once every 90 days). If during the course of a calendar year, there were three quarterly examinations conducted by a licensed nurse and in the fourth quarter the annual physical examination was performed by a physician, the intent of this requirement is met without the nurse performing an additional examination.

W337

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(3)(iv) Be recorded in the client's record; and

Guidance §483.460(c)(3)(iv)

The actual findings of each examination and the date conducted must be incorporated into the client's record.

W338

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(3)(v) Result in any necessary action (including referral to a physician to address client health problems).

Guidance §483.460(c)(3)(v)

The nursing staff document that referrals are made in a timely manner, if indicated, for any concerns identified. Nurses must ensure all concerns they identify are communicated and addressed appropriately, including:

- Need is fully identified in assessment;
- Appropriate referrals are made;
- Revisions are made to IPP/Medical care plan; and
- Follow-up occurs to the new plan.

W339

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(4) Other nursing care as prescribed by the physician or as identified by client needs; and

Guidance §483.460(c)(4)

Nursing interventions are implemented as indicated by the needs of the client and consistent with either standard nursing practice principles or orders from the attending physician. Health and wellness are actively promoted, problems are attended to before they negatively impact the client's health and wellness, and steps are taken to prevent the recurrence of such problems while responding promptly to client's needs.

Client health care complaints that are reported either directly by the client or by the direct care staff are addressed promptly by the nursing staff. Client health care complaints and response by nursing staff are documented in the client's record.

§483.460(c)(5) Implementing with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to –
W340

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(5)(i) Training clients and staff as needed in appropriate health and hygiene methods;
Guidance §483.460(c)(5)(i)

Nursing staff periodically provides training to clients and staff on how to care for health needs or conditions, personal hygiene, health maintenance, and disease prevention. Nursing staff actively participates in periodic discussions with client and staff to promote health habits in the areas of diet, exercise and non-smoking.

Based upon individual training needs, the nursing staff provides training to individuals in areas such as medications, family planning, prevention of sexually transmitted diseases, control of other infectious diseases, self-monitoring of health status and self-prevention of health problems, etc. The nurses may train clients directly on their objectives or train other staff to do this training as appropriate.

W341

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(5)(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

Guidance §483.460(c)(5)(ii)

Nursing staff should actively participate in surveillance and reporting of communicable diseases per the Centers for Disease Control (CDC) guidelines and applicable state laws. They should teach and promote infection control techniques such as hand washing by clients and staff and should be making periodic observations to ensure that such good infection control techniques are consistently utilized.

W342

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(c)(5)(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

Guidance §483.460(c)(5)(iii)

Nursing staff must train and ensure direct support staff demonstrate competency in detecting signs and symptoms of illness, injury, or change in the client's health baseline (e.g. responsiveness, fatigue, irritability, constipation, diarrhea, dehydration, confusion, unexplained weight loss, changes in endurance and changes in respiratory function).

Staff is responsive to health care needs or injuries of clients and receives instruction and support during temporary illness of clients.

If not, review staff training records to determine whether training was provided periodically to the involved employee. Interview direct care staff to determine their level of understanding regarding the signs and symptoms of illness that are to be reported to the medical staff. The records of clients with recent hospitalizations verify that staff detected and reported relevant symptoms promptly.

(d) Standard: Nursing staff

W343

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(d)(1) Nurses providing services in the facility must have a current license to practice in the State.

Guidance §483.460(d)(1)

The facility should have a procedure in place to ensure that any contract nursing staff members are currently licensed prior to the provision of services. Include any contract nurses used by the facility in the sample of nurses reviewed for licensure.

W344

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(d)(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients' health needs including those clients with medical care plans.

Guidance §483.460(d)(2)

The facility provides for nursing services based on the health needs and conditions of clients residing there. Examples include:

- 1) physician ordered treatments that require the skills of a licensed nurse;
- 2) preventive screenings;
- 3) assessment and intervention;
- 4) direct physical examination and examination of body systems;
- 5) teaching; and
- 6) advocacy for the medical services needed by the client.

Client health care needs are met in a timely manner (within 24 hours) by the available nursing staff.

If nurses who do not have experience in the care of persons with intellectual disabilities are employed by the facility, they should be provided with a formal orientation period and on-going educational opportunities to increase their understanding of the client population.

When one or more clients in the facility has an active medical care plan, there must be 24 hour nursing services available to come to the facility as needed to make skilled assessments and interventions.

W345

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(d)(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

Guidance §483.460(d)(3)

Refer to the applicable State Nurse Practice Act.

W346

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(d)(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.

Guidance §483.460(d)(4)

The facility must have written arrangements with a registered nurse (RN) to provide consultation in those instances where LPNs/LVNs provide all the direct nursing care for the clients. Verify that the agreement requires the RN to respond promptly to all calls from the LPN/LVN and to come on-site to the facility if necessary. The facility must also ensure registered nurse back-up when the primary registered nurse consultant is unavailable (vacations, etc.). Review documentation in the client records to confirm that the LPNs/LVNs of the facility are consulting the registered nurse consultant when indicated and that she/he responds promptly to such calls.

W347

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(d)(5) Non- licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

The work of any direct support staff (caring for clients with a medical care plan) is directed by an onsite licensed nurse). The nurse evaluates the care provided by the staff as needed, but at least each shift. If observations of care indicate that direct care staff are not providing care as directed by the medical care plan, then review the supervision provided by the nursing staff.

(e) Standard: Dental services

W348

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(e)(1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.

Guidance §483.460(e)(1)

It is expected that the clients will obtain dental services (both diagnostic and treatment) from community dentists whenever possible. In some instances, there may be clients residing in the facility who are physically unable to travel to the community for services. The facility must secure dental services (both diagnostic and treatment) for these clients either through an in-house program, which is part of the organizational and administrative structure of the facility, or through a written agreement with an outside dental service to come into the facility to provide such services.

W349

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(e)(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

Guidance §483.460(e)(2)

Reports of dental care may be submitted to the IDT for inclusion in their discussions surrounding either development of the plan or update to the plan. This includes procedures a client may have had or be having during the plan development period, such as root canal or singular extractions. Actual attendance at the IDT meeting by the dentist may be left to the request of the IDT.

W350

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(e)(3) The facility must provide education and training in the maintenance of oral health.

Guidance §483.460(e)(3)

Formal or informal training in the maintenance of oral hygiene is provided to clients who require it, and to those staff who are responsible for carrying out such activities. The IPP should include an assessment of the client's ability to perform oral hygiene independently and an associated program if the client is not independent.

(f) Standard: Comprehensive dental diagnostic services

§483.460(f) Comprehensive dental diagnostic services include

W351

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(f)(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's condition not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

Guidance §483.460(f)(1)

A "month" is defined as the interval between the date of admission and close of business of the corresponding day in the following month.

A complete intraoral examination includes an oral cancer screen.

§483.460(f)(2) Periodic examination and diagnosis performed

W352

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(f)(2) at least annually,

Guidance §483.460(f)(2)

Dental examinations occur no less frequently than annually. Clients without teeth must receive an annual oral cancer screening examination by a dental professional.

W353

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(f)(2) including radiographs when indicated and detection of manifestations of systemic disease; and

Guidance §483.460(f)(2)

There should be evidence in dental reports that dentists follow current standards of practice for the performance of x-rays in order to assist in the diagnosis and treatment of the client.

W354

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(f)(3) A review of the results of examination and entry of the results in the client's dental record.

Guidance §483.460(f)(3)

The entry referenced at this regulation is the dental entry into the dental record. See W359 for requirement of copying this dental record into the facility record.

(g) Standard: Comprehensive dental treatment

**§483.460(g) The facility must ensure comprehensive dental treatment services that include- -
W355**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(g)(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

Guidance §483.460(g)(1)

The facility should be able to produce upon request, a written contract/agreement between the facility and a licensed dentist for 24/7 guidance/provision of emergency services for the clients. The agreement should also indicate what back-up coverage will be provided when the dentist is not available.

W356

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(g)(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) Standard: Documentation of dental services

**§483.460(h)(1) If the facility maintains an in-house dental service, the facility must
W357**

keep a permanent dental record for each client,

W358

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(h)(1) with a dental summary maintained in the client's living-unit.

Guidance §483.460(h)(1)

The "dental summary" refers to the summary of each visit entered by the dental professional. The note includes any care instructions to be followed up by facility staff as a result of treatment.

**§483.460(h)(2) If the facility does not maintain an in-house dental service, the facility must
W359**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(h)(2) obtain a dental summary of the results of dental visits

Guidance §483.460(h)(2)

The facility should receive a written report of each dentist visit for inclusion in the client's record at the facility and for reference by the medical and direct support staff.

W360

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(h)(2) and maintain the summary in the client's living unit.

See guideline above at W359.

(i) Standard: Pharmacy services

W361

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(i) The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.

Guidance §483.460(i)

The facility either has an onsite pharmacy or has formal arrangements in place for the provision of routine, unanticipated, or emergency drugs. There are no instances where a client does not receive needed medications due to the unavailability of drugs.

(j) Standard: Drug regimen review

W362

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(j)(1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

Guidance §483.460(j)(1)

The primary function of the pharmacist during the quarterly drug review is to identify possible drug interactions, check for evidence of any side effects associated with the drug usage, determine if laboratory results associated with the drug are within normal limits and verify that the facility is administering the medication appropriately and to comment upon the efficacy of the drug use (e.g. blood sugar controlled, blood pressure within normal limits). In the case of drugs used to manage behavior, the pharmacist may need information from the IDT to determine efficacy. See Appendix PP, Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews, to the State Operations Manual (Pharmaceutical Service Requirements in Long Term Care Facilities).

W363

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(j)(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

Guidance §483.460(j)(2)

The physician and IDT members must discuss, document and take necessary follow-up action for any irregularities noted.

W364

§483.460(j)(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

W365

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(j)(4) An individual medication administration record must be maintained for each client.

W366

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(j)(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

Guidance §483.460(j)(5)

Pharmacist participation on the IDT is at the request of the team. It would not be necessary for the pharmacist to routinely attend all team meetings when the client is on a stable drug regimen that does not appear to be influencing his/her active treatment programs. Pharmacist participation may be appropriate, in situations such as assisting the IDT develop the most effective training programs for when the client is in an evolving situation with their medication.

For example:

- A client begins a new or more complex drug regimen;
- The physician orders off-label use of a medication;
- Frequent changes in the drug regimen are affecting IPP implementation.

(k) Standard: Drug administration

W367

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(k) The facility must have an organized system for drug administration that identifies each drug up to the point of administration.

§483.460(k) The system must assure that

W368

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(k)(1) All drugs are administered in compliance with the physician's orders;

Guidance §483.460(k)(1)

Administration errors identified in previous medication administration records qualify as non-compliance with physician's orders.

W369**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(2) All drugs, including those that are self-administered, are administered without error;****Guidance §483.460(k)(2)**

A medication error is an observed discrepancy during the medication pass between what is ordered and what is administered.

This also applies to self-administered medications.

For small facilities (16 beds or less), the medication administration pass will encompass a total of eight (8) drug doses. The observations should be split between two separate drug passes 4/4 (one in the morning and one in the late afternoon or early evening). The medications observed during the observations may or may not be for clients in the survey sample. Any concerns regarding a medication that is about to be administered should be brought to the attention of the person administering the medication. The record of observation should be reconciled with the most current signed physician's orders.

For large facilities (17 or more beds) with either single or multiple buildings, the medication administration pass will encompass a total of 12 doses. The observations should be split between two separate passes 6/6 (one in the morning and one in late afternoon or early evening). Any concerns regarding a medication that is about to be administered should be brought to the attention of the person administering the medication. The record of observation should be reconciled with the most current signed physician's orders.

W370**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(3) Unlicensed personnel are allowed to administer drugs only if State law permits;****Guidance §483.460(k)(3)**

Unlicensed personnel administer only those forms of medication which state law permits. Licensed nurse(s) in the facility oversee any administration of medications by unlicensed persons and periodically evaluate their performance.

W371**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(4) Clients are taught to administer their own medications if the interdisciplinary team determines that self-administration of medications is an appropriate objective, and if the physician does not specify otherwise;****Guidance §483.460(k)(4)**

The IDT decision that a self-administration program is appropriate, as is the case for all formal training objectives, must be based upon accurate, current, valid assessment of the client's skills and potential. The determination as to the appropriateness of a self-administration program must never be made singularly on the client's diagnosis or current functional abilities.

For clients assessed to be inappropriate for a self-administration program, but determined by the IDT to possess the capacity to functionally, cognitively, emotionally or developmentally benefit from participation in the drug administration process, it is expected that the facility will provide opportunities for the client to participate in the medication administration process under direct supervision. This participation can include but is not limited to, identifying the medication taken, reaching/grasping a cup of water during the process and placing oral medications in the mouth, etc.

W372**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;****Guidance §483.460(k)(5)**

While the IDT may set an objective of self administration of medication for a client, they are required to notify the client's physician of this proposed objective. If the client's physician objects on medical grounds, the team must not proceed with the objective until such time as a discussion is held with the physician and he/she agrees to proceed after receiving additional information.

W373**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(6) No client self-administers medication until he or she demonstrates the competency to do so;****Guidance §483.460(k)(6)**

The written self-administration program for a client must detail the criteria that will be employed by the facility staff to verify that the client successfully completes all phases of the program and continues to comply with all necessary requirements for self administration. Clients who self-administer medications must secure all medications in such a manner as to protect access by other clients or visitors.

W374**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law;****Guidance §483.460(k)(7)**

When clients go out of the facility for home visits, or to attend work or school, drugs they are taking must be packaged and labeled in accordance with state law by a person authorized by state law to package and label.

§483.460(k)(8) Drug administration errors and adverse drug reactions are**Guidance §483.460(k)(8)**

Documentation of any medication error should be entered into the client's record and should include what error was made, who was notified of the error, the response of the medical person notified, the physical condition of the client at the time of the notification and subsequent observations of the clients physical condition related to the error.

W375**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(8) recorded****Guidance §483.460(k)(8)**

Documentation of adverse drug reactions must be entered into the client's record and should include all complaints made by the client or observations made by the staff following the drug administration, the notification of medical personnel, and the response of the medical personnel, any emergency actions that were required and all subsequent observations of the client's condition related to the reaction.

W376**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(k)(8) and reported immediately to a physician.****Guidance §483.460(k)(8)**

"Immediately" means at the time the error or reaction is identified.

(l) Standard: Drug storage and recordkeeping**§483.460(l)(1) The facility must store drugs under proper conditions of****Guidance §483.460(l)(1)**

Drugs are stored according to manufacturer's recommendations.

W377**sanitation,****W378****temperature,****W379****light,****W380****humidity,****W381****and security.****W382**

§483.460(l)(2) The facility must keep all drugs and biologicals locked except when being prepared for administration.

W383

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(l)(2) Only authorized persons may have access to the keys to the drug storage area.

Guidance §483.460(l)(2)

“Authorized persons” is restricted to those who administer the drugs (as allowed by state law) and nursing supervisors (if any). No other personnel should have access to these keys.

W384

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(l)(2) Clients who have been trained to self-administer drugs in accordance with §483.460(k)(4) may have access to keys to their individual drug supply.

Guidance §483.460(l)(2)

Drugs that are self-administered do not have to be double locked. The purpose for the double locking is to limit access to scheduled drugs. Since the client is generally the only one who has access to his/her drug supply (with perhaps the exception of a licensed nurse or whoever has overall responsibility for medication administration at the facility and a facility’s Director of Nursing Services, who may have access to all of the facility’s drug supplies), there is no need to further limit access.

W385

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(l)(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

Guidance §483.460(l)(3)

The facility must follow state requirements for the control and disposition of controlled drugs.

W386

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(l)(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq., as implemented by 21 CFR Part 308).

Guidance §483.460(l)(4)

The facility should follow state requirements for the reconciliation of controlled drugs.

W387

§483.460(l)(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs

§483.460(m) Standard: Drug Labeling

§483.460(m)(1) Labeling of drugs and biologicals must

W388

§483.460(m)(1)(i) Be based on currently accepted professional principles and practices; and

W389

§483.460(m)(1)(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

§483.460(m)(2) The facility must remove from use—

W390

§483.460(m)(2)(i) Outdated drugs; and

W391

§483.460(m)(2)(ii) Drug containers with worn, illegible, or missing labels.

W392

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.460(m)(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client’s current medication supply if discontinued by the physician.

(n) Standard: Laboratory services**W393****(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(n)(1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.****Guidance §483.460(n)(1)**

If the facility performs laboratory services, it must have a current, valid Clinical Laboratory Improvement Amendment (CLIA) certificate for the types of tests it is performing.

For the purposes of this regulation, a “laboratory service or test” is defined as any examination or analysis of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

W394**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.460(n)(1) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.****Guidance §483.460(n)(1)**

A facility performing any laboratory service or test must have applied to CMS, and received a Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. An application for a Certificate of Waiver may be made if the facility performs only those tests on the waived list. A complete list of waived tests can be found at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>.

If the facility performs any test, not appearing on the waived list, a Certificate of Compliance or Certificate of Accreditation is required. An appropriate CLIA certificate is required regardless of the frequency with which the laboratory services or tests are conducted. When no tests are performed, a CLIA certificate is not needed. Facilities only collecting specimens and not performing testing do not need a certificate.

A not-for-profit, a state, or local government organization may have one certificate covering all the facilities it operates (e.g., all the separately certified residences which fall under its governing body), if no more than a total of 15 types of waived or moderately complex laboratory tests are used. This exception applies only to laboratories performing limited public health testing. See State Operations Manual (SOM) 6008. Each location where a laboratory tests are performed must file a separate application to be separately certified unless the laboratory meets one of the exceptions outlined at 42CFR493.35(b), 493.443(b), or 493.55(b).

Any laboratory located in a state that has a CMS-approved laboratory program is exempt from CLIA certification. Currently there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if the laboratory is located in New York, contact the New York State Agency to determine if the exemption applies.

W406**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.470 Condition of participation: Physical environment. (a) Standard: Client living environment.****W407****(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****(1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.****Guidance §§483.470(a)(1)**

Clients of grossly different ages, functional levels, and/or social needs should not be housed together unless all of the following documentation supports the placement:

- Assessment;
- Client program plan;

- Staff documentation of client response to training programs; and
- QIDP notes.

W408

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) Standard: Client bedrooms.

(1) Bedrooms must- -

W409

§483.470(b)(1)(i) Be rooms that have at least one outside wall

W410

§483.470(b)(1)(ii) Be equipped with or located near toilet and bathing facilities;

W411

§483.470(b)(1)(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

§483.470(b)(1)(iv) measure

W412

At least 60 square feet per client in multiple client bedrooms

W413

And at least 80 square feet in single client bedrooms; and

W414

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.

Guidance §483.470(b)(1)(v)

If a facility was initially certified on or after October 3, 1988 and/or is under renovations or conversions, they must have walls that extend floor to ceiling.

W415

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(2) If a bedroom is below grade level, it must have a window that—

(i) Is usable as a second means of escape by client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

Guidance §483.470(b)(2)

The intent of the regulation is to prohibit the housing of clients in basements that are entirely below grade. Clients may be housed on the lower level of housing (e.g. a bi-level house), provided the window height requirements are met and the window is of sufficient size to be used as a means of escape.

W416

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified intellectual disabilities professional—

(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reason why housing in a room of only four or fewer persons would not be medically feasible.

Guidance §483.470(b)(3)

The medical care plan for each client housed in a room with more than four clients should indicate the need for continuous monitoring. The medical care plan will include:

- the physician certification that the client is severely medically impaired and requires direct and continuous monitoring during sleeping hours; and
- the reason why this housing arrangement for fewer than four people would not be medically feasible.

(4) The facility must provide each client with—
W417

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(i) A separate bed of proper size and height for the convenience of the client;

Guidance §483.470(b)(4)(i)

The client's preference, chronological age, and physical and medical needs are the determining factors in bed size and height.

W418

§483.470(b)(4)(ii) A clean, comfortable, mattress;

W419

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(iii) Bedding appropriate to the weather and climate; and

W420

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(iv) Functional furniture, appropriate to the client's needs,

Guidance §483.470(b)(4)(iv)

Client preferences and program needs should be considered in furniture selection. For clients with physical disabilities, furniture is adapted to accommodate the client's physical challenges and enable the client to use the furniture with minimal support.

W421

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

Guidance §483.470(b)(4)(iv)

Closets should have enough space for a reasonable amount of the current season's clothing.

Clients who use wheelchairs or have other physical challenges can reach the racks and shelves in their closets.

The facility is permitted either to provide the client with an individualized closet or with a designated area in a shared closet. The use of central clothing bins in a facility clothing room, in the absence of required client closet space in the bedroom, is not an acceptable practice.

(c) Standard: Storage space in bedrooms.

The facility must provide—

W422

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(1) Space for equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

Guidance §483.470(c)(1)

Sufficient space that permits the use of wheelchairs, walkers and other adaptive equipment should be provided within the bedroom.

W423

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

Guidance §483.470(c)(2)

Each client should have storage in their bedroom for their personal belongings. Clients should have free access to this storage without the assistance of staff. If it is necessary for clients' personal belongings

to be locked due to the behavior of other clients, the client must still be provided free access to his own possessions (See W137 for requirements for locked areas).

(d) Standard: Client bathrooms

The facility must—

W424

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

Guidance §483.470(d)(1)

In a home setting, the toilet facilities need to be of sufficient number to meet the needs of the client without prolonged delay. There must be enough toilets in the living units to meet the program needs of the clients at any given time, as well as provide for intermediate toileting needs of the clients living in the unit.

In a home setting, it may be unrealistic to say a client would never have to wait for a shower or bath or to brush his/her teeth.

Bathrooms and fixtures must be adapted to accommodate clients with physical disabilities.

W425

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

Guidance §483.470(d)(2)

A bathroom containing multiple toilets, showers or bathtubs, must have doors, curtains, or some other means of protecting the client from view when fully or partially unclothed.

Clients should not be able to be seen through the door or window by passersby when they are using the bathrooms.

Client privacy does not preclude the assistance provided by facility staff when necessitated by the client's condition.

W426

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110° Fahrenheit.

(e) Standard: Heating and ventilation.

(1) Each client bedroom in the facility must have—

W427

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(i) At least one window to the outside; and

Guidance §483.470(e)(1)(i)

(See also W415)

W428

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must—

W429

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

Guidance §483.470(e)(2)(i)

A "normal comfort range" in most instances is defined as not going below a temperature of 68 degrees Fahrenheit or exceeding a temperature of 80 degrees Fahrenheit in facilities in most geographic areas of the country.

In extremely hot or extremely cold weather, precautions are taken by the facility to protect the clients, particularly those who are medically compromised, from ill effects of the temperature.

W430

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

Guidance §483.470(e)(2)(ii)

Refer to Life Safety Code Chapters 32 and 33

Unvented fuel fired heaters are prohibited. NFPA 101 2000 Edition.

32/33.2.5.23

(f) Standard: Floors.

The facility must have—

W431

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(1) Floors that have a resilient, nonabrasive, and slip-resistant surface.

W432

§483.470(f) (2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

§483.470(f) (3) Exposed floor surfaces and floor coverings that

W433

promote mobility in areas used by clients,

W434

and promote maintenance of sanitary conditions.

§483.470(g) Standard: Space and Equipment

The facility must—

W435

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services, as required by this subpart and as identified in each client's individual program plan.

Guidance §483.470(g)(1)

Staff and clients must have the space, materials and equipment needed to implement formal and informal active treatment programs.

There must be sufficient space to accommodate group activities, including groups with clients who use wheelchairs.

Recreational supplies, equipment, and materials are available and reflect the interests, physical abilities and chronological age of the clients.

W436

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

Guidance §483.470(g)(2)

The term “furnish” means that the facility is responsible for obtaining or purchasing these items once an assessment has identified the need and is responsible for making any necessary arrangements for the client to receive them. Clients’ personal funds should not be used for these items since this is a covered service under the ICF/IID benefit.

The term “maintain in good repair” means that the facility is responsible for ensuring that these items are kept in good working order, and is responsible for any resulting expense that may be incurred.

Programs must be in place, when identified by assessment and determined by the ID team, to teach clients about the use and care for their equipment to the extent of their capabilities.

W437

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(3) Provide adequate clean linen and dirty linen storage areas.

Guidance §483.470(g)(3)

Clean linen must be separated from dirty linen and stored in a manner which prevents contamination. Linen soiled with bodily fluids must be stored separately and in a manner which protects clients from exposure to possible infectious sources.

A bedroom hamper can be an acceptable dirty linen storage “area” if kept odor free and consistent with the infection control requirements at §483.470(1).

(h) Standard: Emergency plan and procedures.

W438

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

Guidance §483.470(h)(1)

These plans may include identification of transportation and alternative shelter needs in cases when the facility must be evacuated and may incorporate state-specific emergency preparedness requirements as applicable.

W439

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

Guidance §483.470(h)(2)

“Periodic review” is a judgment made by the facility based on the circumstances of the facility. If the facility changes its physical plant or if changes external to the facility necessitates a review of the disaster plan, then the facility is responsible for carrying out the review.

Interview staff about where emergency plans and procedures are located and what the facility policy is regarding how often, and under what circumstances the plans and procedures are reviewed and updated.

(i) Standard: Evacuation drills.

(1) The facility must hold evacuation drills

W440

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

at least quarterly for each shift of personnel

Guidance §483.470(i)(1)

Life Safety Code NFPA 101, 2000 Edition (LSC):

Chapter 32/33 code: Clients have to participate in an evacuation drill each shift at least quarterly.

Chapter 18/19 code: There must be an evacuation drill on each shift at least quarterly. This drill is designed to train staff on evacuation procedures.

Review facility records to verify that evacuations drills are held each shift at least once in each 3-month period.

Refer to (S&C 10-26-LSC)

W441

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

and under varied conditions to—

Guidance §483.470(i)(1)

Life Safety Code NFPA 101, 2000 Edition (LSC):

Chapter 32/33: Expects that all clients living in that unit are capable of self-evacuation during an emergency. This self evacuation should be practiced under varying conditions including various times of the day or night and in various weather conditions.

Chapter 18/19: Requires drills which simulate emergency situations which familiarize facility staff with emergency actions they may be required to perform. The general emphasis of these sections of the code is upon training of the staff and not upon providing practice for the client. Drills should be practiced under varying conditions including various times of the day or night and in various weather conditions.

W442

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;

Guidance §483.470(i)(1)(i)

For facilities under Chapter 18/19 of the LSC

Staff should be able to verbalize the proper procedures to be followed during emergency drills. Staff training records should document that all staff have received training on emergency drills and evacuations.

W443

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

Guidance §483.470(i)(1)(ii)

Staff on all shifts are able to express familiarity with the use of fire extinguisher, alarms, and any other safety features in the facility.

W444

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

Guidance §483.470(i)(1)(iii)

See also W448. The plan(s) must be revised as needed and must be based upon analysis completed under W448.

The facility must–

W445

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(i) Actually evacuate clients during at least one drill each year on each shift;

Guidance §483.470(i)(2)(i)

All clients totally evacuate the building at least once per year per shift, regardless of the occupancy chapter under which the building falls.

All facilities, regardless of their size require actual evacuation. "Actually evacuate", as used in this standard, applies to all clients. The drills are conducted not only to rehearse the clients and staff for a fire emergency (see §483.470(i)(2)(v)), but for other disasters such as hurricanes, tornadoes, floods, etc. Such disasters would require the entire occupancy to be evacuated, and, therefore, the actual evacuation must be practiced, as required.

W446

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(ii) Make special provisions for the evacuation of clients with physical disabilities;

Guidance §483.470(i)(2)(ii)

Clients with physical or medical disabilities may require special procedures for evacuation, taking into account equipment or staff that must be maintained for the client's care at all times. The facility's evacuation plan should:

- identify such clients;
- clearly delineate any special evacuation procedures for those clients.

Staff should be familiar with the facility's special evacuation procedures when working with clients who are in need of unique provisions.

W447

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(iii) File a report and evaluation on each evacuation drill;

Guidance §483.470(i)(2)(iii)

There is a written report of each evacuation drill held.

W448

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(iv) Investigate all problems with evacuation drills, including accidents,

Guidance §483.470(i)(2)(iv)

The documentation for each evacuation drill includes an analysis of:

- The timeliness of the evacuation;

- Any difficulties observed during the drill;
- Investigates the cause of the difficulties; and
- Develops a plan to ensure the difficulties will not reoccur.

W449

**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)
and take corrective action; and**

Guidance §483.470(i)(2)(iv)

When a problem is identified during the evacuation drill and the facility develops a plan to prevent reoccurrence, there is evidence the facility implemented corrective action and follow-up completed to ensure corrective action was successful.

W450

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

Guidance §483.470(i)(2)(v)

The Life Safety Code NFPA 101, 2000 Edition at 3.3.167 defines safe location as “a location remote or separated from the effects of a fire so that such effects no longer pose a threat.”

W451

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(3) Facilities must meet the requirements of paragraph (i)(1) and (2) of this section for any live-in and relief staff they utilize.

Guidance §483.470(i)(3)

In the case of live-in staff, drills must occur quarterly. Typically, live-in staff can be found in facilities that fall under Chapter 32/33 of the LSC code. Drills should be held at varying times of the day and night for clients to practice evacuation including morning, afternoon, evening and the middle of the night.

(j) Standard: Fire protection.**Guidance §483.470(j)**

These standards are covered by the Life Safety Code (LSC) survey. The facility must meet the appropriate chapter of the Life Safety Code, 2000 edition.

When surveying an ICF/IID for compliance with the LSC, it is first necessary to determine whether the facility will be surveyed under Health Care (HC) or Board and Care (BC) occupancy.

- If clients receive nursing services, or if the provider elects to use Health Care, the facility should be surveyed as a Health Care Facility under Chapter 18 or 19 of the LSC, as appropriate.

- If clients receive personal care and protective oversight but not continuing nursing services, the facility is to be surveyed under Board and Care and the following three steps should be followed:

- 1) Determine the size (16 or less = small; 17 or more = large);

- 2) Determine the Evacuation Difficulty (PROMPT, SLOW, or IMPRACTICAL) using Appendix F of the fire safety evaluation system for board and care facilities (FSES/BC); and

- 3) Survey the building using one of two methods:

- a. The prescriptive requirements of Chapters 32 or 33; or

- b. The FSES/BC, Appendix G.

(1) General. Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted LSC does not apply to a facility.

Guidance §483.470(j)(1)(ii)

Roller latches are prohibited on corridor doors as a latching device.

(2) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(3) A facility that meets the LSC definition of a residential board and care occupancy must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the Fire Safety Evaluation System for Board and Care facilities (FSES/BC).

Guidance §483.470(j)(3)

The evacuation capability of residents is determined using Chapter 6 of NFPA 101A, 2001 edition.

4) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects a facility's clients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

5) Beginning March 13, 2006, a facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

Guidance §483.470(j)(5)

Battery powered emergency lighting must last at least 90 minutes.

6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to a facility.

Guidance §483.470(j)(6)

Roller latches are prohibited on corridor doors as a latching device.

(7) Facilities that meet the LSC definition of a health care occupancy.

(i) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

Guidance §483.470(j)(7)(i)

Waivers may be granted only to facilities that meet the Life Safety Code definition of a Health Care Occupancy. Waivers are not granted to facilities that met the requirements of a Residential Board and Care Occupancy.

Waivers are recommended by the State Survey Agency and approved by the Regional Office.

(A) The waiver would not adversely affect the health and safety of the clients.

B) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

ii) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a facility may install alcohol-based hand rub dispensers if—

(A) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(B) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(C) The dispensers are installed in a manner that adequately protects against inappropriate access;

D) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(E) The dispensers are maintained in accordance with dispenser manufacturer guidelines

(k) Standard: Paint.

The facility must—

W452

§483.470(k)(1) Use lead-free paint inside the facility; and

W453

§483.470(k)(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

§483.470(l) Standard: Infection Control

W454

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(1) The facility must provide a sanitary environment to avoid sources and transmission of infections.

Guidance §483.470(l)(1)

The facility is clean and staff have eliminated opportunities for cross-contamination of infections. Food is stored, prepared, distributed, and served in a sanitary manner to prevent food borne illness.

W455

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

There must be an active program for the prevention, control, and investigation of infection and communicable diseases.

Guidance §483.470(l)(1)

Facilities maintain an ongoing surveillance program of communicable disease control and investigation of infections and an active training program that ensures the clients served receive adequate prevention of transmission information and skills, according to needs.

The facility's infection control program should include procedures for:

- identification of the extent of infestation or infection;
- protection of clients;
- treatment of clients;
- notification of family or legal guardian;
- reporting to the health department as indicated; and
- continued follow-up to resolution.

Both the Occupational Safety and Health Administration (OSHA) and the CDC have specific requirements regarding human immuno-deficiency virus (HIV), TB, and hepatitis precautions. These requirements should be incorporated into the facility's practices when relevant to the clients residing in the facility. Concerns about OSHA violations should be referred to OSHA.

W456

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(2) The facility must implement successful corrective action in affected problem areas.

W457

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(3) The facility must maintain a record of incidents and corrective actions related to infections.

W458

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.

Guidance §483.470(l)(4)

The facility should have and implement a policy that clearly delineates those signs and symptoms for which they will restrict staff access to clients or to clients' food.

W459

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480 Condition of participation: Dietetic services

(a) Standard: Food and nutrition services

W460

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(a)(1) Each client must receive a nourishing, well balanced, diet including modified and specially prescribed diets.

Guidance §483.480(a)(1)

“Well balanced diets” are defined as diets that contain a variety of foods from the food groups currently recommended by the Academy of Nutrition and Dietetics (AND).

“Modified and specially-prescribed” diets are defined as diets that are altered in any way to enable the client to eat (e.g. food that is chopped, pureed) or diets that are intended to correct or prevent a nutritional deficiency or health problem.

Refer to W463 and W474 regarding modified and specially prescribed diets.

The following may be indicators of or may lead to compromised nutritional status:

- Unplanned significant weight gain or loss;
- Fever/infection;
- Diarrhea;
- Chronic disease;
- Chewing and Swallowing problems;
- Teeth and gum diseases;
- Excessive use of laxatives;
- Abnormal laboratory values;
- Brittle, dry hair;
- Ridged or spoon shaped nails;
- Dry flaky skin; and
- Unexplained changed in mood such as general fatigue, apathy, irritability, lack of concentration.

If one or more of these indicators are present, determine the facility’s response through observation, interview, and record review.

Surveyors should assure the facility is responsive to client food allergies and the potential for adverse food/drug interactions. If surveyors suspects these may exist, investigate further.

Examples of facility responsiveness to allergies and food/drug interactions include, but are not limited to:

- Clients on long term anticonvulsant drug regimens (e.g., phenobarbital, phenytoin, primidone) are periodically monitored per facility policy for decreased serum levels of folic acid and vitamin D;
- Therapeutic doses of nutrients are provided to decrease the likelihood of anemia and prevent decreased bone density, etc.; and
- Fiber and fluids are increased in the diet of clients to decrease the likelihood of constipation.

Guidance §483.470(a)(1)

Clients of grossly different ages, functional levels, and/or social needs should not be housed together unless all of the following documentation support the placement:

- Assessment;
- Client program plan;
- Staff documentation of client response to training programs; and
- QIDP notes.

W461

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(a)(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility’s discretion.

Guidance §483.480(a)(2)

The facility employs a registered dietitian either on a part-time, full-time or on a consultant basis.

W462

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(a)(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

Guidance §483.480(a)(3)

Where the facility does not have a full-time qualified dietitian, verify that the director of food services coordinates with a dietitian to assure the nutritional adequacy of meals and snacks.

The food service director coordinates with the part-time or consultant dietitian to develop client meal plans and monitor client nutritional status.

The qualifications of the food service director may be dictated by facility policy or by state law, if applicable.

In small group home settings where the staff and clients plan and prepare meals cooperatively, there may not be a designated food services director. In these cases, the consultant or part-time dietitian would meet with the available home staff to ensure adequacy of menus and diets.

§483.480(a)(4) The client's interdisciplinary team, including a qualified dietitian and physician must prescribe

W463

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(a)(4) all modified and special diets

W464

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(a)(4) including those used as a part of a program to manage inappropriate client behavior.

Guidance §483.480(a)(4)

Modifying a clients' diet must never be used as punishment.

W465

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(a)(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

Guidance §483.480(a)(5)

This regulation addresses the use of food in shaping positive adaptive behavior. Where clients have specialized nutritional needs, these needs must be taken into consideration.

When food is used as a primary reinforcement of behavior for a client who has a dietary restriction, these foods should be consistent with the foods allowed by the prescribed diet.

Food used as a reinforcement must be part of a behavior plan approved by the IDT and consistent with nutritional parameters for that client. For example, a client with diabetes does not receive concentrated sweets as a reinforcement.

W466

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(a)(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

Guidance §483.480(a)(6)

For suggested guidelines write to:

U.S. Department of Agriculture

Human Nutrition Information Services

Washington, D.C. 20250

<http://fnic.nal.usda.gov>

(b) Standard: Meal services

W467

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(b)(1) Each client must receive at least three meals daily,

Guidance §483.480(b)(1)

Meal times may be flexible and accommodate a variety of activities (e.g. holiday and weekend activities).

Clients should be offered the opportunity of three meals every day, but may be given the choice of not participating in a meal due to their schedule or preference.

For example, a client wakes up late on a Saturday morning and decides to have brunch.

W468**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.480(b)(1) at regular times comparable to normal mealtimes in the community****Guidance §483.480(b)(1)**

Generally, meal times conform to the norms of the community, however the clients' schedules and preferences may result in slight variations. Slight variations are acceptable, but gross variations such as breakfast at 3 am would not be acceptable.

§483.480(b)(1) with –**W469****(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.480(b)(1)(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day,****Guidance §483.480(b)(1)(i)**

A "substantial evening meal" is defined as an offering of three or more items at one time, one of which includes a high quality protein such as meat, fish, eggs, or cheese. The meal should represent no less than 20 percent of the day's total nutritional requirements.

W470**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.480(b)(1)(i) except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may lapse between a substantial evening meal and breakfast; and****Guidance §483.480(b)(1)(i)**

A "nourishing snack" is an offering of items, single or in combination, from the basic food groups. Snack supplies are available in the facility and are accessible to clients. Interview staff and clients about their access to snacks.

W471**§483.480(b)(1)(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i).****§483.480(b)(2) Food must be served–****Facility Practices §483.480(b)(2)(i)**

Portions served, either by staff or by the individuals themselves, closely match designated serving sizes on menus. Slight variations are not significant enough or frequent enough to affect individual's health.

W472**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.480(b)(2)(i) In appropriate quantity;****Guidance §483.480(b)(2)(i)**

Meal observations verify that portions served, either by staff or by the clients, match the designated serving sizes on menus.

W473**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.480(b)(2)(ii) At appropriate temperature;****Guidance §483.480(b)(2)(ii)**

Hot foods are served hot and cold foods are served cold, according to facility policy specific to the type of food or as desired by the client. The facility follows current state requirements for safe food temperatures.

W474**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)****§483.480(b)(2)(iii) In a form consistent with the developmental level of the client; and****Guidance §483.480(b)(2)(iii)**

The term "form", as used in this requirement, refers to food consistency (e.g., pureed, chopped, ground, etc.). Food that is ground, chopped or pureed is based on assessed client need, and only to the extent required.

Food consistency modifications due to an acute medical or dental condition are temporary and; client's food consistency is upgraded at the soonest possible time. Clients with chronic medical or dental conditions are periodically reviewed and at least annually for the possibility of an upgrade in food consistency.

Client assessments must document the justification for modified texture of the client's diet.

W475

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(b)(2)(iv) With appropriate utensils.

Guidance §483.480(b)(2)(iv)

“Appropriate utensils” refers to eating utensils and adaptive eating equipment that enable clients to eat as independently as possible in accordance with their highest functional level.

Commonly used utensils (fork, knife, and spoon) appropriate to the food being consumed are provided to all clients except those using adaptive equipment instead. Clients should be afforded the opportunity to use forks, spoons, and knives as indicated by the food served.

Utensils must be in good condition, clean, allow portion sizes appropriate to the client's prescribed diet and meet the client's needs.

W476

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(b)(3) Food served to clients individually and uneaten must be discarded.

Guidance §483.480(b)(3)

This standard does not apply to food served in family-style dishes, unless the length of time the food is on the table or other considerations (such as clients fingering or drooling in the food) compromise the safety and nutritive value for later consumption of the food.

(c) Standard: Menus

W477

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(c)(1)(i) Be prepared in advance;

Guidance §483.480(c)(1)(i)

The facility should be able to produce a copy of client menus prospectively to verify that meal planning is done in advance.

W478

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(c)(1)(ii) Provide a variety of foods at each meal;

Guidance §483.480(c)(1)(ii)

A “variety” of food at each meal includes offerings from each of the food groups.

W479

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(c)(1)(iii) Be different for the same days of each week and adjusted for seasonal changes; and

Guidance §483.480(c)(1)(iii)

Menus should make use of seasonal foods in order to capitalize on the availability of fresher more vitamin enriched foods.

In certain portions of the country, there may be cultural preferences that influence the frequency with which a food appears on the menu. This is acceptable in the facility if it is acceptable in the community.

W480

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(c)(1)(iv) Include the average portion sizes for menu items.

Guidance §483.480(c)(1)(iv)

Verify the menu lists client portion sizes and observe that the portions served correspond to the clients prescribed diet.

W481

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(c)(2) Menus for food actually served must be kept on file for 30 days.

(d) Standard: Dining areas and service

§483.480(d) The facility must –
W482

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

Guidance §483.480(d)(1)

For purposes of this standard, “dining areas” mean discrete eating areas located outside of bedrooms, established, furnished, and equipped for the purpose of eating meals.

When a client is not eating in a designated dining area, there must be either a medical rationale or this must be an isolated instance when the client has a personal reason to eat in another area, such as a television area to watch his or her favorite program.

Interview with the client should confirm that this is not routine, but is for a particular isolated reason.

W483

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;

Guidance §483.480(d)(2)

Clients must have the opportunity to participate in the normal dining experience with their companions in the dining room.

Clients in wheelchairs are included in dining groupings of their peers without physical disabilities.

Clients in wheelchairs eat at the table and not with lap trays/hospital trays unless medically contraindicated.

W484

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;

Guidance §483.480(d)(3)

Clients use adaptive equipment or are being trained to use such equipment when the need is identified in the IPP.

Examples of adaptive equipment that may be needed are:

- Double suction cups or other devices to anchor dishes on a table or tray for clients with major coordination problems;
- Rocking one-handed knife-fork or knife-spoon for a client with the use of only one hand;
- Built-up or extended handles or silverware for those with problems of grasp or range of motion;
- Plate guards or plates with raised rims to provide a surface against which the client with a physical disability can push food onto a fork or a spoon;
- Flexible drinking straws;
- Spoon bent to a 90 degree angle at the bowl or a swivel spoon to assist a client without normal wrist motions; and
- Any other adaptive device deemed by the team as needed by the client to eat more independently.

W485

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(4) Supervise and staff dining rooms adequately

Guidance §483.480(d)(4)

There should be sufficient staff to implement eating programs for clients who require them and to provide necessary intervention and supervision for normalization including normal meal time behavior.

Client mealtime should not be inadequately delayed due to insufficient staff assistance.

W486

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(4) to direct self-help dining procedures,**Guidance §483.480(d)(4)**

Staff is present during meal times to monitor clients who are able to eat independently, promoting, supporting, reinforcing and encouraging them to eat in an appropriate and normalized manner (e.g., manners, social behaviors, etc.)

W487

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(4) to assure that each client receives enough food and**Guidance §483.480(d)(4)**

Clients can request and receive second helpings unless contraindicated by a prescribed diet.

For clients on restrictive diets that prefer not to be on these diets or seek seconds, the facility resolves the personal choice issues vs. health risks.

W488

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(4) to assure that each client eats in a manner consistent with his or her developmental level; and**Guidance §483.480(d)(4)**

The intent of this regulation is to promote the acquisition of skills that lead to greater independence in eating.

Clients should be actively encouraged to eat independently to the extent possible and in accordance with their assessed abilities.

Clients should receive training to develop independent eating skills consistent with their developmental potential as identified through the CFA.

Clients learn skills in accordance with their functional levels. Skills may include:

- Use of utensils;
- Meal preparation;
- Socialization during meals;
- Family style dining; and
- Ordering food in restaurants.

Clients' eating programs are implemented in accordance with their training objectives.

To the maximum extent possible, staff model appropriate mealtime behavior and conversation by sitting at the table with clients, and when possible, eating meals with clients.

W489

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.480(d)(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.**Guidance §483.480(d)(5)**

If a client eats in any position other than an upright position, the physician should document the medical necessity for the position, and/or the IPP should include the program plan to teach the client the physical skill necessary for eating upright.

This applies to all clients, including those fed by nasogastric tube or gastrostomy tube. The IPP should identify the most appropriate position for the client to be positioned during mealtime, in relation to the placement of the food contents.

[ARC 3109C, IAB 6/7/17, effective 7/12/17]

CHAPTER 65
INTERMEDIATE CARE FACILITIES
FOR PERSONS WITH MENTAL ILLNESS (ICF/PMI)

481—65.1(135C) Definitions. For the purposes of these rules, the following terms shall have the meaning indicated in this chapter. The definitions set out in Iowa Code section 135C.1 shall be considered incorporated verbatim in the rules. The use of the words “shall” and “must” indicate these standards are mandatory.

“*Academic services*” means those activities provided to assist a person to acquire general information and skills which establish the basis for subsequent acquisition and application of knowledge.

“*Activity coordinator*” means a person who has completed the state-approved activity coordinator’s course.

“*Age appropriate*” means those activities, settings, and personal appearance and possessions commensurate with the person’s chronological age.

“*Chronic mental illness*” (see the definition of “Mental illness”).

“*Commission*” means the mental health and disability services commission.

“*Community living training services*” are those activities provided to assist a person to acquire or sustain the knowledge and skills essential to independent functioning to the person’s maximum potential in the physical and social environment. These services may focus on the following areas:

1. Independent living skills which include those skills necessary to sustain oneself in the physical environment and are essential to the management of one’s personal property and business. This includes self-advocacy skills.

2. Socialization skills which include self-awareness and self-control, social responsiveness, group participation, social amenities and interpersonal skills.

3. Communication skills which include expressive and receptive skills in verbal and nonverbal language, including reading and writing.

4. Leisure time and recreational skills which include the skills necessary for a person to use leisure time in a manner which is satisfying and constructive to the person.

5. Parenting skills which include those skills necessary to meet the needs of the person’s child. This service is designed to assist the person with mental illness to acquire or sustain the skills necessary for parenting.

“*Department*” means the Iowa department of inspections and appeals.

“*Dependent adult abuse*” is as defined in rule 481—52.1(235E).

“*Diagnosis*” means the investigation and analysis of the cause or nature of a person’s condition, situation or problem.

“*Direct care staff*” means those staff persons who provide a homelike environment for the residents and assist or supervise the resident in meeting the goals in the resident’s program plan.

“*Evaluation services*” means those activities designed to identify a person’s current functioning level and those factors which are barriers to maintaining the current level or achieving a higher level of functioning.

“*Exploitation*” means the act or process of taking unfair advantage of a resident, or the resident’s physical or financial resources for one’s own personal or pecuniary profit by the use of undue influence, harassment, duress, deception, false representation or false pretenses.

“*Goals*” means general statements of attainable expected accomplishments to be achieved in meeting identified needs.

“*Incident*” means all accidental, purposeful, or other occurrences within the facility or on the premises affecting residents, visitors, or employees whether there is apparent injury or where hidden injury may have occurred.

“*Individual program plan (IPP)*” means a written plan for the provision of services to the resident that is developed and implemented using an interdisciplinary process that is based on the resident’s functional status, strengths, and needs and that identifies service activities designed to enable a person

to maintain or move toward independent functioning. The plan identifies a continuum of development and outlines progressive steps and anticipated outcomes of services.

"Informed consent" means an agreement by a person, or by the person's legally authorized representative, based upon an understanding of:

1. A full explanation of the procedures to be followed including an identification of those that are and are not experimental;
2. A description of the attendant discomforts, risks, and benefits to be expected; and
3. A disclosure of appropriate alternative procedures that would be advantageous for the person.

"Interdisciplinary process" means an approach to assessment, individual program planning, and service implementation in which planning participants function as a team. Each participant utilizing the skills, competencies, insights and perspectives provided by the participant's training and experience focuses on identifying the service needs of the resident and the resident's family. The purpose of the process is for participants to review and discuss, face-to-face, all information and recommendations and to reach decisions as a team. Participants share all information and recommendations, and develop as a team, a single, integrated individual program plan to meet the resident's needs and, when appropriate, the resident's family's needs.

"Interdisciplinary team" means the group of persons who develop a single, integrated individual program plan to meet a resident's needs for services. The interdisciplinary team consists of, at a minimum, the resident, the resident's legal guardian, if applicable, the resident's advocate, if desired by the resident, a referral agency representative, other appropriate staff members, the resident's attending psychiatrist and QMHP, other providers of services, and other persons relevant to the resident's needs.

"Least restrictive environment" means the environment in which the interventions in the lives of people with mental illness can be carried out with a minimum of limitation, intrusion, disruption, and departure from commonly accepted patterns of living.

It is the environment which allows residents to participate, to the maximum extent possible, in everyday life and to have control over the decisions that affect them. It is an environment that provides needed supports which do not interfere with personal liberty and do not unduly interfere with a person's access to the normal events of life.

"Legal services" means those activities designed to assist the person in exercising constitutional and legislatively enacted rights.

"Level of functioning" means a person's current physiological and psychological status and current academic, community living, self-care and vocational skills.

"Mechanical restraint" means a device applied to a person's limbs, head or body which restricts a person's movement and includes, but is not limited to, leather straps, leather cuffs, camisoles or handcuffs.

"Mental abuse" means, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.

"Mental health counselor" means a person who is certified or eligible for certification as a mental health counselor by the National Academy of Certified Clinical Mental Health Counselors.

"Mental health, mental retardation commission" means the commission described in Iowa Code section 225C.5.

"Mental illness" means a substantial disorder of thought or mood which significantly impairs judgment, behavior, or the capacity to recognize reality or the ability to cope with the ordinary demands of life. Mental illnesses include the organic and functional psychoses, neuroses, personality disorders, alcoholism and drug dependence, behavioral disorders and other disorders as defined by the current edition of "American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders." Mental illness is chronic when it is of long duration or marked by frequent recurrences.

"Normalization" means helping persons, in accordance with their needs and preferences, to achieve a lifestyle that is consistent with the norms and patterns of general society in ways which incorporate the age-appropriate and least restrictive principles.

"Objectives" means specific, time-limited, and measurable statements showing outcomes or accomplishments necessary to progress toward the goal.

“Physical abuse” means, but is not limited to, corporal punishment and the use of restraints as punishment.

“Physical injury” means damage to any bodily tissue to the extent the tissue must undergo a healing process in order to be restored to a sound and healthy condition. It may also mean damage to the extent the bodily tissue cannot be restored to a sound and healthy condition, or results in the death of the resident whose bodily tissue sustained the damage.

“Physical or physiological treatment” means those activities designed to prevent, halt, control, relieve, or reverse symptoms or conditions which interfere with the physical or physiological functioning of the human body.

“Physical restraint” means a technique involving the use of one or more of a staff person’s arms, legs, hands or other body areas to restrict or control the movements of a resident. This does not include the use of mechanical restraint.

“Physician” means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy.

“Primary care provider” means any of the following who provide primary care and meet certification standards:

1. A physician who is a family or general practitioner or an internist.
2. An advanced registered nurse practitioner.
3. A physician assistant.

“Program” means a set of related resources and services directed to the accomplishment of a fixed set of goals and objectives for any of the following:

1. Special target populations;
2. The population of a specified geographic area(s);
3. A specified purpose; and
4. A person.

“Psychiatric nurse” means a person who meets the requirements of certified psychiatric-mental health nurse practitioner pursuant to 655—Chapter 7, Iowa Administrative Code, or is eligible for certification.

“Psychiatrist” means a doctor of medicine or osteopathic medicine and surgery who is certified by the American Board of Psychiatry and Neurology or who is eligible for certification.

“Psychologist” means a person who is licensed to practice psychology in the state of Iowa, or is certified by the Iowa department of education as a school psychologist, or is eligible for certification.

“Psychotherapeutic treatment” means those activities designed to assist a person in the identification or modification of beliefs, emotions, attitudes, or behaviors in order to maintain or improve the person’s functioning in response to the physical, emotional and social environment.

“Qualified mental health professional (QMHP)” means a person who:

1. Holds at least a master’s degree in a mental health field, including but not limited to: psychology, counseling and guidance, nursing and social work; or is a doctor of medicine (M.D.) or a doctor of osteopathic medicine and surgery (D.O.); and
2. Holds a current Iowa license when required by the Iowa licensure law; and
3. Has at least two years of postdegree experience, supervised by a mental health professional, in assessing mental problems and needs of individuals and in providing appropriate mental health services for those individuals. See rule 481—65.4(135C) for variance procedures.

“Resident” means a person who has been admitted to the facility to receive care and services.

“Seclusion” means the isolation of the resident in a locked room which cannot be opened by the resident.

“Self-care training services” means those activities provided to assist a person to acquire or sustain the knowledge, habits and skills essential to the daily needs of the person. The activities focus on personal hygiene, general health maintenance, mobility skills and other activities of daily living.

“Service” means a set of interrelated activities provided to a resident pursuant to the IPP.

“Sexual abuse” means, but is not limited to, the exposing of pubes to a resident, the exposure of a resident’s genitals, pubes, breasts or buttocks for sexual satisfaction, fondling or touching the inner thigh,

groin, buttocks, anus or breast of a resident or the clothing covering these areas, sexually suggestive comments or remarks made to a resident, a genital to genital or rectal, or oral to genital or rectal contact, or the commission of a sexual offense under Iowa Code chapter 709 or Iowa Code section 726.2.

“*Social worker*” means a person who is licensed to practice social work in the state of Iowa, or who is eligible for licensure.

“*Support services*” means those activities provided to or on behalf of a person in the areas of personal care and assistance and property maintenance in order to allow a person to live in the least restrictive environment.

“*Transportation services*” means those activities designed to assist a person to travel from one place to another to obtain services or carry out life’s activities.

“*Verbal abuse*” means, but is not limited to, the use of derogatory terms or names, undue voice volume and rude comments, orders or responses to residents.

“*Vocational training services*” means those activities designed to familiarize a person with production or employment requirements and to maintain or develop the person’s ability to function in a work setting. This service includes programming which allows or promotes the development of skills, attitudes and personal attributes appropriate to the work setting.

“*Work*” means any activity during which a resident provides goods or services for wages.

“*Written, in writing or recorded*” means that an account or entry is made in a permanent form. [ARC 0766C, IAB 5/29/13, effective 7/3/13; ARC 1204C, IAB 12/11/13, effective 1/15/14; ARC 1752C, IAB 12/10/14, effective 1/14/15]

481—65.2(135C) Application for license. In order to obtain an initial license for an ICF/PMI, the applicant must comply with the rules and standards contained in Iowa Code chapter 135C and the standards in 481—Chapter 61. Waivers from 481—Chapter 61 regulations are allowed under rule 481—61.2(135C). An application must be submitted to the department which states the type and category of license for which the facility is applying.

65.2(1) Each application shall include:

- a. A floor plan of each floor of the facility drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathroom, and designation of the use to which room will be put and window and door location;
- b. A photograph of the front and side elevation of the facility;
- c. The statutory fee for an intermediate care facility license;
- d. Evidence of a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules.

65.2(2) A résumé of care with a narrative which includes the following information shall be submitted:

- a. The purpose of the facility;
- b. A description of the target population and limitations on resident eligibility;
- c. An identification and description of the services the facility will provide. This shall include at least specific and measurable goals and objectives for each service available in the facility and a description of the resources needed to provide each service including staff, physical facilities and funds;
- d. A description of the human service system available in the area, including, but not limited to, social, public health, visiting nurse, vocational training, employment services, sheltered living arrangements, and services of private agencies; and
- e. A description of working relationships with the human service agencies when applicable which shall include at least how the facility will coordinate with:
 - (1) The department of human services to facilitate continuity of care and coordination of services to residents; and
 - (2) Other agencies to identify unnecessary duplication of services and plan for development and coordination of needed services.

65.2(3) In order to obtain a renewal or change of ownership license of the ICF/PMI the applicant must:

- a. Submit to the department the completed application form 30 days prior to annual license renewal or change of ownership date of the ICF/PMI license;
- b. Submit the statutory license fee for an ICF/PMI with the application for renewal or change of ownership;
- c. Have an approved current certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules; and
- d. Submit documentation of review of résumé of care pursuant to subrule 65.2(1), paragraph “a,” and a copy of any revisions to the plan.

This rule is intended to implement Iowa Code sections 135C.7 and 135C.9.
[ARC 1205C, IAB 12/11/13, effective 1/15/14; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—65.3(135C) Licenses for distinct parts. Separate licenses may be issued for distinct parts which are clearly identifiable parts of a health care facility, containing contiguous rooms in a separate wing or building or on a separate floor of the facility, which provide care and services of separate categories.

The following requirements shall be met for a separate licensing of a distinct part:

1. The distinct part shall serve only residents who require the category of care and services immediately available to them within that part. (III)
2. The distinct part shall meet all the standards, rules and regulations pertaining to the category for which a license is being sought.
3. The distinct part must be operationally and financially feasible.
4. A separate personal care staff with qualifications appropriate to the care and services being rendered must be regularly assigned and working in the distinct part under responsible management. (III)
5. Separately licensed distinct parts may have certain services such as management, building maintenance, laundry and dietary in common with each other.

This rule is intended to implement Iowa Code section 135C.6(2).

481—65.4(135C) Waivers. Waivers from these rules may be granted by the director of the department when:

1. The need for a waiver has been established consistent with the résumé of care or the resident’s individual program plan.
2. There is no danger to the health, safety, welfare or rights of any resident.
3. The waiver will apply only to a specific intermediate care facility for the mentally ill.

Waivers shall be reviewed at least at the time of each licensure survey and any other time by the department to see if the need for the waiver is still acceptable.

65.4(1) To request a waiver, the licensee must:

- a. Apply in writing on a form provided by the department;
- b. Cite the rule or rules from which a waiver is desired;
- c. State why compliance with the rule or rules cannot be accomplished;
- d. Explain how the waiver is consistent with the résumé of care or the individual program plan; and
- e. Demonstrate that the requested waiver will not endanger the health, safety, welfare or rights of any resident.

65.4(2) Upon receipt of a request for waiver, the director will:

- a. Examine the rule from which the waiver is requested;
- b. Evaluate the requested waiver against the requirement of the rule to determine whether the request is necessary to meet the needs of the residents;
- c. Examine the effect of the requested waiver on the health, safety or welfare of the residents;
- d. Consult with the applicant to obtain additional written information if required; and
- e. Obtain approval of the Iowa mental health and disability services commission, when the request is for a waiver from the requirement for qualification of a mental health professional.

65.4(3) Based upon this information, approval of the waiver will be either granted or denied within 120 days of receipt.

[ARC 0766C, IAB 5/29/13, effective 7/3/13; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—65.5(135C) General requirements.

65.5(1) A valid license shall be posted in each facility so the public can easily see it. (III)

65.5(2) Each license is valid only for the premises and person named on the license and is not transferable.

65.5(3) The posted license shall accurately reflect the current status of the facility. (III)

65.5(4) Each citation or a copy of each citation issued by the department for a Class I or Class II violation shall be prominently posted by the facility in plain view of the residents, visitors, and persons inquiring about placement in the facility. The citation or copy of the citation shall remain posted until the violation is corrected to the satisfaction of the department. (III)

65.5(5) Licenses expire one year after the date of issuance or as indicated on the license.

65.5(6) There shall be no more beds erected than are stipulated on the license. (II, III)

This rule is intended to implement Iowa Code section 135C.8.

481—65.6(135C) Notification required by the department. The department shall be notified within 48 hours, by letter, of any reduction or loss of personal care or dietary staff lasting more than seven days which places the staff ratio below that required for licensing. No additional residents shall be admitted until the minimum staff requirements are achieved. (II, III)

65.6(1) Other required notification and time periods are:

a. Within 30 days of any proposed change in the résumé of care for the ICF/PMI; (II, III)

b. Thirty days before addition, alteration, or new construction is begun in the ICF/PMI or on the premises; (III)

c. Thirty days before the ICF/PMI closes; (III)

d. Within two weeks of any change of administrator; (II, III) and

e. Within 30 days when any change in the category of license is sought. (III)

65.6(2) Prior to the purchase, transfer, assignment, or lease of an ICF/PMI the licensee shall:

a. Inform the department in writing of the pending sale, transfer, assignment, or lease of the facility; (III)

b. Inform the department in writing of the name and address of the prospective purchaser, transferee, assignee or lessee at least 30 days before the sale, transfer, assignment or lease is completed; (III) and

c. Submit a written authorization to the department permitting the department to release information of whatever kind from the department's files concerning the licensee's ICF/PMI to the named prospective purchaser, transferee, assignee or lessee. (III)

65.6(3) After the authorization has been submitted to the department, the department shall upon request send or give copies of all recent licensure surveys and any other pertinent information relating to the facility's licensure status to the prospective purchaser, transferee, assignee or lessee. Costs for copies requested shall be paid by the prospective purchaser, transferee, assignee or lessee. No information personally identifying any resident shall be provided to the prospective purchaser, transferee, assignee or lessee. (II, III)

This rule is intended to implement Iowa Code sections 135C.6(3) and 135C.16(2).

481—65.7(135C) Administrator. Each ICF/PMI shall have one person in charge, duly approved by the department or acting in a provisional capacity in accordance with these regulations. (II, III)

65.7(1) The administrator shall be at least 21 years of age and shall meet at least one of the following conditions:

a. Be licensed in Iowa as a nursing home administrator, or certified as a residential care administrator. No residential care facility administrator certified under a waiver from the department shall administrate an intermediate care facility for persons with mental illness. The administrator must

have at least two years' experience in direct care or supervision of people with mental illness and at least one year of experience in an administrative capacity; (II, III) or

b. Be a qualified mental health professional (QMHP) with at least one year of experience in an administrative capacity. (II, III)

If an ICF/PMI is a distinct part of a licensed health care facility, the administrator of the facility as a whole may serve as the administrator of the ICF/PMI without meeting the requirements of subrule 65.7(1), paragraph "a" or "b." When this occurs, the person in charge of the ICF/PMI distinct part shall meet the requirements of subrule 65.7(1), paragraph "a" or "b." (II, III)

65.7(2) The administrator of more than one facility shall be responsible for no more than 150 beds in total. (II, III)

a. The distance between the two farthest facilities shall be no greater than 50 miles. (II, III)

b. An administrator of more than one facility must designate an administrative staff person in each facility who shall be responsible for directing programs in the facility during the administrator's absence. (II, III)

65.7(3) The administrative staff person shall be designated in writing and immediately available to the facility on a 24-hour basis when the administrator is absent and residents are in the facility. (II, III)

The person(s) designated shall:

a. Have at least two years' experience or training in a supervisory or direct care position in a mental health setting; (II, III)

b. Be knowledgeable of the operation of the facility; (II, III)

c. Have access to records concerned with the operation of the facility; (II, III)

d. Be capable of carrying out administrative duties and of assuming administrative responsibilities; (II, III)

e. Be at least 21 years of age; (III)

f. Be empowered to act on behalf of the licensee during the administrator's absence concerning the health, safety and welfare of the residents; (II, III) and

g. Have training to carry out assignments and take care of emergencies and sudden illnesses of residents. (II, III)

65.7(4) If an administrator serves more than one facility, a written plan shall be developed, implemented and available for review by the department designating regular and specific times the administrator will be available to meet with the staff and residents to provide direction and supervision of resident care and services. (II, III)

65.7(5) When a facility has been unable to replace the administrator, through no fault of its own, a provisional administrator meeting the qualifications of the administrative staff person may be appointed on a temporary basis by the licensee to assume the administrative responsibilities for the facility. This person shall not serve more than three months without approval from the department. The department must be notified before the appointment of the provisional administrator. (III)

65.7(6) A facility applying for initial licensing shall not have a provisional administrator. (III)

This rule is intended to implement Iowa Code section 135C.14(2).

481—65.8(135C) Administration.

65.8(1) The licensee shall:

a. Be responsible for the overall operation of the ICF/PMI; (III)

b. Be responsible for compliance with all applicable laws and with the rules of the department; (II, III)

c. Establish written policies, which shall be available for review by the department or other agencies designated by Iowa Code section 135C.16(3), for the operation of the ICF/PMI including, but not limited to: (III)

(1) Personnel; (III)

(2) Admission; (III)

(3) Evaluation services; (II, III)

(4) Programming and individual program plan; (II, III)

- (5) Crisis intervention; (II, III)
- (6) Discharge or transfer; (III)
- (7) Medication management; (II)
- (8) Resident property; (II, III)
- (9) Financial affairs; (II, III)
- (10) Records; (III)
- (11) Health and safety; (II, III)
- (12) Nutrition; (III)
- (13) Physical facilities and maintenance; (III)
- (14) Resident rights; (II, III) and

d. Furnish statistical information concerning the operation of the facility to the department within 30 days of request. (III)

65.8(2) The administrator shall be responsible for the implementation of procedures to support the policies established by the licensee. (III)

This rule is intended to implement Iowa Code section 135C.14.

[ARC 1205C, IAB 12/11/13, effective 1/15/14]

481—65.9(135C) Personnel.

65.9(1) The personnel policies and procedures shall include the following requirements:

a. Written job descriptions for all employees or agreements for all consultants, which include duties and responsibilities, education, experience, or other requirements, and supervisory relationships; (III)

b. Annual performance evaluations of all employees and consultants which are dated and signed by the employee or consultant and the supervisor; (III)

c. Personnel records which are current, accurate, complete and confidential to the extent allowed by law. The record shall contain documentation of how the employee's or consultant's education and experience are relevant to the position for which they were hired; (III)

d. Roles, responsibilities, and limitation of student interns and volunteers; (III)

e. An orientation program for all newly hired employees and consultants which includes introduction to facility personnel policies and procedures and a discussion of the safety plan. Subparagraphs 65.9(1) "f"(3), (5) and (9) shall be included; (II, III)

f. A plan for a continuing education program with a minimum of 12 in-service programs per year. There shall be a written, individualized staff development plan implemented for each employee. The plan shall take into consideration the duties of the employee and the needs of the facility identified in the résumé of care. The plan shall ensure that each employee has the opportunity to develop and enhance skills and to broaden and increase knowledge needed to provide effective resident care including, but not limited to:

(1) First aid; (II, III)

(2) Human needs and behavior; (II, III)

(3) Problems and needs of persons with mental illness; for example, diagnosis and treatment, suicide assessment and prevention; (II, III)

(4) Medication; (II, III)

(5) Crisis intervention; for example, use of restraints and seclusion; (II)

(6) Delivery of services in accordance with the principles of normalization; (III)

(7) Infection control and wellness; (III)

(8) Fire safety, disaster, and tornado preparation; (II, III) and

(9) Resident rights. (II, III)

g. Equal opportunity and affirmative action employment practices; (III)

h. Procedures to be used when disciplining an employee; (III) and

i. Appropriate dress and personal hygiene for staff and residents. (III)

65.9(2) There shall be written personnel policies for each facility. Personnel policies shall include the following requirements:

a. Employees shall have a physical examination before employment and at least every four years after beginning employment. (III)

b. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59. (I, II, III)

c. No one shall provide services in a facility if the person has a disease:

(1) Which is transmissible through required workplace contact; (I, II, III)

(2) Which presents a significant risk of infecting others; (I, II, III)

(3) Which presents a substantial possibility of harming others; (I, II, III)

(4) For which no reasonable accommodation can eliminate the risk. (I, II, III)

Refer to Guideline for Infection Control in Hospital Personnel, 1998, Centers for Disease Control, U.S. Department of Health and Human Services, to determine (1), (2), (3) and (4).

d. There shall be written policies for emergency medical care for employees in case of sudden illness or accident. These policies shall include the administrative individuals to be contacted. (III)

e. Health certificates for all employees shall be available for review by the department. (III)

65.9(3) Staffing. The facility shall establish, subject to approval of the department, the numbers and qualifications of the staff required in an ICF/PMI using as its criteria the services being offered as indicated on the résumé of care and as required for implementation of individual program plans. (II, III)

a. Direct care staff. Direct care staff shall be present in the facility unless all residents are involved in activities away from the facility. The policies and procedures shall provide for an on-call staff person to be available when residents and staff are absent from the facility. (II, III)

(1) The on-call staff person shall be designated in writing. (II, III)

(2) Residents or another responsible person shall be informed of how to contact the on-call person. (II, III)

The staffing plan shall ensure that at least one qualified direct care staff person is on duty to carry out and implement the individual program plans. (II, III)

b. Qualified mental health professional. The ICF/PMI shall, by direct employment or contract, provide for sufficient services of a qualified mental health professional to attain or maintain the highest practicable mental and psychosocial well-being of each resident. Attainment shall be determined by resident assessment and individual plans of care. (I, II, III) Responsibilities of the QMHP shall include, but not be limited to:

(1) Approval of each resident's individual program plan; (II, III)

(2) Monitoring the implementation of each resident's individual program plan, including periodic personal contact; (II, III) and

(3) Participation on each resident's interdisciplinary team. (II, III)

c. Nursing staff. Each facility shall have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practical physical, mental and psychosocial well-being of each resident. Attainment shall be determined by resident assessments and individual plans of care.

(1) The director of nursing (DON) shall be a registered nurse who is employed by the facility at least 40 hours per week. This person shall have two years' experience in direct care or supervision of people with mental illness. (II, III)

(2) The facility shall provide 24-hour service by licensed nurses, including at least one registered nurse on the day tour of duty, seven days a week. (II, III)

(3) If the DON has other institutional responsibilities, a qualified registered nurse shall serve as the DON's assistant so there is the equivalent of a full-time nursing supervisor on duty. (II, III)

(4) The department shall establish, on an individual facility basis, the numbers and qualifications of the staff required in the facility using as its criteria the services being offered as indicated on the résumé of care and as required for implementation of individual program plans. (II, III)

(5) The DON shall not serve as charge nurse in a facility with an average daily total occupancy of 60 or more residents. (II, III)

(6) A waived licensed practical nurse shall not be allowed as a charge nurse on any shift. (II, III)

(7) There shall be at least two people capable of rendering nursing service awake, dressed, and on duty at all times. (II, III)

d. Activity staff. Each ICF/PMI shall employ a recreational therapist, occupational therapist or activity coordinator to direct the activity program both inside and outside the facility in accordance with each resident's individual program plan. (III)

Staff for the activity program shall be based on the needs of the residents being served as identified on the IPP. (III)

(1) The activity program director shall attend workshops or educational programs which relate to activity programming. These shall total a minimum of ten contact hours per year. (III)

(2) Personnel coverage shall be provided when the activity program director is absent during scheduled activities. (III)

(3) The activity program director shall have access to all information about residents necessary to carry out the program. (III)

e. Responsibilities of the activity program director shall include:

(1) Coordinating all activities, including volunteer or auxiliary activities and religious services; (III)

(2) Ensuring that all records required are kept; (III)

(3) Coordinating the activity program with all other services in the facility; (III) and

(4) Participating in the in-service training program in the facility. This shall include attending as well as presenting sessions. (III)

65.9(4) Personnel record.

a. A personnel record shall be kept for each employee. (III)

b. The record shall include the employee's:

(1) Name and address, (III)

(2) Social security number, (III)

(3) Date of birth, (III)

(4) Date of employment, (III)

(5) References, (III)

(6) Position in the facility, (III)

(7) Job description, (III)

(8) Documentation of experience and education, (III)

(9) Staff development plan, (III)

(10) Annual performance evaluation, (II, III)

(11) Documentation of disciplinary action, (II, III)

(12) Date and reason for discharge or resignation, (III) and

(13) Current physical examination. (III)

65.9(5) Employee criminal record checks, child abuse checks and dependent adult abuse checks and employment of individuals who have committed a crime or have a founded abuse. The facility shall comply with the requirements found in Iowa Code section 135C.33 as amended by 2013 Iowa Acts, Senate File 347, and rule 481—50.9(135C) related to completion of criminal record checks, child abuse checks, and dependent adult abuse checks and to employment of individuals who have committed a crime or have a founded abuse. (I, II, III)

This rule is intended to implement Iowa Code sections 135C.14(2) and 135C.14(6).

[ARC 0663C, IAB 4/3/13, effective 5/8/13; ARC 0903C, IAB 8/7/13, effective 9/11/13; ARC 1205C, IAB 12/11/13, effective 1/15/14]

481—65.10(135C) General admission policies. There shall be admission policies which address the following:

1. No resident shall be admitted or retained who is in need of greater services than the facility can provide. (II, III)

2. Residents shall be admitted only on a written order signed by a physician. (II, III)

3. A preplacement visit shall be completed prior to admission, except in case of an emergency admission or readmission, to familiarize the applicant with the facility and services offered. The policies and procedures may allow for waiving the requirement at the request of a person seeking admission when the completion of the visit would create a hardship for the person seeking admission. If the distance to be

traveled makes it impossible to complete the visit in an eight-hour day, this may be considered to create a hardship. (III)

4. Prior to admission of an applicant, the facility shall obtain sufficient information to determine if its program is appropriate and adequate to meet the person's needs. (III)

5. Admission criteria shall include, but not be limited to, age, sex, current diagnosis from an American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, substance abuse, dual diagnosis and criteria that are consistent with the résumé of care. (III)

6. Each facility shall maintain a waiting list with selection priorities identified. (III)

7. No ICF/PMI may admit more residents than the number of beds for which it is licensed. (II, III)

8. There shall be a written, organized orientation program for all residents which shall be planned and implemented to resolve or reduce personal, family, business, and emotional problems that may interfere with the health care, recovery, and rehabilitation of the individual and which shall be available for review by the department. (III)

9. Infants and children under the age of 18 shall not be admitted as residents to an ICF/PMI for adults unless given prior written approval by the department. A distinct part of an ICF/PMI, segregated from the adult section, may be established based on a résumé of care submitted by the licensee or applicant which is commensurate with the needs of the residents of the health care facility and has received the department's review and approval. (III)

10. Within 30 days of a resident's admission to a health care facility receiving reimbursement through the medical assistance program under Iowa Code chapter 249A, the facility shall ask the resident or the resident's personal representative whether the resident is a veteran and shall document the response. If the facility determines that the resident is a potential veteran, the facility shall report the resident's name along with the names of the resident's spouse and any dependent children, as well as the name of the contact person for this information, to the Iowa department of veterans affairs. Where appropriate, the facility may also report such information to the Iowa department of human services. If a resident is eligible for benefits through the United States Department of Veterans Affairs or other third-party payor, the facility first shall seek reimbursement from the identified payor source before seeking reimbursement from the medical assistance program established under Iowa Code chapter 249A.

The provisions of this paragraph shall not apply to the admission of an individual as a resident to a state mental health institute for acute psychiatric care. (II, III)

This rule is intended to implement Iowa Code sections 135C.3 and 135C.23.

481—65.11(135C) Evaluation services. Each resident admitted shall have a physical examination and tuberculin test no more than 30 days before admission and a physical examination annually after that. Each annual examination shall be sufficient to ensure the resident has no physical condition which precludes living in the facility. If the resident is admitted directly from a hospital, a copy of the hospital admission physical and discharge summary may meet this requirement. (II, III)

65.11(1) In addition to the required initial physical examination, each resident shall be evaluated to identify physical health, current level of functioning and the need for services. This evaluation shall be completed within 30 days of admission and annually after that. Information from other sources may be used in the evaluation if the information meets the requirements of subrules 65.11(2) and 65.11(3). (II, III)

65.11(2) The portion of the evaluation which describes the resident's physical health shall:

a. Identify current illnesses and disabilities and include recommendations for physical and physiological treatment and services; (II, III)

b. Include a description of the resident's ability for health maintenance; (II)

c. Include a mental status examination and history of mental health and treatments; (II, III) and

d. Be performed by a physician with a valid license to practice medicine and surgery, osteopathic medicine and surgery or osteopathy in Iowa. If the evaluation is not conducted in Iowa, it must be by a physician who holds a current license in the state in which the examination is performed. If the doctor

is not a psychiatrist, a psychiatrist or health service provider in psychology licensed under Iowa Code section 154B.7 shall be consulted regarding the results of the mental status examination. (II, III)

65.11(3) The portion of the evaluation which describes the resident's current functioning level and need for services shall:

- a. Identify the functioning level and need for services in self-care, community living skills, psychotherapeutic treatment, vocational skills, and academic skills as appropriate; (II, III)
- b. Contain sufficient detail about skills and needs to determine appropriate placement; (II, III)
- c. Be made without regard to the availability of services; (III) and
- d. Be performed by a QMHP, consulting with an interdisciplinary team. (III)

65.11(4) Results of all evaluations shall be in writing and maintained in resident records. After the initial evaluation, all subsequent evaluations shall contain sufficient detail to determine changes in the resident's physical and mental health, skills, and need for services. (II, III)

65.11(5) A narrative social history shall be completed for each resident within 30 days of admission. The social history shall be completed and approved by the qualified mental health professional before the IPP is developed. (III)

a. When a social history is secured from another provider, the information shall be reviewed within 30 days of admission. The date of the review and a summary of significant changes in the information shall be entered in the resident's record. The social worker who reviews the history shall sign it. (III)

b. An annual review of the social history information shall be incorporated in the individual program plan progress notes. (III)

c. The social history shall address at least the following areas:

- (1) Referral source and reason for admission; (II, III)
- (2) Legal status; (II, III)
- (3) Previous living arrangements; (III)
- (4) Services received previously and current service involvements; (II, III)
- (5) Significant medical and mental health conditions including at least illnesses, hospitalizations, past and current drug therapy, and special diets; (II, III)
- (6) Substance abuse history; (II, III)
- (7) Work history; (III)
- (8) Education history; (II)
- (9) Relationship with family, significant others, and other support systems; (III)
- (10) Cultural, ethnic and religious background; (II, III)
- (11) Hobbies and leisure time activities; (III)
- (12) Likes, dislikes, habits, and patterns of behavior; (II, III)
- (13) History of aggressive or suicidal behavior; (I, II, III) and
- (14) Impressions and recommendations. (II, III)

This rule is intended to implement Iowa Code section 135C.14(7).

481—65.12(135C) Individual program plan (IPP). An initial program plan shall be developed within 24 hours of admission. This plan shall be based on information gained from the resident, family, physician or referring facility. Services to be provided shall be addressed. Intervention to be provided, if and when the need arises, shall also be addressed in the IPP. The plan shall be followed until the IPP required in subrule 65.12(1) is complete. The initial plan shall be completed by a registered nurse, a qualified social worker or a QMHP. (II, III)

65.12(1) An individual program plan for each resident shall be developed by an interdisciplinary team. The resident or the resident's legal guardian has the ultimate authority to accept or reject the plan unless otherwise determined by the court. The IPP shall be approved and have implementation monitored by the QMHP. (II, III)

a. The IPP shall be based on the individual service plan of the referring agency, if available, the information contained in the social history, the need for services identified in the evaluation, and any other pertinent information. (III)

b. The facility shall assist the resident in obtaining access to academic services, community living skills training, legal services, self-care training, support services, transportation, treatment, and vocational education as needed. These services may be provided by the facility or obtained from other providers. (III)

c. Services to the resident shall be provided in the least restrictive environment and shall incorporate the principle of normalization. (III)

d. If needed services are not available and accessible, the facility shall document the actions taken to locate and obtain those services. The documentation shall identify needs which will not be met because of the lack of available services. (III)

e. The IPP shall be developed within 30 days following admission to the facility and renewed at least annually. (II, III)

f. The IPP shall be written, dated, signed by the interdisciplinary team members, and maintained in the resident's record. (III)

g. Written notice of the meeting to develop an IPP shall be mailed or delivered to everyone included in the interdisciplinary team conference at least two weeks before the scheduled meeting. (III)

65.12(2) The IPP shall include the following:

a. Goals, (III)

b. Objectives, (III)

c. Specific services to be provided, (III)

d. People or agency responsible for providing services, (III)

e. Beginning date, (III) and

f. Anticipated duration of services. (III)

65.12(3) The IPP shall set out the procedure to be used to evaluate whether objectives are achieved. This procedure shall incorporate a process for ongoing review and revision. (III)

65.12(4) The interdisciplinary team shall review the IPP at a team meeting at least quarterly and when the resident's condition changes. (II, III)

a. The interdisciplinary team shall develop a written report which addresses:

(1) The resident's progress toward objectives; (II, III)

(2) The need for continued services; (II, III)

(3) Recommendations concerning alternative services or living arrangements; (II, III) and

(4) Any recommended change in guardianship, conservatorship or commitment status. (II, III)

b. The report shall reflect those involved in the review, the date of the review, and be maintained in the resident's record. (III)

65.12(5) There shall be procedures for recording the activities of each service provider and a mechanism to coordinate the activities of all service providers. Resident response to all activities shall be recorded. (III)

a. Staff shall create a record at the time of a service required by the IPP. If this is not possible, the record shall be written no more than seven days later. (III)

b. When the services are provided more than once a week, staff may make a monthly summarized entry in the resident's record. (III)

c. Entries shall be dated and signed by the person who provides the service. (III)

d. Entries shall be made when incidents occur. (III)

e. Entries shall be written in terms of behavioral observations and specific activities. Entries that involve subjective interpretations of a resident's behavior or progress shall be clearly identified and shall be supplemented with descriptions of behavior upon which the interpretation was based. (III)

This rule is intended to implement Iowa Code section 135C.14.

481—65.13(135C) Activity program. Each ICF/PMI shall have an organized activity program which is directed by a person qualified as required by 65.9(3)“d.”

65.13(1) An activity program plan for the facility shall be based on needs identified in IPPs and on other interests expressed by residents. The activity program shall include leisure time management. (III)

65.13(2) Activities shall be offered at least daily during the daytime hours if residents are present, twice weekly in the evening and twice on the weekend. (III)

65.13(3) Activities offered shall be varied and shall be planned for individuals, small groups or large groups. (III)

65.13(4) Monthly calendars shall be prepared in advance and shall be kept for review by the department. Substitutions and cancellations shall be noted. (III)

65.13(5) Activities department personnel shall coordinate programs with other facility personnel. (III)

481—65.14(135C) Crisis intervention. There shall be written policies and procedures concerning crisis intervention. (II) These policies and procedures shall be:

1. Directed to maximizing the growth and development of the individual by incorporating a hierarchy of available alternative methods that emphasize positive approaches; (II, III)

2. Available in each program area and living unit; (II, III)

3. Available to individuals and their families; (II, III) and

4. Developed with the participation, as appropriate, of individuals served. (II, III)

65.14(1) Corporal punishment, physical abuse, and verbal abuse, for example, shouting, screaming, swearing, name calling, or any other activity which might damage an individual's self-respect shall be prohibited. All residents shall be treated with fairness and respect as required by rule 481—65.25(135C). (II)

65.14(2) Medication shall not be used as punishment, for the convenience of staff, or as a substitute for a program. Direct care staff shall monitor residents on medication and notify the physician if a resident is too sedated to participate in the IPP. (I, II)

481—65.15(135C) Restraint or seclusion. Physician's orders are required to use any kind of mechanical restraints or seclusion. (I, II, III) Restraints are defined as the following:

1. Type I is physical restraint which uses equipment to promote the safety of the individual. It is not applied directly to a person. Examples: divided doors and side rails.

2. Type II is mechanical restraint applied to someone's body. A device is applied to the body to promote safety of the individual. Examples: vests or soft tie devices, hand socks, geriatric chairs.

3. Type III is mechanical restraint applied to any part of the body which inhibits only the movement of that part of the body. Examples: wrist, ankle or leg restraints and waist straps.

65.15(1) Temporary restraint of residents shall be used only to prevent injury to the resident or to others. (I, II)

65.15(2) Temporary seclusion may be used:

a. To prevent injury to the resident or to others; (I, II)

b. To prevent serious disruption to the treatment program of other residents; (I, II)

c. To decrease stimulation which contributes to psychotic behavior; (I, II) and

d. When other interventions have failed. (I, II)

Restraint and seclusion shall not be used for punishment, for the convenience of staff, or as a substitution for supervision of program. Seclusion shall be used only in a department approved seclusion room. (I, II)

65.15(3) Restraints shall be stored in an area easily accessible to staff. (I, II, III) Type II and Type III restraints shall be specifically designed, manufactured, and customarily used to restrain individuals hospitalized in licensed psychiatric hospitals. Metal and plastic handcuffs, rope and makeshift devices are prohibited. (I, II)

65.15(4) Under no circumstances shall a resident be allowed to participate in the restraint of another resident. (I, II)

65.15(5) There shall be written policies that address the basic assumption and philosophy that govern the use of seclusion and physical and mechanical restraint. These shall:

a. Define the uses of seclusion and mechanical restraints; (III)

b. Designate staff who may authorize its use; (III)

c. Identify procedures to follow when implementing the policy which shall include provisions to ensure privacy and safety for restrained residents; (III) and

d. A written plan for treatment following the use of restraint or seclusion.

65.15(6) The physician and QMHP shall be notified immediately of the resident's need for placement in restraint or seclusion. An order for restraint or seclusion identifying the type, purpose and duration of use shall be obtained from the physician. If the resident is in seclusion longer than four hours, the physician and qualified mental health professional shall visit and evaluate the resident before the seclusion order is continued. If the resident is in restraint for two hours, the physician shall be called before the restraint order can be continued. If the resident is in restraint longer than four hours, the physician and QMHP shall visit and evaluate the resident before a restraint order is continued. Standing or PRN orders for seclusion or restraint are prohibited. (I, II)

65.15(7) If a resident is restrained with Type II or Type III restraints for 6 hours or secluded for 12 hours in a 24-hour period; or if the resident is secluded or restrained with Type II or Type III restraints for any amount of time in three consecutive 24-hour periods, the physician and QMHP shall visit the resident and assess the resident's need for a higher level of care. If the need for restraint or seclusion continues, the resident shall be transferred to an acute level of care. (I, II)

65.15(8) During any period of mechanical restraint or seclusion, the facility shall provide for the emotional and physical needs of the resident. (I, II)

65.15(9) The resident shall be informed of the reason for seclusion and restraint and conditions for release. The resident's guardian shall be notified when Type II or Type III restraints or seclusion is used. The facility shall also notify the resident's family or other significant person if the resident has previously signed a form granting consent to do so. (I, II, III)

65.15(10) Each resident's record shall contain all information about restraints or seclusion. The administrator shall maintain a daily record of seclusion use. This record shall be available for review by the department. (II, III)

Documentation of each incident of restraint or seclusion shall include at least:

- a. Clinical assessment before the resident is secluded or restrained; (I, II)
- b. Circumstances that led to seclusion or restraint; (I, II)
- c. Explanation of less restrictive measures used before restraint or seclusion; (I, II)
- d. Physician's order; (I, II)
- e. Visual observation of the resident every 15 minutes, or more frequently if needed, to monitor general well-being including respirations, circulation, positioning and alertness as indicated; (I, II)
- f. Description of the resident's activity at the time of observation to include verbal exchange and behavior; (I, II)
- g. Description of safety procedures taken (removal of dangerous objects, etc.); (I, II)
- h. Vital signs, including blood pressure, pulse and respiration unless contraindicated by resident behavior and reasons documented; (I, II)
- i. Release of each mechanical restraint and exercise and massage every two hours; (I, II, III)
- j. Record of intake of food and fluid; (I, II, III)
- k. Use of toilet; (II, III) and
- l. Number of hours and minutes in seclusion. (II, III)

65.15(11) The facility shall educate staff on restraint and seclusion theory and techniques. The training shall be conducted by people with experience and documented education in the appropriate use of restraint and seclusion. (II, III)

a. The facility shall keep a record of the training for review by the department and shall include attendance. (II, III)

b. Only staff who have documented training in restraint and seclusion theory and techniques shall be authorized to assist with seclusion or restraint of a resident. (I, II, III)

65.15(12) The facility shall maintain a record of the hours and minutes of each type of restraint and seclusion used on a monthly basis.

481—65.16(135C) Discharge or transfer. Procedures for the discharge or transfer of the resident shall be established and followed. (II, III)

65.16(1) Discharge plan. The decision to discharge a person and the plan for doing so shall be established through the participation of the resident, members of the interdisciplinary team and other resource personnel as appropriate for the welfare of the individual. (II, III)

a. Discharge planning shall begin within 30 days of admission and be carried out in accordance with the IPP. (II, III)

b. As changes occur in a resident's physical or mental condition necessitating services or care which cannot be adequately provided by the facility, the resident shall be transferred promptly to another appropriate facility pursuant to subrule 65.10(1). (II, III)

c. Notification shall be made to the next of kin, legal representative, attending physician, and sponsoring agency, if any, prior to transfer or discharge of any resident. (III)

d. Proper arrangements shall be made for the welfare of the resident prior to the transfer or discharge in the event of an emergency or inability to reach the next of kin or legal representative. (III)

e. The licensee shall not refuse to discharge or transfer a resident when directed by the physician, resident, legal representative, or court. (II, III)

f. Advanced notification by telephone shall be made to the receiving facility prior to the transfer of any resident. (III)

g. When a resident is transferred or discharged, the current evaluation and treatment plan and progress notes for the last 30 days, as set forth in these rules, shall accompany the resident. (II, III)

h. Prior to the transfer or discharge of a resident to another health care facility, arrangements to provide for continuity of care shall be made with the facility to which the resident is being sent. (II, III)

i. A discharge or transfer authorization and summary shall be prepared for each resident who has been discharged or transferred from the facility. It shall be disseminated to appropriate persons to ensure continuity of care and in accordance with the requirements to ensure confidentiality. (II, III)

j. A transfer to a part of a facility that has a different license must be handled the same way as a transfer to another facility, and not as an intrafacility transfer. (II, III)

65.16(2) Intrafacility transfer. Residents shall not be arbitrarily moved from room to room within a health care facility. (II, III)

a. Involuntary relocation may occur only to implement goals and objectives in the IPP and in the following situations:

(1) Incompatibility with or behavior disturbing to roommates, as documented in the residents' records; (I, II)

(2) To allow a new admission to the facility which would otherwise not be possible due to separation of roommates by sex; (II, III)

(3) Reasonable and necessary administrative decisions regarding the use and functioning of the building. (II, III)

b. Unreasonable and unjustified reasons for changing a resident's room without the concurrence of the resident or legal guardian include:

(1) Punishment or behavior modification; (II) and

(2) Discrimination on the basis of race or religion. (II, III)

c. If intrafacility relocation is necessary for reasons outlined in paragraph "a," the resident shall be notified at least 48 hours prior to the transfer and the reason shall be explained. The legal guardian shall be notified as soon as possible. The notification shall be documented in the resident's record and signed by the resident or legal guardian within seven days unless documentation indicates that it was not possible to contact the legal guardian or obtain their signature. (II, III)

d. If emergency relocation is required to protect the safety or health of the resident or other residents, the notification requirements may be waived. The conditions of the emergency shall be documented. The family and legal guardian shall be notified immediately, or as soon as possible, of the condition requiring emergency relocation, and the notification shall be documented. (II, III)

e. A transfer to a part of a facility that has a different license must be handled the same way as a transfer to another facility and not as an intrafacility transfer. (II, III)

65.16(3) *Involuntary discharge or transfer permitted.* A facility may involuntarily discharge or transfer a resident for only one of the following reasons:

- a.* Medical reasons, based on the resident's needs and determined and documented in the resident's record by the primary care provider;
- b.* The resident's social, emotional or physical well-being or that of other residents, as documented by the administrator or designee with specific information to support the determination that the resident's continued presence in the facility would adversely affect the resident's own well-being or that of other residents;
- c.* Due to action pursuant to Iowa Code chapter 229; or
- d.* Nonpayment for the resident's stay, as described in the admission agreement for the resident's stay. (I, II, III)

65.16(4) *Involuntary transfer or discharge—written notice.* Involuntary transfer or discharge of a resident from a facility shall be preceded by a written notice to the resident or the resident's legal representative. (II, III)

- a.* The notice shall contain all of the following information:
 - (1) The stated reason for the proposed transfer or discharge. (II)
 - (2) The effective date of the proposed transfer or discharge. (II)
 - (3) A statement, in not less than 12-point type, that reads as follows:

You have a right to appeal the facility's decision to transfer or discharge you. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after the department's receipt of your request and you will not be transferred before a final decision is rendered. In emergency circumstances, provision may be made for extension of the 14-day requirement upon request to the department designee. If you lose the hearing, you will not be transferred before the expiration date of either (1) 30 days following your receipt of the original notice of the discharge or transfer, or (2) no sooner than 5 days following final decision of such hearing, including the exhaustion of all appeals, whichever occurs later. To request a hearing or receive further information, call the department at (515)281-4115 or you may write to the department to the attention of: Administrator, Division of Health Facilities, Iowa Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319. (II)

b. The notice shall be personally delivered to the resident, and a copy shall be placed in the resident's record. A copy shall also be transmitted to the department, the resident's legal representative, primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. The notice shall indicate that copies have been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent. (II)

c. The notice required by paragraph 65.16(4) "*a*" shall be provided at least 30 days in advance of the proposed transfer or discharge unless one of the following occurs:

(1) An emergency transfer or discharge is mandated by the resident's health care needs and is in accordance with the written orders and medical justification of the primary care provider. Emergency transfers or discharges may also be mandated in order to protect the health, safety, or well-being of other residents and staff. (II)

(2) The transfer or discharge is subsequently agreed to by the resident or the resident's legal representative, and notification is given to the legal representative, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. (II)

d. A hearing requested pursuant to this subrule shall be held in accordance with subrule 65.16(6).

65.16(5) *Involuntary transfer or discharge—emergency transfer or discharge.* In the case of an emergency transfer or discharge, the resident must be given a written notice prior to or within 48 hours following the transfer or discharge. (II, III)

a. A copy of this notice must be placed in the resident's file. The notice must contain all of the following information:

- (1) The stated reason for the transfer or discharge. (II)
- (2) The effective date of the transfer or discharge. (II)
- (3) A statement, in not less than 12-point type, that reads:

You have a right to appeal the facility's decision to transfer or discharge you on an emergency basis. If you think you should not have to leave this facility, you may request a hearing, in writing or verbally, with the Iowa department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after the department's receipt of your request. You may be transferred or discharged before the hearing is held or before a final decision is rendered. If you win the hearing, you have the right to be transferred back into the facility. To request a hearing or receive further information, call the department at (515)281-4115, or write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. (II)

b. The notice shall be personally delivered to the resident, and a copy shall be placed in the resident's record. A copy shall also be transmitted to the department, the resident's legal representative, the resident's primary care provider, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. The notice shall indicate that copies have been transmitted to the required parties by using the abbreviation "cc:" and listing the names of all parties to whom copies were sent.

c. A hearing requested pursuant to this subrule shall be held in accordance with subrule 65.16(6).

65.16(6) *Involuntary transfer or discharge—hearing.*

a. Request for hearing.

- (1) The resident must request a hearing within 7 days of receiving written notice.
- (2) The request must be made to the department, either in writing or verbally.

b. The hearing shall be held no later than 14 days after the department's receipt of the request unless either party requests an extension due to emergency circumstances.

c. Except in the case of an emergency discharge or transfer, a request for a hearing shall stay a transfer or discharge pending a final decision, including the exhaustion of all appeals. (II)

d. The hearing shall be heard by a department of inspections and appeals administrative law judge pursuant to Iowa Code chapter 17A and 481—Chapter 9. The hearing shall be public unless the resident or representative requests in writing that the hearing be closed. In a determination as to whether a transfer or discharge is authorized, the burden of proof by a preponderance of evidence rests on the party requesting the transfer or discharge.

e. Notice of the date, time, and place of the hearing shall be sent by certified mail or delivered in person to the facility, the resident and the resident's legal representative not later than five full business days after the department's receipt of the request. The notice shall also inform the facility and the resident or the resident's legal representative that they have a right to appear at the hearing in person or be represented by an attorney or other individual. The appeal shall be dismissed if neither party is present or represented at the hearing. If only one party appears or is represented, the hearing shall proceed with one party present.

f. The administrative law judge's written decision shall be sent by certified mail to the facility, resident, and resident's legal representative within 10 working days after the hearing has been concluded.

65.16(7) *Nonpayment.* If nonpayment is the basis for involuntary transfer or discharge, the resident shall have the right to make full payment up to the date that the discharge or transfer is to be made and then shall have the right to remain in the facility. (II)

65.16(8) *Discussion of involuntary transfer or discharge.* Within 48 hours after notice of involuntary transfer or discharge has been received by the resident, the facility shall discuss the involuntary transfer or discharge with the resident, the resident's legal representative, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. (II)

a. The facility administrator or other appropriate facility representative serving as the administrator's designee shall provide an explanation and discussion of the reasons for the resident's involuntary transfer or discharge. (II)

b. The content of the explanation and discussion shall be summarized in writing, shall include the names of the individuals involved in the discussion, and shall be made part of the resident's record. (II)

c. The provisions of this subrule do not apply if the involuntary transfer or discharge has already occurred pursuant to subrule 65.16(6) and emergency notice is provided within 48 hours.

65.16(9) *Involuntary discharge or transfer—transfer or discharge planning.*

a. The facility shall develop a plan to provide for the orderly and safe transfer or discharge of each resident to be transferred or discharged. (II)

b. To minimize the possible adverse effects of the involuntary transfer, the resident shall receive counseling services by the sending facility before the involuntary transfer and by the receiving facility after the involuntary transfer. Counseling shall be documented in the resident's record. (II)

c. The counseling requirement in paragraph 65.16(9) "b" does not apply if the discharge has already occurred pursuant to subrule 65.16(5) and emergency notice is provided within 48 hours.

d. Counseling, if required, shall be provided by a licensed mental health professional as defined in Iowa Code section 228.1(6). (II)

e. The health care facility that receives a resident who has been involuntarily transferred shall immediately formulate and implement a plan of care which takes into account possible adverse effects the transfer may cause. (II)

65.16(10) *Transfer upon revocation of license or voluntary closure.* Residents shall not have the right to a hearing to contest an involuntary discharge or transfer resulting from the revocation of the facility's license by the department of inspections and appeals. In the case of the voluntary closure of a facility, a period of 30 days must be allowed for an orderly transfer of residents to other facilities.

This rule is intended to implement Iowa Code section 135C.14(8).

[ARC 1205C, IAB 12/11/13, effective 1/15/14; ARC 1752C, IAB 12/10/14, effective 1/14/15; ARC 3523C, IAB 12/20/17, effective 1/24/18]

481—65.17(135C) Medication management. Medications shall be prescribed on an individual basis by a person who is authorized by Iowa law to prescribe. (I, II)

1. Medication orders shall be correctly implemented by qualified personnel. (II)

2. Qualified staff shall ensure that residents are able to take their own medication. (I, II)

3. Each physician order allowing a resident to self-administer medications shall specify whether this self-medication shall be without supervision or under the supervision of qualified staff as defined in 65.17(2). (I, II)

65.17(1) A properly trained person shall be charged with the responsibility of administering nonparenteral medications.

a. The individual shall have knowledge of the purpose of the drugs, their dangers, and contraindications.

b. This person shall be a licensed nurse or physician or shall have successfully completed a department-approved medication aide course or passed a department-approved medication aide challenge examination administered by an area community college.

c. Prior to taking a department-approved medication aide course, the individual shall:

(1) Successfully complete an approved nurse aide course, nurse aide training and testing program or nurse aide competency examination.

(2) Be employed in the same facility for at least six consecutive months prior to the start of the medication aide course. This requirement is not subject to waiver.

(3) Have a letter of recommendation for admission to the medication aide course from the employing facility.

d. A person who is a nursing student or a graduate nurse may take the challenge examination in place of taking a medication aide course. This individual shall do all of the following before taking the medication aide challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination;

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination;

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating the individual is competent in medication administration;

(4) Successfully complete a department-approved nurse aide competency evaluation.

e. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination.

The requirements of paragraph "c" of this subrule do not apply to this individual.

f. Unit dose medication shall remain in the identifiable unit dose package until given to the resident. (II)

g. Medications that are not contained in unit dose packaging shall be set up, identified by resident name and medication name, and administered by the same person. The medications shall be administered within one hour of preparation. (II)

h. The person administering medications must observe and check to make sure the resident swallows oral medications and must record the date, time, amount and name of each medication given. (II)

i. Injectable medications shall be administered as permitted by Iowa law by a qualified nurse, physician, pharmacist, or physician assistant (PA). In the case of a resident who has been certified by the resident's physician or physician assistant (PA) as capable of taking the resident's own insulin, the resident may prepare and inject the resident's own insulin. (II)

j. Current and accurate records must be kept on the receipt and disposition of all Schedule II drugs. (II, III)

65.17(2) For each resident who is taking medication with or without supervision, there shall be documentation on the individual's record to include:

a. Name of resident; (II, III)

b. Name of drug, dose, and schedule; (II, III)

c. Method of administration; (II, III)

d. Identified drug allergies and observed adverse reactions; (I, II)

e. Special precautions for that resident; (I, II) and

f. Documentation of resident's continuing ability to administer own medication. (I, II)

65.17(3) Medication counseling shall be provided for all residents in accordance with the IPP on an ongoing basis and as part of discharge planning unless contraindicated in writing by the physician with reasons and pursuant to 65.12(2)"c." (II, III)

Each resident and when appropriate, a family member or other identified caregiver, shall be given verbal and written information about all medications the resident is currently using, including over-the-counter medications. A suggested reference is "USPDI, Advice for the Patient." (II, III)

The information shall include:

a. Name, reason for, and amount of medication to be taken; (II)

b. Time medication is to be taken and reason that the schedule was established; (II)

c. Possible benefits, risks and side effects of each medication, including over-the-counter medications; (II)

d. A list of resources in the community qualified to answer questions about medications; (II, III) and

e. A list of available resources or agencies which may assist the resident to obtain medication after discharge. (III)

65.17(4) Residents who have been certified in writing by the physician as capable of taking their own medications may retain these medications in a secure centralized location. Individual locked storage shall be utilized. (II, III)

a. Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

(1) Adequate size cabinet with lock which can be used for storage of drugs, solutions, and prescriptions. A locked drug cart may be used. (II, III)

(2) A bathroom shall not be used for drug storage. (II, III)

(3) The drug storage cabinet shall be kept locked when not in use. (II, III)

(4) The drug storage cabinet key shall be in the possession of the employee charged with the responsibility of administering medication. (II, III)

(5) Medications requiring refrigeration which are stored in a common refrigerator shall be kept in a locked box properly labeled, and separated from food and other items. (II, III)

(6) Drugs for external use shall be stored separately from drugs for internal use. External medications are those to be applied to the outside of the body and include, but are not limited to, salves, ointments, gels, paste, soaps, baths, and lotions. Internal medications are those to be applied inside the body or ingested and include, but are not limited to, oral and injectable medications, eye drops and ointments, ear drops and ointments, and suppositories. Also, eye drops and ear drops shall be separated from each other as well as from other internal and external medications. (II, III)

(7) All potent, poisonous, or caustic materials shall be stored in a separate room from the medications. (II, III)

(8) Inspection of the condition of stored drugs shall be made by the administrator and a licensed pharmacist not less than once every three months. The inspection shall be verified by a report signed by the administrator and the pharmacist and filed with the administrator. The report shall include, but need not be limited to, certifying absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current order, and drugs improperly stored. (III)

(9) Double-locked storage of Schedule II drugs shall not be required under single unit package drug distribution systems in which the quantity stored does not exceed a seven-day supply and a missing dose can be readily detected but must be kept in a locked medication cabinet. Quantities in excess of a seven-day supply must be double-locked. (II)

b. Bulk supplies of prescription drugs shall not be kept. (III)

65.17(5) All labels on medications must be legible. If labels are not legible, the medication shall be sent back to the dispenser as defined in Iowa Code section 147.107 for relabeling. (II, III)

a. The medication for each resident shall be kept or stored in the original dispensed containers. (II, III)

b. The facility shall adopt policies and procedures to destroy unused prescription drugs for residents who die. The policies and procedures shall include, but not be limited to, the following:

(1) Drugs shall be destroyed by the person in charge in the presence of the administrator or the administrator's designee or, if a unit dose system is used, the drugs shall be returned to the supplying pharmacist; (III)

(2) Notation of the destruction shall be made in the resident's chart, with signatures of the persons involved in the destruction; (III)

(3) The manner in which the drugs are disposed of shall be identified (i.e., incinerator, sewer, landfill). (II, III)

c. Reserved.

d. The facility shall also adopt policies and procedures for the disposal of controlled substances as defined by the Iowa board of pharmacy dispensed to residents whose administration has been discontinued by the prescriber. These policies and procedures shall include, but not be limited to, the following:

(1) Procedures for obtaining a release from the resident; (II, III)

(2) The manner in which the drugs were destroyed and by whom, including witnesses to the destruction; (II, III)

(3) Mechanisms for recording the destruction; (II, III)

(4) Procedures to be used when the resident or the conservator or guardian refuses to grant permission for destruction. (II, III)

e. The facility shall adopt policies and procedures for the disposal of unused, discontinued medication. The procedures shall include, but not be limited to:

(1) A specified time after which medication must be destroyed, sent back to the dispenser or placed in long-term storage; (II, III)

(2) Procedures for obtaining permission of the resident, or the conservator or guardian; (II, III)

(3) Procedures to be used when the resident, conservator or guardian refuses to grant permission for disposal; (II, III)

(4) Unused, discontinued medication shall be locked and shall be separate from current medication. (II, III)

f. Reserved.

g. Residents shall not keep any prescription or over-the-counter medication in their possession unless the resident has been determined to be capable of self-administration of medications. (I, II, III)

h. No prescription drugs shall be administered to a resident without a written order signed by a person qualified to prescribe the medication and renewed quarterly. (II)

i. Prescription drugs shall be reordered only with the permission of the attending prescriber. (II, III)

j. No medications prescribed for one resident may be administered to or allowed in the possession of another resident. (II)

65.17(6) Each facility shall establish policies and procedures to govern the administration of prescribed medications to residents on leave from the facility. (III)

a. Medication may be issued to residents who will be on leave from a facility for less than 24 hours. Non-child-resistant containers may be used. Each container may hold only one medication. A label on each container shall indicate the date, the resident's name, the facility, the medication, its strength, dose, and time of administration. (II, III)

b. Medication for residents on leave from a facility longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy examiners. (II, III)

c. Medication distributed as described in this subrule may be issued only by facility personnel responsible for administering medication. (II, III)

65.17(7) Each ICF/PMI that administers controlled substances shall annually obtain a registration from the Iowa board of pharmacy examiners pursuant to Iowa Code section 204.302(1). (III)

This rule is intended to implement Iowa Code section 135C.14.

[ARC 1050C, IAB 10/2/13, effective 11/6/13]

481—65.18(135C) Resident property and personal affairs. The admission of a resident does not give the facility or any employee of the facility the right to manage, use, or dispose of any property of the resident except with the written authorization of the resident or the resident's legal guardian. (II, III)

65.18(1) The admission of a resident shall not grant the ICF/PMI the authority or responsibility to manage the personal affairs of the resident except as may be necessary for the resident's safety and for safe and orderly management of the facility as required by these rules and in accordance with the IPP. (III)

65.18(2) An ICF/PMI shall provide for the safekeeping of personal effects, funds, and other property of its residents. The facility may require that items of exceptional value or which would convey unreasonable responsibilities to the licensee be removed from the premises of the facility for safekeeping. (III)

65.18(3) Residents' funds held by the ICF/PMI shall be in a trust account and kept separate from funds of the facility. (III)

65.18(4) No administrator, employee or their representative shall act as guardian, trustee, or conservator for any resident or the resident's property, unless the resident is related to the person acting as guardian within the third degree of consanguinity. (III)

65.18(5) If a facility is a county care facility, upon the verified petition of the county board of supervisors, the district court may appoint, without fee, the administrator of a county care facility as conservator or guardian, or both, of a resident of such a county care facility. The administrator may establish either separate or common bank accounts for cash funds of these residents. (III)

This rule is intended to implement Iowa Code section 135C.24.

481—65.19(135C) Financial affairs. Residents who have not been assigned a guardian or conservator by the court may manage their personal financial affairs, and to the extent, under written authorization by the residents that the facility assists in management, the management shall be carried out in accordance with Iowa Code section 135C.24. (II)

65.19(1) *Written account of resident funds.* The facility shall maintain a written account of all residents' funds received by or deposited with the facility. (II)

a. An employee shall be designated in writing to be responsible for resident accounts. (II)

b. The facility shall keep on deposit personal funds over which the resident has control when requested by the resident. (II)

c. If the resident requests these funds, they shall be given to the resident with a receipt maintained by the facility and a copy to the resident. If a conservator or guardian has been appointed for the resident, the conservator or guardian shall designate the method of disbursing the resident's funds. (II)

d. If the facility makes a financial transaction on a resident's behalf, the resident or the resident's legal guardian or conservator must receive or acknowledge having seen an itemized accounting of disbursements and current balances at least quarterly. A copy of this statement shall be maintained in the resident's financial or business record. (II)

65.19(2) *Contracts.* There shall be a written contract between the facility and each resident which meets the following requirements:

a. States the base rate or scale per day or per month, the services included, and the method of payment; (III)

b. Contains a complete schedule of all offered services for which a fee may be charged in addition to the base rate; (III)

c. Stipulates that no further additional fees shall be charged for items not contained in complete schedule of services listed in this subrule; (III)

d. States the method of payment of additional charges; (III)

e. Contains an explanation of the method of assessment of additional charges and an explanation of the method of periodic reassessment, if any, resulting in changing such additional charges; (III)

f. States that additional fees may be charged to the resident for nonprescription drugs, other personal supplies, and services by a barber, beautician, etc.; (III)

g. Contains an itemized list of those services, with the specific fee the resident will be charged and method of payment, as related to the resident's current condition, based on the program assessment at the time of admission, which is determined in consultation with the administrator; (III)

h. Includes the total fee to be charged initially to the specific resident; (III)

i. States the conditions whereby the facility may make adjustments to its overall fees for residential care as a result of changing costs. (III) Furthermore, the contract shall provide that the facility shall give:

(1) Written notification to the resident and responsible party, when appropriate, of changes in the overall rates of both base and additional charges at least 30 days prior to the effective date of changes; (III)

(2) Notification to the resident and payer, when appropriate, of changes in additional charges based on a change in the resident's condition. Notification must occur prior to the date the revised additional charges begin. If notification is given orally, subsequent written notification must also be given within a reasonable time, not to exceed one week, listing specifically the adjustments made; (III) and

(3) The terms of agreement in regard to refund of all advance payments, in the event of transfer, death, or voluntary or involuntary discharge; (III)

j. States the terms of agreement concerning holding and charging for a bed in the event of temporary absence of the resident, which terms shall include, at a minimum, the following provisions:

(1) If a resident has a temporary absence from a facility for medical treatment, the facility shall hold the bed open and shall receive payment for the absent period in accordance with provisions of the contract between the resident or the legal guardian and the facility. (II)

(2) If a resident has a temporary absence from a facility in accordance with the IPP, the facility shall ask the resident and payer if they wish the bed held open. This shall be documented in the resident's record including the response. The bed shall be held open and the facility shall receive payment for the absent periods in accordance with the provisions of the contract between the resident or the legal guardian and the facility. (II)

k. States the conditions under which the involuntary discharge or transfer of a resident would be affected; (III)

l. States the conditions of voluntary discharge or transfer; (III) and

m. Sets forth any other matters deemed appropriate by the parties to the contract. No contract or any provision shall be drawn or construed so as to relieve any health care facility of any requirement or obligation imposed upon it by this chapter or any standards or rules in force pursuant to this chapter. (III)

65.19(3) *Contract—copy to party.* Each party shall receive a copy of the signed contract. (III)

65.19(4) The contract shall state the terms of agreement concerning the holding and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons. The terms shall contain a provision that the bed will be held at the request of the resident or the resident's legal representative.

a. The facility shall ask the resident or legal representative if they want the bed held. This request shall be made before the resident leaves or within 48 hours after the resident leaves. The inquiry and the response shall be documented. (II)

b. The facility shall reserve the bed when requested for as long as payments are made in accordance with the contract. (II)

This rule is intended to implement Iowa Code sections 135C.23(1) and 135C.24.

481—65.20(135C) Records.

65.20(1) *Resident record.* The licensee shall keep a permanent record about each resident with all entries current, dated, and signed. (II) The record shall include:

- a.* Name and previous address of resident; (III)
- b.* Birth date, sex, and marital status of resident; (III)
- c.* Church affiliation; (III)
- d.* Physician's name, telephone number, and address; (III)
- e.* Dentist's name, telephone number, and address; (III)
- f.* Name, address and telephone number of next of kin or legal representative; (III)
- g.* Name, address and telephone number of the person to be notified in case of emergency; (III)
- h.* Funeral director, telephone number, and address; (III)
- i.* Pharmacy name, telephone number, and address; (III)
- j.* Results of evaluation pursuant to rule 481—65.11(135C); (III)
- k.* Certification by the physician that the resident requires no higher level of care than the facility is licensed to provide; (III)
- l.* Physician's orders for medication and treatments in writing, signed by the physician quarterly and diet orders renewed yearly; (III)
- m.* A notation of yearly or other visits to physician or other professionals, all consultation reports and progress notes; (III)
- n.* Any change in the resident's condition; (II, III)
- o.* A notation describing the resident's condition on admission, transfer, and discharge; (III)

p. In the event of a resident's death, notations in the resident's record shall include the date and time of the resident's death, the circumstances of the resident's death, the disposition of the resident's body, and the date and time that the resident's family and physician were notified of the resident's death; (III)

q. A copy of instructions given to the resident, legal representative, or facility in the event of discharge or transfer; (III)

r. Disposition of personal property; (III)

s. Copy of IPP pursuant to subrule 65.12(1); (III) and

t. Progress notes pursuant to subrules 65.12(4) and 65.12(5). (III)

65.20(2) Confidentiality of resident records. The facility shall have policies and procedures providing that each resident shall be ensured confidential treatment of all information, including information contained in an automatic data bank. The resident's or the resident's legal guardian's written informed consent shall be required for the release of information to persons not otherwise authorized under law to receive it. (II)

A release of information form shall be used which includes to whom the information shall be released, the reason for the information being released, how the information is to be used, and the period of time for which the release is in effect. A third party, not requesting the release, shall witness the signing of the release of information form. (II)

a. The facility shall limit access to any resident records to staff and consultants providing professional service to the resident. Information shall be made available to staff only to the extent that the information is relevant to the staff person's responsibilities and duties. (II)

Only those personnel concerned with financial affairs of the residents may have access to the financial information. This is not meant to preclude access by representatives of state or federal regulatory agencies. (II)

b. The resident, or the resident's legal guardian, shall be entitled to examine all information and shall have the right to secure full copies of the record at reasonable cost upon request, unless the physician or QMHP determines the disclosure of the record or section is contraindicated in which case this information will be deleted prior to making the record available to the resident. This determination and the reasons for it must be documented in the resident's record by the physician or qualified mental health professional in collaboration with the resident's interdisciplinary team. (II)

65.20(3) Incident records. Each ICF/PMI shall maintain an incident record report and shall have available incident report forms. (II, III)

a. The report of every incident shall be in detail on a printed incident report form. (II, III)

b. The person in charge at the time of the incident shall oversee the preparation and sign the report. (III)

c. A copy of the incident report shall be kept on file in the facility available for review and a part of administrative records. (III)

65.20(4) Retention of records. Records shall be retained in the facility for five years following termination of services to the resident even when there is a change of ownership. (III)

When the facility ceases to operate, the resident's record shall be released to the facility to which the resident is transferred. If no transfer occurs, the record shall be released to the individual's physician. (III)

This rule is intended to implement Iowa Code section 135C.24.

481—65.21(135C) Health and safety.

65.21(1) Physician. Each resident shall have a designated licensed physician who may be called when needed. (III)

65.21(2) Emergency care. Each facility shall have written policies and procedures for emergency medical or psychiatric care to include:

a. A written agreement with a hospital or psychiatric facility or documentation of attempt to obtain a written agreement for the timely admission of a resident who, in the opinion of the attending physician, requires inpatient services; (II, III)

- b. Provisions consistent with Iowa Code chapter 229; (II, III) and
- c. Immediate notification by the person in charge to the physician or QMHP, as appropriate, of any accident, injury or adverse change in the resident's condition. (I, II)

65.21(3) First-aid kit. A first-aid emergency kit shall be available on each floor in every facility. (II, III)

65.21(4) Infection control. Each facility shall have a written and implemented infection control program addressing the following:

- a. Techniques for hand washing consistent with Guidelines for Handwashing and Hospital Control, 1985, Centers for Disease Control, U.S. Department of Health and Human Services, PB85-923404; (I, II, III)

- b. Techniques for handling of blood, body fluids, and body wastes consistent with Guideline for Isolation Precautions in Hospitals, Centers for Disease Control, U.S. Department of Health and Human Services, PB96-138102; (I, II, III)

- c. Decubitus care; (I, II, III)

- d. Infection identification; (I, II, III)

- e. Resident care procedures to be used when there is an infection present consistent with Guideline for Isolation Precautions in Hospitals, Centers for Disease Control, U.S. Department of Health and Human Services, PB96-138102; (I, II, III)

- f. Sanitation techniques for resident care equipment; (I, II, III)

- g. Techniques for sanitary use and reuse of enteral feeding bags, feeding syringes and urine collection bags; (I, II, III)

- h. Techniques for use and disposal of needles, syringes, and other sharp instruments consistent with Guideline for Isolation Precautions in Hospitals, Centers for Disease Control, U.S. Department of Health and Human Services, PB96-138102; (I, II, III) and

- i. Aseptic techniques when using:

- (1) Intravenous or central line catheter consistent with Guideline for Prevention of Intravascular Device Related Infections, Centers for Disease Control, U.S. Department of Health and Human Services, PB97-130074, (I, II, III)

- (2) Urinary catheter, (I, II, III)

- (3) Respiratory suction, oxygen or humidification, (I, II, III)

- (4) Dressings, soaks, or packs, (I, II, III)

- (5) Tracheostomy, (I, II, III)

- (6) Nasogastric or gastrostomy tubes, (I, II, III)

- (7) Sanitary use and reuse of feeding syringes and single-resident uses and reuse of urine collection bags. (I, II, III)

CDC Guidelines may be obtained from the U.S. Department of Commerce, Technology Administration, National Technical Information Service, 5285 Port Royal Rd., Springfield, Virginia 22161 (1-800-553-6847).

65.21(5) Disposable items. There shall be disposable or one-time use items available with provisions for proper disposal to prevent reuse except as allowed by 65.21(4) "g."

65.21(6) Infection control committee. Each facility shall establish an infection control committee of representative professional staff responsible for overall infection control in the facility. (III)

- a. The committee shall annually review and revise the infection control policies and procedures to monitor effectiveness and suggest improvement. (III)

- b. The committee shall meet at least quarterly, submit reports to the administrator, and maintain minutes in sufficient detail to document its proceedings and actions. (III)

- c. The committee shall monitor the health aspect and the environment of the facility. (III)

These rules are intended to implement Iowa Code sections 135C.14(3), 135C.14(5) and 135C.14(8).

65.21(7) Dental services. The facility shall assist residents to obtain regular and emergency dental services and provide necessary transportation. Dental services shall be performed only on the request of the resident or legal guardian. The resident's physician shall be advised of the resident's dental problems. (III)

65.21(8) *Safe environment.* The licensee of an ICF/PMI is responsible for the provision and maintenance of a safe environment for residents and personnel. (I, II) The ICF/PMI may have locked exit doors and shall meet the fire and safety rules and regulations as promulgated by the state fire marshal. (I, II)

65.21(9) *Disaster.* The licensee shall have a written emergency plan to be followed in the event of fire, tornado, explosion, or other emergency. (II, III)

a. The plan shall be posted. (II, III)

b. Training shall be provided to ensure that all employees and residents are knowledgeable of the emergency plan. The training shall be documented. (II, III)

c. Residents shall be permitted to smoke only in posted areas where proper facilities are provided. Smoking by residents considered to be careless shall be prohibited except under direct supervision and in accordance with the IPP. (II, III)

65.21(10) *Safety precautions.* The facility shall take reasonable measures to ensure the safety of residents and shall involve the residents in learning the safe handling of household supplies and equipment in accordance with the policies and procedures established by the facility. (II)

All potent, poisonous, or caustic materials shall be plainly labeled and stored in a specific locked, well-illuminated cabinet, closet, or storeroom and made accessible only to authorized persons. (I, II)

65.21(11) *Hazards.* Entrances, exits, steps, and outside steps and walkways shall be cleared of ice and snow as soon as possible, and kept free of other hazards. (II, III)

65.21(12) *Laundry.* All soiled linens shall be collected in and transported to the laundry room in closed, leakproof laundry bags or covered, impermeable containers. (III)

a. Except for related activities, the laundry room shall not be used for other purposes. (III)

b. Personal laundry shall be marked with an identification unless the residents are responsible for doing their own laundry as indicated in the individual program plan. (III)

c. There shall be an adequate supply of clean, stain-free linens so that each resident shall have at least three washcloths, hand towels, and bath towels per week. (III)

d. Each bed shall be provided with clean, stain-free washable bedspreads and sufficient lightweight serviceable blankets. A complete change of bed linens shall be available for each bed. Linens on beds shall be clean, stain-free and in good repair at all times. (III)

65.21(13) *Supplies, equipment, and storage.* Each facility shall provide a variety of supplies and equipment of a nature calculated to fit the needs and interests of the residents. These may include: books (standard and large print), magazines, newspapers, radio, television, bulletin boards, board games, game equipment, songbooks, cards, craft supplies, record player, movie projector, piano, and outdoor equipment. Supplies and equipment shall be appropriate to the chronological age of the residents. (III)

Storage shall be provided for recreational equipment and supplies. (III)

This rule is intended to implement Iowa Code section 135C.14(1).

481—65.22(135C) *Nutrition.* There shall be policies and procedures written and implemented for dietary staffing.

1. The person responsible for planning menus and monitoring the kitchens in each facility shall have completed training, approved by the department, in sanitation and food preparation. (III)

2. In facilities licensed for over 15 beds, food service personnel shall be on duty during a 12-hour span extending from the preparation of breakfast through supper. (III)

3. There shall be written work schedules and time schedules covering each type of job in the food service department for facilities over 15 beds. These work and time schedules shall be posted or kept in a notebook which is available for use in the food service area. (III)

65.22(1) *Nutrition and menu planning.* Residents shall be encouraged to the maximum extent possible to participate in meal planning, shopping, and in preparing and serving the meal and cleaning up. The facility shall be responsible for helping residents become knowledgeable of what constitutes a nutritionally adequate diet. (III)

a. Menus shall be planned and served to meet nutritional needs of residents in accordance with the physician's diet orders which shall be renewed yearly. Menus shall be planned and served to include

foods and amounts necessary to meet the recommended daily dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. Other foods shall be included to meet energy requirements (calories) to add to the total nutrients and variety of meals. (II, III)

b. At least three meals or their equivalent shall be made available to each resident daily, consistent with those times normally existing in the community. (II, III)

(1) There shall be no more than a 14-hour span between the substantial evening meal and breakfast. (III)

(2) To the extent medically possible, bedtime nourishments, containing a protein source, shall be offered routinely to all residents. Special nourishments shall be available when ordered by the physician. (II, III)

c. Menus shall include a variety of foods prepared in various ways. The same menus shall not be repeated on the same day of the following week. (III)

d. If modified diets are ordered by the physician, the person responsible for writing the menus shall have completed department-approved training in simple therapeutic diets. A copy of a modified diet manual approved by the department and written within the past five years shall be available in the facility. (II, III)

e. Therapeutic diets shall be served accurately. (II, III)

f. Menus shall be written at least one week in advance. The current menu shall be located in an accessible place in the dietetic service department for easy use by persons purchasing, preparing, and serving food. (III)

g. Records of menus as served shall be filed and maintained for 30 days and shall be available for review by departmental personnel. When substitutions are necessary, they shall be of similar nutritive value and recorded on the menu or in a notebook. (III)

h. A file of tested recipes adjusted to the number of people to be fed in the facility shall be maintained. (III)

65.22(2) *Dietary storage, food preparation, service.* In each stage, food shall be handled with maximum care for safety and good health.

a. The use of foods from salvaged, damaged, or unlabeled containers is prohibited. (II, III)

b. No perishable food shall be allowed to stand at room temperature any longer than is required to prepare and serve. (II, III)

c. Canning food is prohibited. The facility may freeze fruits, vegetables, and meats provided strict sanitary procedures are followed and in accordance with recommendations in the "Food Service Sanitation Manual," revised 1976, U.S. Department of Health, Education, and Welfare, Public Health Service, U.S. Government Printing Office, Washington, D.C. (II)

d. Supplies of staple foods for a minimum of a one-week period and of perishable foods for a minimum of a three-day period shall be maintained on the premises. (III)

e. If family-style service is used, all leftover prepared food that has been on the table shall be safely handled. (III)

f. Poisonous compounds shall not be kept in food storage or preparation areas except for a sanitizing agent which shall be kept in a locked cabinet. (II, III)

65.22(3) *Sanitation in food preparation area.* The facility shall develop and implement policies and procedures to address sanitation, meal preparation and service in accordance with recommendations in the "Food Service Sanitation Manual" reference in 65.22(2) "c," which shall be used as the established, nationally recognized reference for establishing and determining satisfactory compliance with the department's food service and sanitation rules. (III)

a. In facilities of 15 beds or fewer, residents may be allowed in the food preparation area in accordance with their IPP. (III)

b. In facilities licensed for over 15 beds, the kitchen shall not be used for serving meals to residents, food service personnel, or other staff. (III)

c. All appliances and work areas shall be kept clean and sanitary. (III)

d. There shall be written procedures established for cleaning all work and serving areas in facilities over 15 beds and a schedule of duties to be performed daily shall be posted in each food area. (III)

e. The food service area shall be located so it will not be used as a passageway by residents, guests, or nonfood service staff in facilities over 15 beds. (III)

f. Dirty linen shall not be carried through the food service area unless it is in sealed, leakproof containers. (III)

g. Mops, scrub pails, and other cleaning equipment used in the resident areas shall not be stored or used in the dietary area. (III)

65.22(4) *Hygiene of food service personnel.* If food service employees are assigned duties outside the dietetic service, these duties shall not interfere with sanitation, safety, or time required for dietetic work assignments. (II, III)

a. Employees shall wear clean, washable uniforms that are not used for duties outside the food service area in facilities over 15 beds. (III)

b. Hair nets shall be worn by all food service personnel and residents who do work in the kitchen in facilities over 15 beds and effective hair restraints in facilities with fewer than 15 beds. (III)

c. People who handle food shall use correct hand-washing and food-handling techniques as identified in the "Food Service Sanitation Manual." People who handle dirty dishes shall not handle clean dishes without washing their hands. (III)

This rule is intended to implement Iowa Code section 135C.14.

481—65.23(135C) Physical facilities and maintenance.

65.23(1) *Housekeeping.* The facility shall have written procedures for daily and weekly cleaning (III) which include, but need not be limited to:

a. All rooms including furnishings, all corridors, storage areas, linen closets, attics, and basements shall be kept in a clean, orderly condition, free of unserviceable furniture and equipment or accumulations of refuse. (III)

b. All resident bedrooms, including furnishings, shall be cleaned and sanitized before use by another resident. (III)

c. Polishes used on floors shall provide a slip-resistant finish. (III)

65.23(2) *Equipment.* Housekeeping and maintenance personnel shall be provided with well-constructed and properly maintained equipment appropriate to the function for which it is to be used. (III)

a. All facilities shall be provided with clean and sanitary storage for cleaning equipment, supplies, and utensils. In facilities over 15 beds, a janitor's closet shall be provided. It shall be equipped with water for filling scrub pails and a janitor's sink for emptying scrub pails. A hallway or corridor shall not be used for storage of equipment. (III)

b. Sufficient numbers of noncombustible trash containers, which have covers, shall be available. (III)

c. All containers for trash shall be watertight, rodent-proof, and have tight-fitting covers and shall be thoroughly cleaned each time a container is emptied. (III)

d. All wastes shall be properly disposed of in compliance with the local ordinances and state codes. (III)

65.23(3) *Bedrooms.* Each resident shall be provided with a bed, substantially constructed and in good repair. (III)

a. Rollaway beds, metal cots, or folding beds are not acceptable. (III)

b. Each bed shall be equipped with the following: casters or glides; clean springs in good repair; a clean, comfortable, well-constructed mattress approximately 5 inches thick and standard in size for the bed; and clean, comfortable pillows of average bed size. (III)

c. There shall be a comfortable chair, either a rocking chair or arm chair, per resident bed. The resident's personal wishes shall be considered and documented. (III)

d. There shall be drawer space for each resident's clothing. In a multiple bedroom, drawer space shall be assigned each resident. (III)

e. There shall be a bedside table with a drawer and a reading lamp for each resident. (III)

f. All furnishings and equipment shall be durable, cleanable, and appropriate to its function. (III)

g. All resident areas shall be decorated, painted, and furnished to provide a homelike atmosphere and in a manner which is age and culture appropriate. (III)

h. Upholstery materials shall be moisture- and soil-resistant, except on furniture which is provided and owned by the resident. (III)

i. Beds and other furnishings shall not obstruct free passage to and through doorways. (III)

j. Beds shall not be placed with the side of the bed against a radiator or in close proximity to it unless the radiator is covered to protect the resident from contact with it or from excessive heat. (III)

65.23(4) Bath and toilet facilities. All lavatories shall have nonreusable towels or an air dryer and an available supply of soap. (III)

65.23(5) Dining and living rooms. Dining rooms and living rooms shall be available for use by residents at appropriate times to allow social, diversional, individual, and group activities. (III)

a. Every facility shall have a dining room and a living room easily accessible to all residents which are never used as bedrooms. (III)

b. A combination dining room and living room may be permitted if the space requirements of a multipurpose room as provided in 481—subrule 61.6(2) are met. (III)

c. Living rooms shall be suitably furnished and maintained for the use of residents and their visitors and may be used for recreational activities. (III)

d. Dining rooms shall be furnished with dining tables and chairs appropriate to the size and function of the facility. These rooms and furnishings shall be kept clean and sanitary. (III)

65.23(6) Family and employee accommodations. Resident bedrooms shall not be occupied by employees, family members of employees, or family members of the licensee. (III)

a. In facilities where the total occupancy of family, employees, and residents is five or fewer, one toilet and one tub or shower is the minimum requirement. (III)

b. In all health care facilities, if the family or employees live within the facility, living quarters shall be required for the family or employees separate from areas provided for residents. (III)

65.23(7) Pets—policies. Any facility in which a pet is living shall implement written policies and procedures addressing the following:

a. Vaccination schedule; (III)

b. Veterinary visit schedule; (III)

c. Housing or sleeping quarters; (III) and

d. Assignment of responsibility for feeding, bathing and cleanup. (III)

65.23(8) Maintenance. Each facility shall establish a program to ensure continued maintenance of the facility, to promote good housekeeping procedures, and to ensure sanitary practices throughout. In facilities over 15 beds, this program shall be in writing and be available for review by the department. (III)

a. The buildings, furnishings and grounds shall be maintained in a clean, orderly condition and be in good repair. (III)

b. The buildings and grounds shall be kept free of flies, other insects, rodents, and their breeding areas. (III)

65.23(9) Buildings, furnishings, and equipment.

a. Battery-operated, portable emergency lights in good working condition shall be available at all times, at a ratio of one light per employee on duty from 6 p.m. to 6 a.m. (III)

b. All windows shall be supplied with curtains and shades or drapes which are kept in good repair. (III)

c. Wherever glass sliding doors or transparent panels are used, they shall be marked conspicuously and decoratively. (III)

65.23(10) Water supply. Every facility shall have an adequate water supply from an approved source. A municipal source of water shall be considered as meeting this requirement. Private sources of water to a facility shall be tested annually and the report submitted with the annual application for license. (III)

a. A bacterially unsafe source of water shall be grounds for denial, suspension, or revocation of license. (III)

b. The department may require testing of private sources of water to a facility at its discretion in addition to the annual test. The facility shall supply reports of tests as directed by the department. (III)
This rule is intended to implement Iowa Code section 135C.14.

481—65.24(135C) Care review committee. Rescinded **ARC 1205C**, IAB 12/11/13, effective 1/15/14.

481—65.25(135C) Residents' rights in general. Each facility shall ensure that policies and procedures are written and implemented which include at least provisions in subrules 65.25(1) to 65.25(21). These shall govern all services provided to staff, residents, their families or legal representatives. The policies and procedures shall be available to the public and shall be reviewed annually. (II)

65.25(1) Grievances. Written policies and procedures shall include a method for submitting grievances and recommendations by residents or their legal representatives and for ensuring a response and disposition by the facility. The written procedure shall ensure protection of the resident from any form of reprisal or intimidation and shall include:

a. An employee or an alternate designated to be responsible for handling grievances and recommendations; (II)

b. Methods to investigate and assess the validity of a grievance or recommendation; (II) and

c. Methods to resolve grievances and take action. (II)

65.25(2) Informed of rights. Policies and procedures shall include a provision that residents be fully informed of their rights and responsibilities as residents and of all rules governing resident conduct and responsibilities. This information must be provided upon admission, or when the facility adopts or amends residents' rights policies. It shall be posted in locations accessible to all residents. (II)

a. The facility shall make known to residents what they may expect from the facility and its staff, and what is expected from residents. The facility shall communicate these expectations during a period not more than two weeks before or later than five days after admission. The communication shall be in writing in a separate handout or brochure describing the facility. It shall be interpreted verbally, as part of a preadmission interview, resident counseling, or in individual or group orientation sessions after admission. (II)

b. Residents' rights and responsibilities shall be presented in language understandable to residents. If the facility serves residents who are non-English-speaking or deaf or hard of hearing, steps shall be taken to translate the information into a foreign or sign language. Blind residents shall be provided either Braille or a recording. Residents shall be encouraged to ask questions about their rights and responsibilities. Their questions shall be answered. (II)

c. A statement shall be signed by the resident and legal guardian, if applicable, to indicate the resident understands these rights and responsibilities. The statement shall be maintained in the record. The statement shall be signed no later than five days after admission. A copy of the signed statement shall be given to the resident or legal guardian. (II)

d. All residents, next of kin, or legal guardian shall be advised within 30 days of changes made in the statement of residents' rights and responsibilities. Appropriate means shall be used to inform non-English-speaking, deaf or hard-of-hearing, or blind residents of changes. (II)

65.25(3) Resident abuse prohibited. Each resident shall receive kind and considerate care at all times and shall be free from physical, sexual, mental and verbal abuse, exploitation, neglect, and physical injury. (I, II)

65.25(4) Allegations of dependent adult abuse. Allegations of dependent adult abuse shall be reported and investigated pursuant to Iowa Code chapter 235E and 481—Chapter 52. (I, II, III)

65.25(5) Report of abuse. Rescinded IAB 12/11/13, effective 1/15/14.

65.25(6) Informed of health condition. Each resident or legal guardian shall be fully informed by a physician of the health and medical condition of the resident unless a physician documents reasons not to in the resident's record. (II)

65.25(7) Research. The resident or legal guardian shall decide whether a resident participates in experimental research. Participation shall occur only when the resident or guardian is fully informed and signs a consent form. (II, III)

Any clinical investigation involving residents must be sponsored by an institution with a human subjects review board functioning in accordance with the requirement of Public Law 93-348, as implemented by Part 46 of Title 45 of the Code of Federal Regulations, as amended December 1, 1981 (45 CFR 46). (III)

65.25(8) Resident work. Services performed by the resident for the facility shall be in accordance with the IPP. (II)

a. Residents shall not be used to provide a source of labor for the facility against the resident's will. Physician's approval is required for all work programs and must be renewed yearly. (II, III)

b. If the individual program plan requires activities for therapeutic or training reasons, the plan for these activities must be professionally developed and implemented. Therapeutic or training goals must be clearly stated and measurable and the plan shall be time limited and reviewed at least quarterly. (II, III)

c. A resident engaged in work programs in the ICF/PMI shall be paid wages commensurate with wage and hour regulations for comparable work and productivity. (II)

d. The resident shall have the right to employment options commensurate with training and skills. (II)

e. Residents performing work shall not be used to replace paid employees to fulfill staff requirements. (II)

65.25(9) Encouragement to exercise rights. Residents shall be encouraged and assisted throughout their period of stay to exercise resident and citizen rights. Residents may voice grievances and recommend changes in policies and services to administrative staff or to an outside representative of their choice free from interference, coercion, discrimination, or reprisal. (II)

65.25(10) Posting of names. The facility shall post in a prominent area the name, telephone number, and address of the survey agency, local law enforcement agency, administrator, members of the board of directors, corporate headquarters, and the protection and advocacy agency designated pursuant to Iowa Code section 135C.2(4) and the text of Iowa Code section 135C.46 to provide to residents another course of redress. (II)

65.25(11) Dignity preserved. Residents shall be treated with consideration, respect, and full recognition of their dignity and individuality, including privacy in treatment and in care of personal needs. (II)

a. Staff shall display respect for residents when speaking with, caring for, or talking about them as constant affirmation of the individuality and dignity of human beings. (II)

b. Schedules of daily activities shall allow maximum flexibility for residents to exercise choice about what they will do and when they will do it. Residents' individual preferences regarding such things as menus, clothing, religious activities, friendships, activity programs, entertainment, sleeping, eating, and times to retire at night and arise in the morning shall be elicited and considered by the facility. The facility shall make every effort to match nonsmokers with other nonsmokers. (II)

c. Residents shall not have their personal lives regulated beyond reasonable adherence to meal schedules, bedtime hours, and other written policies which may be necessary for the orderly management of the facility and as required by these rules; however, residents shall be encouraged to participate in recreational programs. (II)

d. Residents shall be examined and treated in a manner that maintains the privacy of their bodies. A closed door shall shield the resident from passersby. People not involved in the care of a resident shall not be present without the resident's consent during examination or treatment. (II)

e. Privacy for each person shall be maintained when residents are being taken to the toilet or being bathed and while they are being helped with other types of personal hygiene, except as needed for resident safety or assistance. (II)

f. Staff shall knock and be acknowledged before entering a resident's room unless the resident is not capable of response. This does not apply under emergency conditions. (II)

65.25(12) Communications. Each resident may communicate, associate, and meet privately with persons of the resident's choice, unless to do so would infringe upon the rights of other residents. Each resident may send and receive personal mail unopened unless prohibited in the IPP which has

explicit approval of the resident or legal guardian. Telephones consistent with ANSI standards 42 CFR 405.1134(c) (10-1-86) shall be available and accessible for residents to make and receive calls with privacy. Residents who need help shall be assisted in using the telephone. (II)

Arrangements shall be made to provide assistance to residents who require help in reading or sending mail. (II)

65.25(13) *Visiting policies and procedures.* Subject to reasonable scheduling restrictions, visiting policies and procedures shall permit residents to receive visits from anyone they wish. Visiting hours shall be posted. (II)

a. Reasonable, regular visiting hours shall not be less than 12 hours per day and shall take into consideration the special circumstances of each visitor. A particular visitor(s) may be restricted by the facility for one of the following reasons:

- (1) The resident refuses to see the visitor(s). (II)
- (2) The visit would not be in accordance with the IPP. (II)
- (3) The visitor's behavior is unreasonably disruptive to the functioning of the facility. (II)

Reasons for denial of visitation shall be documented in resident records. (II)

b. Decisions to restrict a visitor shall be reevaluated at least quarterly by the QMHP or at the resident's request. (II)

c. Space shall be provided for residents to receive visitors in comfort and privacy. (II)

65.25(14) *Resident activities.* Each resident may participate in activities of social, religious, and community groups as desired unless contraindicated for reasons documented by the attending physician or qualified mental health professional, as appropriate, in the resident's record. (II)

Residents who wish to meet with or participate in activities of social, religious or community groups in or outside the facility shall be informed, encouraged, and assisted to do so. (II)

Residents shall be permitted to leave the facility and environs at reasonable times unless there are justifiable reasons established in writing by the attending physician, QMHP, or facility administrator for refusing permission. (II)

65.25(15) *Resident property.* Each resident may retain and use personal clothing and possessions as space permits and provided use is not otherwise prohibited in these rules. (II)

a. Residents shall be permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility. The personal property shall be kept in a secure location which is convenient to the resident. (II)

b. Residents shall be advised, prior to or at the time of admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items, e.g., cleaning and laundry. (II)

c. Any personal clothing or possession retained by the facility for the resident shall be identified and recorded on admission and the record placed on the resident's chart. The facility shall be responsible for secure storage of items. They shall be returned to the resident promptly upon request or upon discharge from the facility. (II)

65.25(16) *Sharing rooms.* Residents, including spouses staying in the same facility, shall be permitted to share a room, if available, if requested by both parties, unless reasons to the contrary are in the IPP. Reasons for denial shall be documented in the resident's record. (II)

65.25(17) *Choice of physician and pharmacy.* Each resident shall be permitted free choice of a physician and a pharmacy. The facility may require the pharmacy selected to use a drug distribution system compatible with the system currently used by the facility. (II)

This rule is intended to implement Iowa Code section 135C.14 and Iowa Code chapter 235E. [ARC 1205C, IAB 12/11/13, effective 1/15/14; ARC 1204C, IAB 12/11/13, effective 1/15/14; ARC 5711C, IAB 6/16/21, effective 7/21/21]

481—65.26(135C) *Incompetent residents.* Each facility shall provide that all rights and responsibilities of incompetent residents devolve to the legal guardian when a hearing has been held and the resident is judged incompetent in accordance with state law. (II)

A facility is not absolved from advising incompetent residents of their rights to the extent the resident is able to understand them. The facility shall also advise the legal guardian, if any, and acquire a statement indicating an understanding of resident's rights. (II)

This rule is intended to implement Iowa Code sections 135C.14(8) and 135C.24.

481—65.27(135C) County care facilities. In addition to these rules, county care facilities licensed as intermediate care facilities for persons with mental illness must also comply with department of human services rules 441—Chapter 37. Violation of any standard established by the department of human services is a Class II violation pursuant to 481—56.2(135C).

This rule is intended to implement Iowa Code section 227.4.

481—65.28(135C) Violations. Classification of violations is I, II and III, determined by the division using the provisions in 481—Chapter 56, “Fining and Citations,” to enforce a fine to cite a facility.

481—65.29(135C) Another business or activity in a facility. A facility is allowed to have another business or activity in a health care facility or in the same physical structure of the facility, if the other business or activity is under the control of and is directly related to and incidental to the operation of the health care facility, or the business or activity is approved by the department and the state fire marshal.

To obtain the approval of the department and the state fire marshal, the facility must submit to the department a written request for approval which identifies the service(s) to be offered by the business and addresses the factors outlined in paragraphs “a” through “j” of this rule. (I, II, III)

65.29(1) The following factors will be considered by the department in determining whether a business or activity will interfere with the use of the facility by residents, interfere with services provided to residents, or be disturbing to residents:

- a. Health and safety risks for residents;
- b. Compatibility of the proposed business or activity with the facility program;
- c. Noise created by the proposed business or activity;
- d. Odors created by the proposed business or activity;
- e. Use of entrances and exits for the business or activity in regard to safety and disturbance of residents and interference with delivery of services;
- f. Use of the facility's corridors or rooms as thoroughfares to the business or activity in regard to safety and disturbance of residents and interference with delivery of services;
- g. Proposed staffing for the business or activity;
- h. Sharing of services and staff between the proposed business or activity and the facility;
- i. Facility layout and design; and
- j. Parking area utilized by the business or activity.

65.29(2) Approval of the state fire marshal shall be obtained before approval of the department will be considered.

65.29(3) A business or activity conducted in a health care facility or in the same physical structure as a health care facility shall not reduce space, services or staff available to residents below minimums required in these rules and 481—Chapter 61. (I, II, III)

481—65.30(135C) Respite care services. Respite care services means an organized program of temporary supportive care provided for 24 hours or more to a person in order to relieve the usual caregiver of the person from providing continual care to the person. A facility which chooses to provide respite care services must meet the following requirements related to respite care services and must be licensed as a health care facility.

65.30(1) A facility which chooses to provide respite care services is not required to obtain a separate license or pay a license fee.

65.30(2) Rules regarding involuntary discharge or transfer rights do not apply to residents who are being cared for under a respite care contract.

65.30(3) The facility shall have a contract with each resident in the facility. When the resident is there for respite care services, the contract shall specify the time period during which the resident will be considered to be receiving respite care services. At the end of that period, the contract may be amended to extend that period of time. The contract shall specifically state the resident may be involuntarily discharged while being considered as a respite care resident. The contract shall meet other requirements for contracts between a health care facility and resident, except the requirements concerning the holding and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons.

65.30(4) Respite care services shall not be provided by a facility to persons requiring a level of care which is higher than the level of care the facility is licensed to provide.

These rules are intended to implement Iowa Code sections 135C.2(6), 135C.4, 135C.6(2), 135C.6(3), 135C.7, 135C.8, 135C.14, 135C.16(2), 135C.23, 135C.24, 135C.25, 135C.31, and 227.4.

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CHAPTER 71
SUBACUTE MENTAL HEALTH CARE FACILITIES

481—71.1(135G) Purpose—subacute mental health services. Subacute mental health services are intended to be short-term, intensive, recovery-oriented services designed to stabilize an individual who is experiencing a decreased level of functioning due to a mental health condition.

[ARC 1740C, IAB 11/26/14, effective 12/31/14]

481—71.2(135G) Definitions. For the purpose of these rules, the following terms shall have the meanings indicated in this chapter. The definitions set out in Iowa Code section 135G.1 are adopted by reference in the rules.

“Administrator” means an individual who administers, manages, supervises, and is in general administrative charge of a subacute care facility, whether or not such individual has an ownership interest in the facility and whether or not the functions and duties are shared with one or more individuals.

“Assessment” means the evaluation of a person in psychiatric crisis in order to ascertain the person’s current and previous level of functioning, psychiatric and medical history, potential for dangerousness, current psychiatric and medical condition factors contributing to the crisis and support systems that are available.

“Distinct part” means a clearly identifiable area or section within a health care facility, consisting of at least a residential unit, wing, floor, or building containing contiguous rooms.

“Incident” means an unusual occurrence within a facility or on its premises affecting residents, visitors, or employees whether or not there is apparent injury or where hidden injury may have occurred.

“Medication” means any drug including over-the-counter substances ordered and administered under the direction of a physician, physician assistant or advanced registered nurse practitioner.

“Peer support” means services that are provided by individuals in recovery from serious mental illness and delivered to others who also have mental illness.

“Psychiatric care” means the provision of care to patients in a psychiatric unit of an acute care hospital; a freestanding psychiatric hospital; or a mental health clinic.

“Recovery” means a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.

“Recovery principles” means the ten guiding principles of recovery outlined by the federal Substance Abuse and Mental Health Services Administration (www.samhsa.gov): hope, person-driven, many pathways, holistic, peer support, relational, culture, addresses trauma, strengths/responsibility, and respect.

“Responsible party” means the person who signs or cosigns the admission agreement required in rule 481—71.13(135G) or the resident’s guardian or conservator if one has been appointed. In the event that a resident does not have a guardian, conservator or other person signing the admission agreement, the term “responsible party” shall include the resident’s sponsoring agency, e.g., the department of human services, the U.S. Department of Veterans Affairs, a religious group, fraternal organization, or foundation that assumes responsibility and advocates for its client patients and pays for their health care.

“Restraint” means the application of physical force, use of a chemical agent, or a mechanical device for the purpose of restraining the free movement of an individual’s body to protect the individual or others from immediate harm. Restraint does not include briefly holding without undue force an individual to calm or comfort the individual or holding an individual’s hand to safely escort the individual from one area to another.

“Restricted means of egress” means an exit door alarm system for safety of the residents and the public.

“Seclusion” means the involuntary confinement of a resident alone in a room or an area from which the resident is physically prevented from leaving.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.3(135G) Application for licensure.

71.3(1) *Initial application and licensing.* In order to obtain an initial license for a subacute care facility, the applicant must meet all the requirements of the rules, regulations, and standards contained in Iowa Code chapter 135G and in this chapter and must make application at least 30 days prior to the proposed licensure date of the subacute care facility on forms provided by the department. The applicant must:

- a. Submit a résumé of care with a narrative which includes the following information:
 - (1) The purpose of the facility.
 - (2) A description of the target population and limitations on resident eligibility.
 - (3) Identification and description of the services the facility will provide, which shall minimally include specific and measurable goals and objectives for each of the services to be made available by the facility and a description of the resources needed to provide each of the services, including staff, physical facilities and funds.
 - (4) A description of the human services system available in the area including, but not limited to, social, public health, visiting nurse, vocational training, and employment services, residential living arrangements, and services of private agencies.
 - (5) A description of working relationships with human services agencies when applicable, which shall include at a minimum:
 1. A description of how the facility will coordinate with human services agencies to facilitate continuity of care and coordination of services to residents; and
 2. A description of how the facility will coordinate with human services agencies to identify unnecessary duplication of services and plan for development and coordination of needed services;
- b. Submit a floor plan of each floor of the facility drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, the designation of the use to which each room will be put, and window and door location;
- c. Submit a photograph of the front and side elevation of the facility;
- d. Submit the statutory fee for a subacute care facility license;
- e. Show evidence of a certificate signed by the state fire marshal or deputy state fire marshal, or the designee of either, certifying compliance with fire safety rules.

71.3(2) *Conversion from an intermediate care facility for persons with mental illness.* An intermediate care facility for persons with mental illness may be converted to a subacute care facility pursuant to Iowa Code section 135G.4(2) if the facility:

- a. Provides written notice to the department that the facility has employed a full-time psychiatrist and desires to make the conversion; and
- b. Submits an application to the department.

71.3(3) *Renewal application or change of ownership.* In order to obtain a renewal or change of the subacute care facility license, the applicant must:

- a. Submit to the department the completed application form 30 days prior to the annual license renewal or change of ownership date;
- b. Submit the statutory license fee for a subacute care facility with the application for renewal or change of ownership;
- c. Have an approved, current certificate signed by the state fire marshal or deputy state fire marshal, or the designee of either, certifying compliance with fire safety rules and regulations; and
- d. Submit appropriate changes in the résumé of care to reflect any changes in the resident care program or other services.

71.3(4) *Issuance of license.* Licenses are issued to the person or governmental unit with responsibility for the operation of the facility and authority to comply with all applicable statutes, rules or regulations. The person or governmental unit must be the owner of the facility or, if the facility is leased, the lessee.

71.3(5) *Beds per facility.* A single facility shall not be licensed for more than 16 beds.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 2068C, IAB 7/22/15, effective 8/26/15; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.4(135G) Licenses for distinct parts.

71.4(1) Separate licenses may be issued for distinct parts of a health care facility which are clearly identifiable, include specifically designated rooms within the facility, and provide separate categories of care and services.

71.4(2) The following requirements shall be met for a separate licensing of a distinct part:

a. The distinct part shall serve only residents who require the category of care and services immediately available to the residents within that part;

b. The distinct part shall meet all the standards, rules, and regulations pertaining to the category for which a license is being sought;

c. A distinct part must be operationally and financially feasible.

[ARC 1740C, IAB 11/26/14, effective 12/31/14]

481—71.5(135G) Waivers.

71.5(1) Waivers from these rules may be granted by the director of the department if, in addition to the requirements of 481—Chapter 6:

a. The need for a waiver has been established consistent with the résumé of care or the resident's individual program plan; and

b. There is no danger to the health, safety, welfare, or rights of any resident.

71.5(2) The waiver will apply only to a subacute care facility.

71.5(3) Waivers shall be reviewed by the department at the time of each licensure survey to verify whether the facility is still eligible for the waiver.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 5719C, IAB 6/16/21, effective 7/21/21]

481—71.6(135G) Provisional license.

71.6(1) *Provisional license procedure.* The department may issue a provisional license to a subacute care facility pursuant to Iowa Code section 135G.8. The procedure for issuance of a provisional license shall be as follows:

a. The department shall first issue to the facility a report which identifies the deficiency.

b. Within 10 working days after receipt of the report, the facility shall provide the department with a written plan of correction.

c. The department shall review the written plan of correction within 10 working days of receipt. The department may request additional information or revision to the plan, which shall be provided as requested.

d. After accepting the written plan of correction, the department shall then issue a provisional license to the facility, which shall not exceed one year in duration.

71.6(2) *Written plan of correction.* The written plan of correction shall contain:

a. How the facility will correct the deficient practice;

b. How the facility will act to protect residents;

c. The measures the facility will take or the systems it will alter to ensure that the deficient practice does not recur; and

d. The date when the plan of correction will be completed, not to exceed 30 days from the date of the department's report.

[ARC 1740C, IAB 11/26/14, effective 12/31/14]

481—71.7(135G) General requirements.

71.7(1) The license shall be displayed in the facility in a conspicuous place which is viewed by the public.

71.7(2) The license shall be valid only for the premises and person named on the license and is not transferable.

71.7(3) The posted license shall accurately reflect the current status of the subacute care facility's license.

71.7(4) A license shall expire one year after the date of issuance or as indicated on the license.

71.7(5) There shall be no more beds added than are stipulated on the license.
 [ARC 1740C, IAB 11/26/14, effective 12/31/14]

481—71.8(135G) Required notifications to the department.

71.8(1) The department shall be notified:

- a. Thirty days in advance of any proposed change in the subacute care facility's functional operation or the addition or deletion of required services;
- b. Thirty days before any addition, alteration, or new construction is begun in the subacute care facility or on the premises;
- c. Thirty days in advance of any closure of the subacute care facility;
- d. Within two weeks of any change in administrator;
- e. Within 30 days of the date on which any change in the category of license is sought;
- f. Within 30 days of any proposed change in the résumé of care for the subacute care facility.

71.8(2) Prior to the purchase, transfer, assignment, or lease of a subacute care facility, the licensee shall:

- a. Inform the department of the pending sale, transfer, assignment, or lease of the facility; and
- b. Inform the department of the name and address of the prospective purchaser, transferee, assignee, or lessee at least 30 days before the sale, transfer, assignment, or lease is completed.

71.8(3) Within 24 hours, or the next business day, by the most expeditious means available, the department shall be notified:

- a. Of any accident causing major injury. "Major injury" shall be defined as any injury which:
 - (1) Results in death; or
 - (2) Requires admission to a higher level of care for treatment, other than for observation; or
 - (3) Requires consultation with the attending physician, or designee of the physician, or advanced registered nurse practitioner who determines, in writing, on a form designated by the department, that an injury is a "major injury" based upon the circumstances of the accident, the previous functional ability of the resident, and the resident's prognosis;
- b. When a resident attempts suicide, regardless of injury;
- c. When damage to the facility is caused by a natural or other disaster;
- d. When a fire occurs in a facility and the fire requires the notification of emergency services, requires full or partial evacuation of the facility, or causes physical injury to a resident;
- e. When a defect or failure occurs in the fire sprinkler system for more than 10 hours or fire alarm system for more than 4 hours in a 24-hour period. (This reporting requirement is in addition to the requirement to notify the state fire marshal or the state fire marshal's designee.)

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.9(135G) Reports of dependent adult abuse. Reports of suspected dependent adult abuse shall be made to the department of human services.

[ARC 1740C, IAB 11/26/14, effective 12/31/14]

481—71.10(135G) Administrator.

71.10(1) *Administrator required.* Each subacute care facility shall have one person in charge who is duly approved by the department or acting in a provisional capacity in accordance with these rules.

71.10(2) *Qualifications of an administrator.* The administrator shall be at least 21 years of age and shall have a high school diploma or equivalent. In addition, the person shall meet at least one of the following conditions:

- a. Be a mental health professional, as defined in Iowa Code section 228.1(7), with at least one year of experience in an administrative capacity; or
- b. Have a four-year degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field and have a minimum of one year of experience in the field; or
- c. Have a master's degree in human services, psychology, sociology, nursing, health care administration, public administration, or a related field; or

d. Be a licensed nursing home administrator.

71.10(3) Administrator—distinct part. If a subacute care facility is a distinct part of a licensed health care facility, the administrator of the facility as a whole may serve as the administrator of the subacute care facility.

71.10(4) Provisional administrator. A provisional administrator may be appointed on a temporary basis by the subacute care facility licensee to assume the administrative responsibilities of the facility for a period not to exceed 12 months when the facility has, through no fault of its own, lost its administrator and has not been able to replace the administrator, provided the department has been notified and has approved the provisional administrator prior to the date of the administrator's appointment. The provisional administrator must meet the requirements of subrule 71.10(2).

71.10(5) Administrator—initial licensing of facility. A facility applying for an initial license shall not have a provisional administrator.

71.10(6) Duties of administrator. An administrator shall:

a. Be responsible for the implementation of procedures to support the policies established by the licensee;

b. Select and direct competent personnel who provide services for the subacute care facility;

c. Make a policies and procedures manual available to all staff;

d. Be responsible for a monthly in-service educational program for all employees and maintain records of programs and participants;

e. Make staff payroll records available for departmental review as needed;

f. Furnish to the department within 30 days of the department's request statistical information concerning the operation of the facility.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.11(135G) Administration.

71.11(1) The licensee shall:

a. Assume the responsibility for the overall operation of the subacute care facility;

b. Be responsible for compliance with all applicable laws and with the rules of the department;

c. Establish written policies, which shall be available for review, for the operation of the subacute care facility.

71.11(2) The policy and procedures shall include:

a. Personnel;

b. Admission;

c. Evaluation services;

d. Treatment and discharge plan;

e. Crisis intervention, including restraint and seclusion;

f. Involuntary discharge or transfer;

g. Medication management;

h. Records;

i. Resident rights.

[ARC 1740C, IAB 11/26/14, effective 12/31/14]

481—71.12(135G) Personnel.

71.12(1) Staffing requirements. Availability of personnel must be sufficient to meet psychiatric and medical treatment needs of the residents served.

71.12(2) Staffing shall include at minimum:

a. Twenty-four-hour-per-day, seven-day-per-week availability of on-call psychiatrist or advanced registered nurse practitioner with at least one year of experience in psychiatric care;

b. Twenty-four-hour-per-day, seven-day-per-week availability of on-call registered nurse with at least two years of experience in psychiatric care or a registered nurse with a bachelor of science in nursing (BSN) and at least one year of experience in psychiatric care;

c. A mental health professional as defined in Iowa Code section 228.1(7);

d. Direct care staff with at least one year of experience in a mental health care setting; and

e. Social service staff at the bachelor level with at least one year of experience in a mental health care setting.

71.12(3) Personnel policies and procedures shall include the following requirements:

a. Written job descriptions for all employees or agreements for all consultants, which include duties and responsibilities, education, experience, or other requirements, and supervisory relationships.

b. Annual performance evaluations of all employees and consultants which are dated and signed by the employee or consultant and the supervisor.

c. Personnel records which are current, accurate, complete, and confidential to the extent allowed by law.

(1) The record shall contain documentation of how the employee's or consultant's education and experience are relevant to the position for which the employee or consultant was hired.

(2) The record shall contain documentation of criminal history, child abuse and dependent adult abuse record checks, which shall be conducted prior to employment.

d. Roles, responsibilities, and limitations of student interns and volunteers.

e. An orientation program for all newly hired employees and consultants that includes an introduction to the facility's personnel policies and procedures and a discussion of the facility's safety plan.

f. Equal opportunity and affirmative action employment practices.

g. Procedures to be used when disciplining an employee.

h. Appropriate dress and personal hygiene for staff.

i. An overview of recovery principles, person-centered planning and residents' rights.

71.12(4) The facility shall require regular health examinations for all personnel. Employees shall have a health examination within 12 months prior to beginning employment and regular examinations thereafter at least every four years. The examination shall include, at a minimum, the health status of the employee, including screening and testing for tuberculosis as described in 481—Chapter 59.

a. No person shall be allowed to provide services in a facility if the person has a disease:

(1) Which is transmissible through required workplace contact;

(2) Which presents a significant risk of infecting others;

(3) Which presents a substantial possibility of harming others; and

(4) For which no reasonable accommodation can eliminate the risk.

b. There shall be written policies for emergency medical care for employees in case of sudden illness or accident. These policies shall include the administrative individuals to be contacted.

c. Health certificates for all employees shall be available for review by the department.

71.12(5) Personnel record.

a. A personnel record shall be kept for each employee.

b. The record shall include the employee's:

(1) Name and address,

(2) Social security number,

(3) Date of birth,

(4) Date of employment,

(5) References,

(6) Position in the facility,

(7) Job description,

(8) Documentation of experience and education,

(9) Criminal history, child abuse and dependent adult abuse background checks,

(10) Staff training records,

(11) Annual performance evaluation,

(12) Documentation of disciplinary action,

(13) Date and reason for discharge or resignation,

(14) Current physical examination.

71.12(6) Orders for medications and treatments shall be correctly implemented by qualified personnel.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.13(135G) Admission, transfer, and discharge.

71.13(1) *General admission policies.*

a. A subacute care facility shall not admit or retain a resident who is in need of greater services than the facility can provide.

b. Prior to admission of an applicant, the facility shall obtain sufficient information to determine if its program is appropriate and adequate to meet the individual's needs.

c. A subacute care facility shall admit only as many residents as indicated by the number of beds for which the facility is licensed.

d. A subacute care facility shall adopt policies regarding the admission requirements outlined in subrule 71.13(2).

71.13(2) *Admission requirements.*

a. Eligibility for individualized subacute mental health services will be determined by the standardized preadmission screening utilized by the facility. The screening shall be conducted by a mental health professional as defined in Iowa Code section 228.1(7), a physician, a physician assistant, or an advanced registered nurse practitioner.

b. In order to be admitted, the individual must:

(1) Be 18 years or older;

(2) During the past year, have had a diagnosable mental, behavioral or emotional disorder that meets the diagnostic criteria specified in the most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);

(3) Demonstrate a high degree of impairment through significantly impaired mental, social, or educational functioning arising from the psychiatric condition or serious emotional disturbance;

(4) Demonstrate an impairment that severely limits the skills necessary to maintain an adequate level of functioning outside a treatment program and requires active treatment to obtain an adequate level of functioning;

(5) Demonstrate a low level of stability through any two of the following conditions:

1. The individual presents moderate to high risk of danger to self or others.

2. The individual lacks adequate skills or social support to address mental health symptoms.

3. The individual is medically stable but requires observation and care for stabilization of a mental health condition or impairment.

71.13(3) *Admission agreement.* A subacute care facility shall provide an admission agreement to each resident upon admission to the facility. Each admission agreement shall include:

a. Method of payment;

b. Schedule of services and any additional fees;

c. The facility's policies regarding length of stay, discharge and transfer.

71.13(4) *Exclusion criteria.*

a. A subacute care facility shall not admit an individual into the facility if:

(1) The individual manifests behavioral or psychiatric symptoms that require acute care;

(2) The individual can be safely maintained and effectively treated with less intensive services in a community setting; or

(3) The symptoms of the individual do not meet admission criteria in subrule 71.13(2).

b. An individual's lack of adequate place of residence, placement, or housing is not reason to receive subacute mental health services.

71.13(5) *Continued stay criteria policies.* By the tenth day following admission and every ten calendar days thereafter, the mental health professional shall conduct and document an assessment of the resident and determine if:

a. The severity of the behavioral and emotional symptoms continues to require the subacute level of intervention and the DSM diagnosis remains the principal diagnosis.

- b. The prescribed interventions remain consistent with the intended treatment plan outcomes.
- c. There is documented evidence of active, individualized discharge planning.
- d. There is a reasonable likelihood of substantial benefit in the resident's mental health condition as a result of active intervention of the 24-hour supervised program.
- e. Symptoms and behaviors that required admission are continuing.
- f. A less intensive level of care would be insufficient to stabilize the resident's condition.
- g. New issues that meet the admission guidelines in subrule 71.13(2) have appeared.
- h. The resident requires further stabilization subsequent to acute care to treat active mental health symptoms such as psychosis, depression or mood disorder.

71.13(6) Discharge criteria policies. A resident may be discharged from subacute level of care if:

- a. The resident's treatment plan goals and objectives for subacute services have been met and a discharge plan to outpatient or other community-based services is in place.
- b. The resident's physical condition necessitates transfer to a more intensive level of care.
- c. The resident is not making progress toward treatment goals and there is no reasonable expectation of progress at the subacute level of care.
- d. The resident becomes a danger to self, others, or facility structure and requires an emergency transfer to a higher level of care.
- e. The resident repeatedly refuses to participate in the resident's treatment plan.

71.13(7) Discharge or transfer.

a. The facility shall give prior notification to the resident, as well as the resident's next of kin, legal representative, attending physician or advanced registered nurse practitioner, and sponsoring agency, if any, prior to transfer or discharge of any resident.

b. The subacute care facility shall make proper arrangements for the welfare of the resident prior to transfer or discharge in the event of an emergency or inability to reach the next of kin or legal representative.

c. The facility shall make advance notification to the receiving facility prior to the transfer of any resident if the resident is to be transferred to another facility.

(1) Notification shall be made no less than 24 hours prior to transfer unless paragraph 71.13(6) "d" applies.

(2) Prior to the transfer or discharge of a resident to another health care facility, arrangements to provide for continuity of care shall be made with the facility to which the resident is being transferred.

d. The appropriate record as set forth in subrule 71.20(1) shall accompany the resident when the resident is transferred or discharged.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 2068C, IAB 7/22/15, effective 8/26/15; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.14(135G) Treatment plan.

71.14(1) A treatment plan must be developed with each resident. The plan must be based on initial and ongoing assessment of need, be designed to resolve the acute or crisis mental health symptoms or the imminent risk of acute or crisis mental health symptoms, and be completed within six hours of admission, or no later than 12 noon following admission if the resident is admitted between 8 p.m. and 6 a.m.

71.14(2) The treatment plan must be documented in the resident's record and must include the following:

- a. The resident's name.
- b. The date the plan is developed.
- c. Standardized diagnostic formulations, including but not limited to the current Diagnostic and Statistical Manual (DSM) or the current International Statistical Classification of Diseases and Related Health Problems (ICD).
- d. Problems and strengths of the resident that are to be addressed.
- e. Observable and measurable individual objectives that relate to the specific problems identified.
- f. Interventions that address specific objectives, identification of staff responsible for interventions, and planned frequency of interventions.

g. Signatures of mental health professionals responsible for developing the plan, including the qualified prescriber.

h. Signatures of the resident and any parent, guardian, conservator, or legal custodian. Reasons for refusal to sign or inability to participate in treatment plan development must be documented.

i. A projected discharge date and anticipated postdischarge needs, including documentation of resources needed in the community.

j. Review of the treatment plan by the appropriate treatment staff at least daily and upon completion of the stated goals or objectives and documentation of the following:

(1) Progress toward each treatment objective, with revisions as indicated; and

(2) Status of discharge plans, including availability of resources needed by the resident in the community, with revisions as indicated.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.15(135G) Crisis intervention.

71.15(1) There shall be written policies and procedures concerning crisis intervention. These policies and procedures shall be:

a. Directed to maximizing the growth and development of the individual by incorporating a hierarchy of available alternative methods that emphasize positive approaches;

b. Available in each program area and living unit;

c. Available to individuals and their families; and

d. Developed with the participation, as appropriate, of individuals served.

71.15(2) An emergency safety intervention must be performed in a manner that is safe, proportionate, and appropriate to the severity of the behavior and to the individual's chronological and developmental age, size, gender, physical, medical, and psychiatric condition and personal history, including any history of physical or sexual abuse.

[ARC 1740C, IAB 11/26/14, effective 12/31/14]

481—71.16(135G) Seclusion and restraint.

71.16(1) *Use of a seclusion room.* Pursuant to Iowa Code section 135G.3(2), a seclusion room used by a subacute care facility must meet the conditions of 42 CFR § 483.364(b).

a. A subacute care facility utilizing a seclusion room shall have written policies regarding its use. The policy shall:

(1) Specify the types of behavior that may result in seclusion room placement.

(2) Delineate the licensed personnel who may authorize use of the seclusion room.

(3) Require documentation of the time in the seclusion room, the reasons for use of the seclusion room, and the reasons for any extension of time beyond one hour. Under no circumstances shall the use of the seclusion room exceed four hours.

(4) Require notice to residents of the types of behavior that may result in seclusion room placement.

b. A staff member shall always be in hearing distance of the seclusion room, and the resident shall be visually checked by the staff at least every 15 minutes. Every check shall be documented in writing.

c. A seclusion room shall not be used for punishment, for the convenience of staff, or as a substitution for supervision. A seclusion room shall only be used when a less restrictive alternative has failed and:

(1) In an emergency to prevent injury to the resident or to others; or

(2) For crisis intervention.

71.16(2) *Use of restraints.* There shall be written policies that define the use of restraint, designate the staff member who may authorize its use, and establish a mechanism for monitoring and controlling its use.

a. Restraint shall not be used for punishment, for the convenience of staff, or as a substitution for supervision. Restraint shall only be used:

(1) In an emergency to prevent injury to the resident or to others; or

(2) For crisis intervention.

b. Restraint must not result in harm or injury to the resident and must be used only to ensure the safety of the resident or others during an emergency situation until the emergency situation has ceased, even if the restraint order has not expired.

c. The use of restraint should be selected only when other less restrictive measures have been found to be ineffective to protect the resident or others. The staff shall demonstrate effective treatment approaches and alternatives to the use of restraint.

d. Under no circumstances shall a resident be allowed to actively or passively assist in the restraint of another resident.

e. Staff trained in the use of emergency safety interventions must be physically present and continually assessing and monitoring the well-being of the resident and the safe use of restraint throughout the duration of the emergency situation.

71.16(3) *Orders for restraint or seclusion.* An order for restraint or seclusion shall not be written as a standing order or on an as-needed basis.

a. Each order for restraint or seclusion shall include:

(1) The name of the ordering physician, physician assistant or advanced registered nurse practitioner.

(2) The date and time the order is obtained.

(3) The emergency safety intervention ordered, including the length of time for which restraint or seclusion is authorized.

b. Orders for restraint or seclusion must be by a physician, physician assistant or advanced registered nurse practitioner.

(1) Verbal orders must be received while the emergency safety intervention is being initiated by staff or immediately after the emergency safety situation ends and must be verified in writing in the resident's record by the physician, physician assistant or advanced registered nurse practitioner.

(2) Once the one-time order for the specific resident in an emergency safety situation has expired, it may not be renewed on a planned, anticipated, or as-needed basis.

71.16(4) *Simultaneous use prohibited.* Restraint and seclusion shall not be used simultaneously.

71.16(5) *Documentation of use of restraint or seclusion.* Staff must document in the resident's record and in a centralized tracking system any use of restraint or seclusion.

a. Documentation must be completed by the end of the shift in which the intervention occurs or during the shift in which it ends.

b. Documentation shall include:

(1) The order for restraint or seclusion.

(2) The time the emergency safety intervention began and ended.

(3) The emergency safety situation that required restraint or seclusion.

(4) The name of staff involved in the emergency safety intervention.

(5) The interventions used and their outcomes.

(6) The signature of the physician, physician assistant or advanced registered nurse practitioner.

71.16(6) *Meeting to process restraint or seclusion.* As soon as reasonably possible after the restraint or seclusion of a resident has terminated, staff must meet to process the restraint or seclusion occurrence and document in writing the meeting.

71.16(7) *Multiple occasions of restraint or seclusion.* A resident who requires restraint or seclusion on multiple occasions should be considered for a higher level of care.

71.16(8) *Staff training.* The facility shall provide to the staff training by qualified professionals on physical restraint and seclusion theory and techniques.

a. The facility shall keep a record of the training, including attendance, for review by the department.

b. Only staff who have documented training in physical restraint and seclusion theory and techniques shall be authorized to assist with the seclusion or physical restraint of a resident.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.17(135G) Medication management.

71.17(1) Medications must be ordered by qualified prescribers and administered by qualified personnel. For purposes of this subrule, “qualified personnel” means, at a minimum, a certified medication aide.

71.17(2) Prescription medication must be legally dispensed and labeled according to state law.

71.17(3) All medication errors, drug reactions and suspected drug overmedication must be documented and reported to the practitioner who prescribed the medication.

71.17(4) All medications and other preparations intended for internal or external human use must be stored in medicine cabinets or drug rooms. When preservation of the medication or other preparation requires refrigeration, the facility must provide a means of securely refrigerating these items. Such cabinets or drug rooms must be kept securely locked when not in use, and the key must be in the possession of the supervising nurse or other authorized person.

71.17(5) Schedule II drugs must be stored within two separately locked compartments at all times and accessible only to qualified personnel in charge of administering medication.

71.17(6) Any unused portions of program-prescribed medication(s) must be either turned over to the resident with written authorization and directions by the qualified prescriber or returned to a pharmacy for proper disposition by the pharmacist.

71.17(7) Whenever a resident brings the resident’s own prescribed medications into the facility, such medications must not be administered unless identified by a qualified prescriber or pharmacist and ordered by a qualified prescriber. If such medications cannot be administered, they must be packaged, sealed, and returned to an adult member of the resident’s immediate family or the legal guardian or securely stored and returned to the resident upon discharge. However, if previously prescribed medication would prove harmful to the resident, the medication may be withheld from the resident and disposed of in accordance with subrule 71.17(6). There must be documentation by the qualified prescriber in the resident’s clinical record citing the dangers or contraindications of the medication being withheld.

71.17(8) All potent, poisonous, or caustic materials shall be stored separately from medications. All potent, poisonous, or caustic materials shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet or storeroom and made accessible only to authorized personnel.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.18(135G) Dietary.

71.18(1) *Nutrition and menu planning.*

- a. Menus shall be planned and followed to meet the nutritional needs of residents.
- b. Menus shall be planned and served to include foods and amounts necessary to meet federal dietary guidelines.
- c. At least three meals or their equivalent shall be served daily, at regular hours.

71.18(2) *Dietary storage, food preparation, and service.* All food shall be handled, prepared, served and stored in compliance with the Food Code adopted pursuant to Iowa Code section 137F.2.

[ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.19(135G) Buildings, furnishings, and equipment.

71.19(1) *Buildings—general requirements.*

- a. All windows shall be supplied with window treatments that are kept clean and in good repair.
- b. Whenever glass sliding doors or transparent panels are used, they shall be marked conspicuously.
- c. The facility shall meet the equivalent requirements of the appropriate group occupancy of the state fire code.

71.19(2) *Furnishings and equipment.*

- a. All furnishings and equipment shall be durable, cleanable, and appropriate to their function.
- b. Upholstery materials shall be moisture- and soil-resistant as needed, except on furniture provided by the resident and the property of the resident.

71.19(3) *Dining area and common area.* Every facility shall have a dining area and a common area easily accessible to all residents.

a. A common area shall be maintained for the use of residents and their visitors and may be used for recreational activities. Common areas shall be suitably furnished.

b. Dining areas shall be furnished with dining tables and chairs appropriate to the size and function of the facility. Dining areas and furnishings shall be kept clean and sanitary.

71.19(4) Bedrooms.

a. Each resident shall be provided with a twin-sized or larger bed, substantially constructed and in good repair. Rollaway beds, metal cots, or folding beds are not acceptable.

b. Each bed shall be equipped with the following: casters or glides; clean springs in good repair; a clean, comfortable, well-constructed mattress approximately five inches thick and standard in size for the bed; and clean, comfortable pillows of average bed size.

c. Each resident shall have a bedside table with a drawer to accommodate personal possessions.

d. There shall be a comfortable chair, either a rocking chair or armchair, per resident bed. The resident's personal wishes shall be considered.

e. There shall be drawer space for each resident's clothing. In a bedroom in which more than one resident resides, drawer space shall be assigned to each resident.

f. Beds and other furnishings shall not obstruct free passage to and through doorways.

g. Beds shall not be placed in such a manner that the side of the bed is against the radiator or in close proximity to it unless the radiator is covered so as to protect the resident from contact with it or from excessive heat.

h. There shall be no more than two residents per room.

71.19(5) Bath and toilet facilities.

a. There shall be a minimum of one toilet and one sink for each four residents and one shower for each eight residents. For example, a facility with the maximum of 16 beds shall have four toilets and sinks and two showers.

b. All sinks shall have paper towel dispensers and an available supply of soap.

c. Toilet paper shall be readily available to residents.

71.19(6) Heating. A centralized heating system shall be maintained in good working order and capable of maintaining a comfortable temperature for residents of the facility. Portable units or space heaters are prohibited from being used in the facility except in an emergency.

71.19(7) Water supply.

a. Private sources of water supply shall be tested annually and the report made available for review by the department upon request.

b. A bacterially unsafe source of water supply shall be grounds for denial, suspension, or revocation of license.

c. The department may require testing of private sources of water supply at its discretion in addition to the annual test. The facility shall supply reports of such tests as directed by the department.

d. Hot and cold running water under pressure shall be available in the facility.

e. Prior to construction of a new facility or new water source, private sources of water supply shall be surveyed and shall comply with the requirements of the department.

[ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.20(135G) Records.

71.20(1) Resident record. The licensee shall keep a permanent record about each resident with all entries current, dated, and signed. The record shall include:

a. Name and previous address of resident;

b. Birth date, sex, and marital status of resident;

c. Provisional or admitting diagnosis;

d. A biopsychosocial history sufficient to provide data on the resident's relevant past history, present situation, social support system, community resource contacts, and other information relevant to appropriate treatment and discharge planning;

e. The name, telephone number and address of the licensed mental health professional completing the biopsychosocial history;

- f.* Name, address and telephone number of next of kin or legal representative;
- g.* Name, address and telephone number of the person to be notified in case of emergency;
- h.* Pharmacy name, telephone number, and address;
- i.* Written orders for treatment and medications, signed by a physician, physician assistant or advanced registered nurse practitioner;
- j.* Any change in the resident's condition;
- k.* Notations describing the resident's condition on admission, transfer, and discharge;
- l.* A copy of instructions given to the resident, legal representative, or facility in the event of discharge or transfer;
- m.* Individualized treatment and discharge or transfer plan pursuant to rule 481—71.14(135G);
- n.* Progress notes, including any use of seclusion or restraint pursuant to rule 481—71.16(135G), recorded by the physician, physician assistant, advanced registered nurse practitioner or mental health professional and, when appropriate, others significantly involved in active treatment modalities. Progress notes must contain a concise assessment of the resident's progress and recommendations for revising the treatment plan as indicated by the resident's condition;
- o.* The discharge summary, including a recapitulation of the resident's hospitalization, recommendations for appropriate services concerning follow-up, and a brief summary of the resident's condition on discharge.

71.20(2) Confidentiality of resident records. The facility shall have policies and procedures providing that each resident shall be assured confidential treatment of all information, including information contained in electronic records.

a. The facility shall limit access to any resident records to staff and consultants providing professional services to the resident. Information shall be made available to staff only to the extent that the information is relevant to the staff person's responsibilities and duties. This restriction shall not preclude access by representatives of state or federal regulatory agencies.

b. The resident, or the resident's legal guardian, shall be entitled to examine all information and shall have the right to secure full copies of the record at reasonable cost upon request, unless the physician, physician assistant, advanced registered nurse practitioner or mental health professional determines the disclosure of the record or a section thereof is contraindicated, in which case the designated information will be redacted prior to making the record available to the resident. This determination and the reasons for it must be documented in the resident's record.

71.20(3) Incident records.

a. Each subacute care facility shall maintain an incident record report and shall have available incident report forms.

b. A report of every unusual occurrence shall be detailed on the printed incident report form.

c. The person in charge at the time of the unusual occurrence shall oversee the preparation of and sign the incident report.

d. A copy of the incident report shall be kept on file in the facility and shall be available for review and a part of administrative records.

71.20(4) Retention of records.

a. Records shall be retained in the facility for five years following termination of services to the resident, even when there is a change of ownership.

b. When the facility ceases to operate, the resident's record shall be released to the facility to which the resident is transferred. If no transfer occurs, the record shall be released to the individual's physician or advanced registered nurse practitioner.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

481—71.21(135G) Residents' rights in general.

71.21(1) Policies and procedures. Each facility shall ensure that policies and procedures are written and implemented, include all of the following subrules, and govern all areas of service provided to staff and residents, their families or legal representatives. The policies and procedures shall be available to the public and shall be reviewed annually by the facility.

71.21(2) Grievances. Written policies and procedures shall include a method for submission of grievances and recommendations by residents or their responsible parties and a method to ensure a response and disposition by the facility. The written grievance procedure shall ensure protection of the resident from any form of reprisal or intimidation and shall include:

a. The name of an employee or an alternate staff person designated to be responsible for handling grievances and recommendations; and

b. Methods to investigate and assess the validity of a grievance or recommendation, resolve grievances, and take action.

71.21(3) Informed of rights and responsibilities. Policies and procedures shall include a provision that each resident shall be fully informed of the resident's rights and responsibilities as a resident and of all rules governing resident conduct and responsibilities. This information must be provided upon admission.

a. The facility shall inform residents about what they may expect from the facility and its staff and what is expected from residents.

b. Residents' rights and responsibilities shall be presented in language understandable to the resident. If the facility serves residents who are non-English-speaking or deaf or hard of hearing, steps shall be taken to translate the information into the person's native language or sign language. In the case of visually impaired residents, either Braille or a recording shall be provided.

c. A statement shall be signed by the resident and legal guardian, if applicable, indicating an understanding of these rights and responsibilities, and the statement shall be maintained in the record. A copy of the signed statement shall be given to the resident or legal guardian.

71.21(4) Informed of health condition. Each resident or legal guardian shall be fully informed by a physician, physician assistant, advanced registered nurse practitioner or mental health professional of the resident's health and medical condition unless medically contraindicated as documented by a physician, physician assistant, advanced registered nurse practitioner or mental health professional in the resident's record.

71.21(5) Posting of names. The facility shall post in a prominent area the name, telephone number, and address of the survey agency, the local law enforcement agency and the protection and advocacy agency designated to provide to residents another course of redress.

71.21(6) Dignity preserved. Each resident shall be treated with consideration, respect, and full recognition of the resident's dignity and individuality, including privacy in treatment and in care of personal needs.

a. Corporal punishment, verbal abuse, or any other activity that would be damaging to an individual's self-respect shall be prohibited by written policy.

b. Medication shall not be used as punishment, for the convenience of staff, or as a substitute for a program.

c. Staff shall display respect for residents when speaking with, caring for, or talking about them, as constant affirmation of the individuality and dignity of human beings.

d. Residents shall be examined and treated in a manner that maintains the privacy of their bodies. A closed door shall shield the resident from passersby. People not involved in the care of the residents shall not be present without the resident's consent while the resident is being examined or treated.

e. Staff shall knock and be acknowledged before entering a resident's room unless the resident is not capable of a response. This requirement does not apply under emergency conditions.

71.21(7) Communications. Each resident may communicate, associate, and meet privately with persons of the resident's choice, unless to do so would infringe upon the rights of other residents. Each resident may send and receive personal mail unopened unless prohibited in the treatment plan, which requires explicit approval of the resident or legal guardian.

71.21(8) Visiting hours. Subject to reasonable scheduling restrictions, visiting policies and procedures shall permit residents to receive visits from anyone they wish. Visiting hours shall be posted.

a. Reasonable, regular visiting hours shall not be less than 12 hours per day and shall take into consideration the special circumstances of each visitor. A particular visitor(s) may be restricted by the facility for one of the following reasons:

- (1) The resident refuses to see the visitor(s).
- (2) The visit would not be in accordance with the treatment plan.
- (3) The visitor's behavior is unreasonably disruptive to the functioning of the facility.

b. Reasons for denial of visitation shall be documented in the resident's records.

71.21(9) Privacy. Space shall be provided for residents to receive visitors in comfort and privacy.

71.21(10) Telephone calls. Telephones shall be available and accessible for residents to make and receive calls with privacy. Residents who need help shall be assisted in using the telephone.

71.21(11) Mail. Arrangements shall be made to provide assistance to residents who require help in reading or sending mail.

71.21(12) Permission to leave premises. Residents shall be permitted to leave the facility and environs at reasonable times if permitted in writing by the physician, physician assistant, advanced registered nurse practitioner, mental health professional, or administrator.

71.21(13) Resident activities. Each resident may participate in recreational activities as desired unless contraindicated for reasons documented in the resident's record.

71.21(14) Resident property. Each resident may retain and use personal clothing and possessions, as space permits, and cash and other financial instruments, provided that the use of such items is not otherwise prohibited.

a. The personal property shall be kept in a secure location which is convenient to the resident.

b. Residents shall be advised, prior to or at the time of admission, of the kinds and amounts of clothing and possessions permitted for personal use and whether the facility will accept responsibility for maintaining these items, e.g., cleaning and laundry.

c. Any personal clothing or possessions retained by the facility for the resident shall be identified and recorded on admission and the record placed on the resident's chart. The facility shall be responsible for secure storage of items, and the items shall be returned to the resident promptly upon request or upon discharge from the facility.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19; ARC 5711C, IAB 6/16/21, effective 7/21/21]

481—71.22(135G) Health and safety.

71.22(1) Emergency care. Each facility shall have written policies and procedures for emergency medical and psychiatric treatment, which shall include immediate notification by the person in charge to the physician, physician assistant, advanced registered nurse practitioner or mental health professional of any accident, injury or adverse change in the resident's condition. "Immediate" for purposes of this subrule means within 24 hours.

71.22(2) First-aid kit. A first-aid emergency kit shall be available on each floor.

71.22(3) Infection control. Each facility shall have a written and implemented infection control program.

71.22(4) Safe environment. The licensee of a subacute care facility is responsible for the provision and maintenance of a safe environment for residents and personnel. The subacute care facility shall meet the fire and safety rules as promulgated by the state fire marshal or the state fire marshal's designee.

71.22(5) Disaster. The licensee shall have a written emergency plan to be followed in the event of fire, tornado, explosion, or other emergency.

a. The plan shall be posted.

b. Training shall be provided to ensure that all employees are knowledgeable of the emergency plan. The training shall be documented.

71.22(6) Smoking. A subacute care facility shall follow the smokefree air Act, Iowa Code chapter 142D.

[ARC 1740C, IAB 11/26/14, effective 12/31/14; ARC 4431C, IAB 5/8/19, effective 6/12/19]

These rules are intended to implement Iowa Code chapter 135G.

[Filed ARC 1740C (Notice ARC 1615C, IAB 9/3/14), IAB 11/26/14, effective 12/31/14]

[Filed ARC 2068C (Notice ARC 1996C, IAB 5/27/15), IAB 7/22/15, effective 8/26/15]

[Filed ARC 4431C (Notice ARC 4328C, IAB 3/13/19), IAB 5/8/19, effective 6/12/19]

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[Filed ARC 5719C (Notice ARC 5560C, IAB 4/21/21), IAB 6/16/21, effective 7/21/21]

TITLE IV
WASTEWATER TREATMENT AND DISPOSAL
CHAPTER 60
SCOPE OF TITLE—DEFINITIONS—FORMS—RULES OF PRACTICE

[Prior to 7/1/83, see DEQ Chs 15 and 24]

[Prior to 12/3/86, Water, Air and Waste Management[900]]

567—60.1(455B,17A) Scope of title. The department has jurisdiction over the surface water and groundwater of the state to prevent, abate and control water pollution by establishing standards for water quality and for direct or indirect discharges of wastewater to waters of the state and by regulating potential sources of water pollution through a system of general rules or specific permits. The construction and operation of any wastewater disposal system and the discharge of any pollutant to a water of the state require a specific permit from the department, unless exempted by the department.

This chapter provides general definitions applicable in this title and rules of practice, including forms, applicable to the public in the department's administration of the subject matter of this title.

567—Chapter 61 contains the water quality standards of the state, including classification of surface waters. 567—Chapter 62 contains the standards or methods for establishing standards relevant to the discharge of pollutants to waters of the state. 567—Chapter 63 identifies monitoring, analytical and reporting requirements pertaining to permits for the operation of wastewater disposal systems. 567—Chapter 64 contains the standards and procedures for obtaining construction, operation and NPDES permits for wastewater disposal systems other than those associated with animal feeding operations. 567—Chapter 65 specifies minimum waste control requirements and permit requirements for animal feeding operations. 567—Chapter 66 specifies restrictions on pesticide application to waters. 567—Chapter 67 contains standards for the land application of sewage sludge. 567—Chapter 68 contains standards and licensing requirements applicable to commercial septic tank cleaners. 567—Chapter 69 specifies guidelines for private sewage disposal systems.

[ARC 7625B, IAB 3/11/09, effective 4/15/09]

567—60.2(455B) Definitions. The following definitions apply to this title, unless otherwise specified in the particular chapter of this title:

“*Act*” means the Federal Water Pollution Control Act as amended through July 1, 2007, 33 U.S.C. §1251 et seq.

“*Acute toxicity*” means that level of pollutants which would rapidly induce a severe and unacceptable impact on organisms.

“*Application for a construction permit*” means the engineering report, plans and specifications and other data deemed necessary by the department for the construction of a proposed wastewater disposal system or part thereof.

“*Application for an operation permit*” means a written application for an operation or NPDES permit made on forms provided by the department.

“*Approved pretreatment program*” means a program administered by a publicly owned treatment works that meets the criteria established in 40 CFR Part 403 and which has been approved by the director.

“*Aquatic pesticide*” means any pesticide, as defined in Iowa Code section 206.2, that is labeled for application to surface water.

“*ASTM*” means “Annual Book of Standards, Part 31, Water.” The publication is available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, Pennsylvania 19103.

“*Average dry weather flow*” or “*ADW*” means the daily average flow when the groundwater is at or near normal and runoff is not occurring.

“*Average wet weather flow*” or “*AWW*” means the daily average flow for the wettest 30 consecutive days for mechanical plants or for the wettest 180 consecutive days for controlled discharge lagoons.

“*Best management practice (BMP)*” means a practice or combination of practices that is determined, after problem assessment, examination of alternative practices, and appropriate public participation, to be the most effective, practicable (including technological, economic and institutional

considerations) means of preventing or reducing the amount of pollution generated by nonpoint sources to a level compatible with water quality goals.

“Biochemical oxygen demand (five-day)” means the amount of oxygen consumed in the biological processes that break down organic matter in water by aerobic biochemical action in five days at 20°C.

“Bypass” means the diversion of waste streams from any portion of a treatment facility or collection system. A bypass does not include internal operational waste stream diversions that are part of the design of the treatment facility, maintenance diversions where redundancy is provided, diversions of wastewater from one point in a collection system to another point in a collection system, or wastewater backups into buildings that are caused in the building lateral or private sewer line.

“Carbonaceous biochemical oxygen demand (five-day)” means the amount of oxygen consumed in the biological processes that break down carbonaceous organic matter in water by aerobic biochemical action in five days at 20°C.

“CFR” or *“Code of Federal Regulations”* means the federal administrative rules adopted by the United States in effect as of January 1, 2015. The amendment of the date contained in this definition shall constitute the amendment of all CFR references contained in 567—Chapters 60 to 69, Title IV, unless a date of adoption is set forth in a specific rule.

“Chronic toxicity” means that level of pollutants which would, over long durations or recurring exposure, cause a continuous, adverse or unacceptable response in organisms.

“Combined sewer overflow” means the discharge from a combined sewer system at a point prior to the treatment works.

“Combined sewer system” means a wastewater collection system owned by a municipality which conveys sanitary wastewater (domestic, commercial, and industrial) and storm water through a single pipe system to the treatment plant.

“Construction permit” means a written approval from the director to construct a wastewater disposal system or part thereof in accordance with the plans and specifications approved by the department.

“Continuing planning process (CPP)” means the continuing planning process, including any revision thereto, required by Sections 208 and 303(e) of the Act (33 U.S.C. §§1288 and 1313(e)) for state water pollution control agencies. The continuing planning process is a time-phased process by which the department, working cooperatively with designated areawide planning agencies:

a. Develops a water quality management decision-making process involving elected officials of state and local units of government and representatives of state and local executive departments that conduct activities related to water quality management.

b. Establishes an intergovernmental process (such as coordinated and cooperative programs with the state conservation commission in aquatic life and recreation matters, and the soil conservation division, department of agriculture and land stewardship in nonpoint pollution control matters) which provides for water quality management decisions to be made on an areawide or local basis and for the incorporation of such decisions into a comprehensive and cohesive statewide program. Through this process, state regulatory programs and activities will be incorporated into the areawide water quality management decision process.

c. Develops a broad-based public participation (such as utilization of such mechanisms as basin advisory committees composed of local elected officials, representatives of areawide planning agencies, the public at large, and conservancy district committees) aimed at both informing and involving the public in the water quality management program.

d. Prepares and implements water quality management plans, which identify water quality goals and established state water quality standards, defines specific programs, priorities and targets for preventing and controlling water pollution in individual approved planning areas and establishes policies which guide decision making over at least a 20-year span of time (in increments of 5 years).

e. Based on the results of the statewide (state and areawide) planning process, develops the state strategy to be updated annually, which sets the state’s major objectives, approach, and priorities for preventing and controlling pollution over a five-year period.

f. Translates the state strategy into the annual state program plan (required under Section 106 of the federal Act), which establishes the program objectives, identifies the resources committed for the state

program each year, and provides a mechanism for reporting progress toward achievement of program objectives.

g. Periodically reviews and revises water quality standards as required under Section 303(c) of the federal Act.

“Crossover point” means that location in a river or stream in which the flow shifts from being principally along one bank to the opposite bank. This crossover point usually occurs within two curves or an S-shaped curve of a water course.

“Culture water” means reconstituted water or other acceptable water used for culturing test organisms.

“Deep well” means a well located and constructed in such a manner that there is a continuous layer of low permeability soil or rock at least 5 feet thick located at least 25 feet below the normal ground surface and above the aquifer from which water is to be drawn.

“Diluted effluent sample” means a sample of effluent diluted with culture water at the same ratio as the dry weather design flow to the applicable receiving stream flow contained in the zone of initial dilution as allowed in 567—subrule 61.2(4), regulatory mixing zones, including paragraphs *“b,” “c”* and *“d.”*

“Dilution ratio” means, for a specific wastewater discharger, the ratio of the seven-day, ten-year low stream flow to the effluent design flow, e.g., a dilution ratio of 2:1 has two parts stream flow to one part effluent flow.

“Discharge of a pollutant” means any addition of any pollutant or combination of pollutants to navigable waters or waters of the state from any point source. *“Discharge of a pollutant”* includes additions of pollutants into navigable waters or waters of the state from surface runoff which is collected or channeled by human activity; discharges through pipes, sewers, or other conveyances owned by a state, municipality, or other person which do not lead to a treatment works; and discharges through pipes, sewers, or other conveyances, leading into privately owned treatment works. *“Discharge of a pollutant”* does not include an addition of pollutants by any indirect discharger.

“Disposal system” means a system for disposing of sewage, industrial waste, or other wastes, or for the use or disposal of sewage sludge. *“Disposal system”* includes sewer systems, treatment works, point sources, dispersal systems, and any systems designed for the usage or disposal of sewage sludge.

“Effluent toxicity test” means a test to determine the toxicity of a chemical or chemicals contained in a wastewater discharge on living organisms in a static 48-hour exposure under laboratory conditions.

“Excessive infiltration/inflow (I/I)” as referred to in the discussion of secondary treatment is the quantity of I/I which is more economical to remove from the sewer system than to transport and treat at a wastewater facility. Within the cost-effectiveness analysis performed to determine excessive I/I, the transportation and treatment costs will be based on the percent removal requirements specified in the appropriate subrule, 567—subrule 62.3(1) or 62.3(3).

“Fecal coliform” means the portion of the coliform group which is present in the gut or the feces of warm-blooded animals. It includes organisms which are capable of producing gas from lactose broth in a suitable culture medium within 24 hours at 44.5 + / - 0.2°C.

“FR” means the Federal Register, published daily by the Office of the Federal Register, National Archives and Record Service, General Services Administration, Washington, D.C. 20408 and distributed by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

“General permit” means an NPDES permit issued to a class of facilities which could be conditioned and described by a single permit.

“Human health criteria” means that level of pollution which, in the case of noncarcinogens, prevents adverse health effects in humans, and in the case of carcinogens, represents a level of incremental cancer risk of 1 in 100,000. The numerical criteria are based on the human consumption of an average of 6.5 grams of fish and shellfish per day by a 70-kilogram individual for a life span of 70 years.

“Indirect discharger” means a non-domestic discharger introducing pollutants to a publicly owned treatment works.

“Industrial waste” means any liquid, gaseous, radioactive, or solid waste substance resulting from any process of industry, manufacturing, trade, or business, or from the development of any natural resource.

“Interference” means a discharge which, alone or in conjunction with a discharge or discharges from other sources, both:

1. Inhibits or disrupts a POTW, its treatment process or operations, or its sludge processes, use or disposal; and
2. Is a cause of a violation of any requirement of a POTW NPDES permit including an increase in the magnitude or duration of a violation or the prevention of sewage sludge use or disposal.

“Intermittent watercourses” means watercourses which contain flow associated with rainfall/runoff events and which periodically go dry even in pooled areas.

“Local public works department” means a city or county public works department, a board of trustees of a city utility organized pursuant to Iowa Code chapter 388, or a sanitary sewer district organized pursuant to Iowa Code chapter 358.

“Losing streams” means streams which lose 30 percent or more of their flow during the seven-day, ten-year low stream flow periods to cracks and crevices of rock formations, sand and gravel deposits, or sinkholes in the streambed.

“Low permeability” means a soil layer of well-sorted, fine grain-sized sediments or of rock that under normal hydrostatic pressures would not be significantly permeable. Low permeability soils may include homogeneous clays below the zone of weathering, mudstone, claystone, shale, and some glacial till.

“Major,” for municipalities, means a facility having an average wet weather design flow of 1.0 million gallons per day (MGD) or greater. For industries “major” means a facility which is designated by EPA as being a major industry based on the EPA point rating system.

“Major permit amendment” or *“major modification”* means a permit modification that is not a minor permit amendment as defined in this rule.

“Maximum wet weather flow” or *“MWW”* means the total maximum flow received during any 24-hour period when the groundwater is high and runoff is occurring.

“Milligrams per liter (mg/l)” means milligrams of solute per liter of solution (equivalent to parts per million—assuming unit density). A microgram (ug) is 1/1000 of a milligram.

“Minimum flow” means that established stream flow in lieu of the seven-day, ten-year low stream flow to which the provisions of 567—Chapter 61 apply.

“Minor” means all remaining municipal and industrial facilities which have wastewater discharge flows and which are not designated as major facilities.

“Minor permit amendment” or *“minor modification”* means a permit modification made with the consent of the permittee that occurs as a result of any of the following:

1. Correction of a typographical error;
2. Modification of the monitoring and reporting requirements in the permit to include more frequent monitoring or reporting;
3. Revision of an interim date in a compliance schedule, provided that the new date is not more than 120 days after the date specified in the permit and does not interfere with the attainment of the final compliance date;
4. Change in facility name or ownership;
5. Deletion of a point source outfall that does not result in the discharge of pollutants from other outfalls; or
6. Incorporation of an approved local pretreatment program.

“Mixing zone” means a delineated portion of a stream or river in which wastewater discharges will be allowed to combine and disperse into the water body. The chronic criteria of 567—subrule 61.3(3) will apply at the boundary of this zone.

“Mortality” means, for the purpose of the 48-hour acute toxicity test, death, immobilization, or serious incapacitation of the test organisms.

“Navigable water” means a water of the United States as defined in 40 CFR Part 122.2.

“*Nephelometric*” means the nephelometric method of determining turbidity as stated in Standard Methods, pp. 132-134.

“*New discharger*” means any building, structure, facility, or installation:

1. From which there is or may be a “discharge of pollutants”;
2. That did not commence the “discharge of pollutants” at a particular “site” prior to August 13, 1979;
3. Which is not a “new source”; and
4. Which has never received a finally effective NPDES permit for discharges at that “site.”

This definition includes an “indirect discharger” which commences discharging into “waters of the United States” after August 13, 1979. It also includes any existing mobile point source (other than an offshore or coastal oil and gas exploratory drilling rig or a coastal oil and gas developmental drilling rig) such as a seafood processing rig, seafood processing vessel, or aggregate plant that begins discharging at a “site” for which it does not have a permit; and any offshore or coastal mobile oil and gas exploratory drilling rig or coastal mobile oil and gas developmental drilling rig that commences the discharge of pollutants after August 13, 1979, at a “site” under EPA’s permitting jurisdiction for which it is not covered by an individual or general permit and which is located in an area determined by the Regional Administrator in the issuance of a final permit to be an area of biological concern. In determining whether an area is an area of biological concern, the Regional Administrator shall consider the factors specified in 40 CFR 125.122(a)(1) through (10).

An offshore or coastal mobile exploratory drilling rig or coastal mobile developmental drilling rig will be considered a “new discharger” only for the duration of its discharge in an area of biological concern.

“*New source*” means any building, structure, facility or installation from which there is or may be a discharge of pollutants to a navigable water, the construction of which commenced after the promulgation of standards of performance under Section 306 of the Act which are applicable to such source, provided that:

1. The building, structure, facility or installation is constructed at a site at which no other source is located; the building, structure, facility or installation totally replaces the process or production equipment that causes the discharge of pollutants at an existing source; or the production or wastewater generating processes of the building, structure, facility or installation are substantially independent of an existing source at the same site. In determining whether these are substantially independent, factors, such as the extent to which the new facility is integrated with the existing plant and the extent to which the new facility is engaged in the same general type of activity as the existing source, should be considered.

2. Construction on a site at which an existing source is located results in a modification rather than a new source if the construction does not create a new building, structure, facility or installation meeting the criteria of paragraph “1” but otherwise alters, replaces, or adds to existing process or production equipment.

3. Construction of a new source as defined pursuant to this rule has commenced if the owner or operator has:

- Begun, or caused to begin, as part of a continuous on-site construction program, any placement, assembly, or installation of facilities or equipment; or significant site preparation work including clearing, excavation, or removal of existing buildings, structures, or facilities which is necessary for the placement, assembly, or installation of new source facilities or equipment; or

- Entered into a binding contractual obligation for the purchase of facilities or equipment which is intended to be used in the operation of the new source within a reasonable time. Options to purchase or contracts which can be terminated or modified without substantial loss, and contracts for feasibility, engineering, and design studies do not constitute a contractual obligation under this definition.

“*Nonpoint source*” means a source of pollutants that is not a point source.

“*NPDES permit*” means an operation permit, issued after the department has obtained approval of its National Pollutant Discharge Elimination System (NPDES) program from the administrator, that authorizes the discharge of any pollutant into a navigable water.

“*Operation permit*” means a written permit by the director authorizing the operation of a wastewater disposal system or part thereof or discharge source and, if applicable, the discharge of wastes from the disposal system or part thereof or discharge source to waters of the state. An NPDES permit will constitute the operation permit in cases where there is a discharge to a water of the United States and an NPDES permit is required by the Act.

“*Other waste*” means heat, garbage, municipal refuse, lime, sand, ashes, offal, oil, tar, chemicals, and all other wastes which are not sewage or industrial waste.

“*Pass through*” means a discharge which, alone or in conjunction with a discharge or discharges entering the treatment facility from other sources, exits a POTW or semipublic sewage disposal system in quantities or concentrations which cause a violation of any requirement of the treatment facility's NPDES permit including an increase in the magnitude or duration of a violation.

“*Pathogen*” means any microorganism or virus that can cause disease.

“*Permit rationale*” means a document that sets forth the principal facts and the significant factual, legal, methodological, and policy questions considered in preparing a draft operation or NPDES permit.

“*Pesticide*” shall have the definition as stated in Iowa Code section 206.2.

“*pH*” means the hydrogen ion activity of a solution expressed as the logarithm of the reciprocal of the hydrogen ion activity in moles per liter at 25°C. pH is a measure of the relative acidity or alkalinity of the solution. The range extends from 0 to 14; 7 being neutral, 0 to 7 being acidic, and 7 to 14 being alkaline.

“*Point source*” means any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged. This term does not include agricultural storm water discharges and return flows from irrigated agriculture.

“*Pollutant*” means sewage, industrial waste, or other waste.

“*Population equivalent*” means the calculated number of people who would contribute an equivalent amount of biochemical oxygen demand (BOD) per day as the system in question, assuming that each person contributes 0.167 pounds of five-day, 20 degrees Celsius, BOD per day.

“*Positive toxicity test result*” means a statistical significant difference of mortality rate between the control and the diluted effluent test.

“*POTW*” or “*publicly owned treatment works*” means any device or system used in the treatment of municipal sewage or industrial wastes of a liquid nature which is owned by a municipal corporation or other public body created by or under Iowa law and having jurisdiction over disposal of sewage, industrial wastes or other wastes, or a designated and approved management agency under Section 208 of the Act.

“*Pretreatment*” means the reduction of the amount of pollutants, the elimination of pollutants, or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing such pollutants into a POTW. The reduction or alteration may be obtained by physical, chemical, or biological processes, by process changes, or by other means, except as prohibited in 40 CFR 403.6(d).

“*Pretreatment requirements*” means any substantive or procedural requirement related to pretreatment, other than a national pretreatment standard, imposed on an industrial user.

“*Pretreatment standard*” or “*national pretreatment standard*” means any regulation containing pollutant discharge limits promulgated by EPA in accordance with Section 307(b) and (c) of the Act, which applies to industrial users. “Pretreatment standard” includes prohibitive discharge limits established pursuant to 40 CFR 403.5.

“*Primary contact*” means any recreational or other water use in which there is direct human contact with the water involving considerable risk of ingestion of water or contact with sensitive body organs such as the eyes, ears and nose, in quantities sufficient to pose a significant health hazard.

“*Private sewage disposal system*” means a system which provides for the treatment or disposal of domestic sewage from four or fewer dwelling units or the equivalent of less than 16 individuals on

a continuing basis. This includes domestic waste, whether residential or nonresidential, but does not include industrial waste of any flow rate.

“Qualified volunteer” means a person or group of people acting on their own behalf, and not for a government agency or under contract with the department, to produce water quality monitoring data in accordance with a department-approved volunteer monitoring plan. Qualified volunteers must have the training and experience to ensure quality assurance and quality control for the data being produced, or be under the direct supervision of a person having such qualifications. A person or persons identified as participants in a department-approved volunteer monitoring plan will be considered qualified volunteers.

“Records of operation” means department of natural resources report forms or such other report forms, letters or documents which may be acceptable to the department that are designed to indicate specific physical, chemical, or biological values for wastewater during a stated period of time.

“Regional administrator” means the regional administrator of the United States Environmental Protection Agency, Region VII, 901 N. 5th Street, Kansas City, Kansas 66101.

“Secondary contact” means any recreational or other water use in which contact with the water is either incidental or accidental and in which the probability of ingesting appreciable quantities of water is minimal, such as fishing, commercial and recreational boating and any limited contact incidental to shoreline activity. This would include users who do not swim or float in the water body while on a boating activity.

“Semipublic sewage disposal system” means a system for the treatment or disposal of domestic sewage which is not a private sewage disposal system and which is not owned by a city, a sanitary sewer district, or a designated and approved management agency under Section 208 of the Act (33 U.S.C. 1288).

“Seven-day average” means the arithmetic mean of pollutant parameter values for samples collected in a period of seven consecutive days.

“Seven-day, ten-year low stream flow” means the lowest average stream flow which would statistically occur for seven consecutive days once every ten years.

“Severe property damage” means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. “Severe property damage” does not mean economic loss caused by delays in production.

“Sewage” means the water-carried waste products from residences, public buildings, institutions, or other buildings, including the bodily discharges from human beings or animals together with such groundwater infiltration and surface water as may be present.

“Sewage from vessels” means human body wastes and the wastes from toilets and other receptacles intended to receive or retain body wastes that are discharged from vessels and regulated under Section 312 of the Act.

“Shallow well” means a well located and constructed in such manner that there is not a continuous 5-foot layer of low permeability soil or rock between the aquifer from which the water supply is drawn and a point 25 feet below the normal ground surface.

“Significant industrial user” means an industrial user of a POTW that meets any one of the following conditions:

1. Discharges an average of 25,000 gallons per day or more of process wastewater excluding sanitary, noncontact cooling and boiler blowdown wastewater;
2. Contributes a process waste stream which makes up 5 percent or more of the average dry weather hydraulic or organic capacity of the POTW;
3. Is subject to Categorical Pretreatment Standards under 40 CFR 403.6 and 40 CFR Chapter I, Subchapter N; or
4. Is designated by the department as a significant industrial user on the basis that the contributing industry, either singly or in combination with other contributing industries, has a reasonable potential for adversely affecting the operation of or effluent quality from the POTW or for violating any pretreatment standards or requirements.

Upon a finding that an industrial user meeting the criteria in paragraph “1” or “2” of this definition has no reasonable potential for adversely affecting the operation of the POTW or for violating any pretreatment standard or requirement, the department may, at any time on its own initiative or in response to a request received from an industrial user or POTW, determine that an industrial user is not a significant industrial user.

“*Significantly more stringent limitation*” relates to secondary treatment CBOD₅ and SS limitations necessary to meet the percent removal requirements of at least 5 mg/l more stringent than the otherwise applicable concentration-based limitations (i.e., less than 20 mg/l in the case of CBOD₅), or the percent removal limitations in 567—subrules 62.3(1) and 62.3(3), if such limits would, by themselves, force significant construction or other significant capital expenditure.

“*Sinkhole*” means any depression caused by the dissolution or collapse of subterranean materials in a carbonate formation or in gypsum or rock salt deposits through which water may be drained or lost to the local groundwater system. Such depressions may or may not be open to the surface at times. Intermittently, sinkholes may hold water forming a pond.

“*Small municipal separate storm sewer system*” means all separate storm sewer systems that are owned or operated by the United States, the state of Iowa or a city, town, county, district, association or other public body (created by or pursuant to state law) having jurisdiction over disposal of sewage, industrial wastes, storm water, or other wastes, including special districts under state law such as a sewer district, flood control district or drainage district, or similar entity, or a designated and approved management agency under Section 208 of the Clean Water Act that discharges to waters of the United States or of the state of Iowa, and that have a population of less than 100,000 as determined by the 1990 census. This term includes systems similar to separate storm sewer systems in municipalities, such as systems at military bases, large hospital or prison complexes, and highways and other thoroughfares. The term does not include separate storm sewers in very discrete areas such as individual buildings.

“*Storm water*” means storm water runoff, snow melt runoff and surface runoff and drainage. (NOTE: Agricultural storm water runoff is excluded by federal regulation 40 CFR 122.3(e).)

“*Storm water discharge associated with industrial activity*” means the discharge from any conveyance which is used for collecting and conveying storm water and which is directly related to manufacturing, processing or raw materials storage areas at an industrial plant. The term does not include discharges from facilities or activities excluded from the NPDES program under 40 CFR Part 122. For the categories of industries identified in paragraphs “1” to “10” of this definition, the term includes, but is not limited to, storm water discharges from industrial plant yards; immediate access roads and rail lines used or traveled by carriers of raw materials, manufactured products, waste material, or by-products used or created by the facility; material handling sites; refuse sites; sites used for the application or disposal of process wastewaters (as defined at 40 CFR Part 401); sites used for the storage and maintenance of material handling equipment; sites used for residual treatment, storage, or disposal; shipping and receiving areas; manufacturing buildings; storage areas (including tank farms) for raw materials, and intermediate and finished products; and areas where industrial activity has taken place in the past and significant materials remain and are exposed to storm water.

For the categories of industries identified in paragraphs “1” to “9” and “11,” the term includes only storm water discharges from all the areas (except access roads and rail lines) that are listed in the previous sentence where material handling equipment or activities, raw materials, intermediate products, final products, waste materials, by-products, or industrial machinery are exposed to storm water. For the purposes of this paragraph, material handling activities include the: storage, loading and unloading, transportation, or conveyance of any raw material, intermediate product, finished product, by-product or waste product. To qualify for this exclusion, a storm-resistant shelter is not required for: drums, barrels, tanks and similar containers that are tightly sealed with bands or otherwise secured and have no taps or valves, are not deteriorated and do not leak; adequately maintained vehicles used in material handling; and final products other than products that would be mobilized in storm water discharge. The term excludes areas located on plant lands separate from the plant’s industrial activities, such as office buildings and accompanying parking lots as long as the drainage from the excluded areas is not mixed with storm water drained from the above described areas. Industrial facilities (including industrial

facilities that are federally, state, or municipally owned or operated) that meet the description of the facilities listed in paragraphs “1” to “11” of this definition include those facilities designated under 40 CFR 122.26(a)(1)(v). The following categories of facilities are considered to be engaging in “industrial activity” for purposes of this definition:

1. Facilities subject to storm water effluent limitations guidelines, new source performance standards, or toxic pollutant effluent standards under 40 CFR Subchapter N (except facilities with toxic pollutant effluent standards which are exempted under paragraph “11” of this definition);

2. Facilities classified as Standard Industrial Classifications 24 (except 2434), 26 (except 265 and 267), 28 (except 283 and 285), 29, 311, 32 (except 323), 33, 3441, 373;

3. Facilities classified as Standard Industrial Classifications 10 through 14 (mineral industry) including active or inactive mining operations (except for areas of coal mining operations meeting the definition of a reclamation area under 40 CFR 434.11(1)) because the performance bond issued to the facility by the appropriate SMCRA authority has been released, or except for areas of non-coal mining operations which have been released from applicable state or federal reclamation requirements after December 17, 1990, and oil and gas exploration, production, processing, or treatment operations, or transmission facilities that discharge storm water contaminated by contact with, or that has come into contact with, any overburden, raw material, intermediate products, finished products, by-products or waste products located on the site of such operations; (inactive mining operations are mining sites that are not being actively mined, but which have an identifiable owner/operator; inactive mining sites do not include sites where mining claims are being maintained prior to disturbances associated with the extraction, beneficiation, or processing of mined materials, nor sites where minimal activities are undertaken for the sole purpose of maintaining a mining claim);

4. Hazardous waste treatment, storage, or disposal facilities, including those that are operating under interim status or a permit under Subtitle C of RCRA;

5. Landfills, land application sites, and open dumps that have received any industrial wastes (waste that is received from any of the facilities described under this definition) including those that are subject to regulation under Subtitle D of RCRA;

6. Facilities involved in the recycling of materials, including metal scrap yards, battery reclaimers, salvage yards, and automobile junkyards, including, but not limited to, those classified as Standard Industrial Classifications 5015 and 5093;

7. Steam electric power generating facilities, including coal handling sites;

8. Transportation facilities classified as Standard Industrial Classifications 40, 41, 42 (except 4221-4225), 43, 44, 45 and 5171 which have vehicle maintenance shops, equipment cleaning operations, or airport deicing operations. Only those portions of the facility that are either involved in vehicle maintenance (including vehicle rehabilitation, mechanical repairs, painting, fueling, and lubrication), equipment cleaning operations, airport deicing operations, or which are otherwise identified under paragraphs “1” to “7” or “9” or “11” of this definition are associated with industrial activity;

9. Treatment works treating domestic sewage or any other sewage sludge or wastewater treatment device or system used in the storage, treatment, recycling, and reclamation of municipal or domestic sewage, including land dedicated to the disposal of sewage sludge that are located within the confines of the facility, with a design flow of 1.0 mgd or more, or required to have an approved pretreatment program under 40 CFR Part 403. Not included are farmlands, domestic gardens or lands used for sludge management where sludge is beneficially reused and which are not physically located in the confines of the facility, or areas that are in compliance with 40 CFR Part 503;

10. Construction activity including clearing, grading and excavation activities except operations that result in the disturbance of less than 5 acres of total land area which is not part of a larger common plan of development or sale. Effective March 10, 2003, construction activity including clearing, grading and excavation activities except operations that result in the disturbance of less than 1 acre of total land area which is not part of a larger common plan of development or sale;

11. Facilities under Standard Industrial Classifications 20, 21, 22, 23, 2434, 25, 265, 267, 27, 283, 285, 30, 31 (except 311), 323, 34 (except 3441), 35, 36, 37 (except 373), 38, 39, 4221-4225 (and which are not otherwise included within paragraphs “2” to “10”).

“Storm water discharge associated with small construction activity” means the discharge of storm water from:

1. Construction activities including clearing, grading, and excavating that result in land disturbance of equal to or greater than 1 acre and less than 5 acres. Small construction activity also includes the disturbance of less than 1 acre of total land area that is part of a larger common plan of development or sale if the larger common plan will ultimately disturb an area equal to or greater than 1 acre and less than 5 acres. Small construction activity does not include routine maintenance that is performed to maintain the original line and grade, hydraulic capacity, or original purpose of the facility.

2. Any other construction activity designated by the director based on the potential for contribution to a violation of a water quality standard or for significant contribution of pollutants to waters of the United States.

“Storm water point sources” means point sources that serve to collect, channel, direct, and convey storm water and which are subject to Section 402(p) of the federal Clean Water Act and 40 CFR Parts 122, 123, and 124.

“Temperature” means a measure of the heat content of water.

“Thirty-day average” means the arithmetic mean of pollutant parameter values of samples collected in a period of 30 consecutive days.

“Toxicity reduction evaluation (TRE) program” means a step-wise process, similar to that found in EPA Document/600/2-88/062, which combines effluent toxicity tests and analysis of the chemical characteristics of the effluent to determine the cause of the effluent toxicity or the treatment methods which will reduce the effluent toxicity, or both.

“Turbidity” is a measure of the optical property of the particles of mud, clay, silt, finely divided organic matter, or microscopic organisms suspended in water that interfere with light transmission, causing the light to be scattered and absorbed rather than transmitted through the water in straight lines.

“Uncontrolled sanitary landfill” means a landfill or open dump, whether in operation or closed, that does not meet the requirements for runoff or runoff controls established pursuant to subtitle D of the Solid Waste Disposal Act.

“Valid effluent toxicity test” means the mortality in the control test is not greater than 10 percent and all test conditions contained in 567—subrule 63.4(2) “b” “Standard Operating Procedure: Effluent Toxicity Testing, Iowa Department of Natural Resources” are met.

“Water contact recreational canoeing” means the type of activities associated with canoeing outings in which primary contact with the water does occur. This would include users who swim or float in the water body while on a canoeing outing.

“Water of the state” means any stream, lake, pond, marsh, watercourse, waterway, well, spring, reservoir, aquifer, irrigation system, drainage system, and any other body or accumulation of water, surface or underground, natural or artificial, public or private, which are contained within, flow through or border upon the state or any portion thereof.

“Water quality requirement” means the same as defined in 40 CFR §121.1(n).

“Zone of initial dilution” means a delineated portion of a mixing zone in which wastewater discharges will be allowed to rapidly combine and begin dispersing into the water body. The acute criteria of 567—subrule 61.3(3) will apply at the boundary of this zone.

[ARC 7625B, IAB 3/11/09, effective 4/15/09 (See Delay note at end of chapter); ARC 2482C, IAB 4/13/16, effective 5/18/16; ARC 5679C, IAB 6/16/21, effective 7/21/21]

567—60.3(455B,17A) Forms. The following forms shall be used to apply for departmental approvals and to report on activities related to the wastewater programs of the department. Electronic forms may be obtained from the appropriate regional field office. Paper forms may be obtained from the website of the department or by contacting the appropriate regional field office. Properly completed application forms and all attachments shall be submitted in accordance with the instructions. Reporting forms shall be submitted to the appropriate field office.

60.3(1) Construction permit application forms.

a. Schedules 28 — “A” to “S”

- “A” — General Information 542-3129
- “B” — Collection System 542-3095
- “C” — Lateral Sewer System 542-3096
- “D” — Trunk and Interceptor Sewer 542-3097
- “E” — Pump Station 542-3098
- “F” — Treatment Project Site Selection 542-3099
- “G” — Treatment Project Design Data 542-3106
- “H1” — Schematic Flow Diagram 542-3101
- “H2” — Treatment Process Removal Efficiency 542-3102
- “H3” — Mechanical Plant Reliability 542-3239
- “I” — Screening, Grit Removal and Flow Measurement 542-3089
- “J” — Septic Tank System 542-3090
- “K1” — Controlled Discharge Pond 542-3091
- “K2” — Aerated Pond 542-3092
- “K3” — Anaerobic Lagoon 542-3093
- “L” — Settling Tanks 542-3094
- “M” — Fixed Film Reactor—Stationary Media 542-3081
- “N” — Rotating Biological Contactor 542-3082
- “O” — Aeration Tanks or Basins 542-3083
- “P” — Gas Chlorination 542-3084
- “Q” — Sludge Dewatering and Disposal 542-3085
- “R1” — Sludge Dewatering and Disposal 542-3086
- “R2A” — Low Rate Land Application of Sludge (Part I) 542-3087
- “R2B” — Low Rate Land Application of Sludge (Part II) 542-3088
- “S” — Land Application of Wastewater (To be developed)
- b. Form 29 — Sewage Treatment Agreement 542-3219
- 60.3(2) Operation and NPDES permit application forms.**
 - a. Form 30 — public or private domestic sewer systems (municipal and semipublic facilities) 542-3220.
 - (1) Part A — basic information for all applicants.
 - (2) Part B — expanded effluent testing data.
 - (3) Part C — toxicity testing data.
 - (4) Part D — industrial user discharges and RCRA/CERCLA wastes.
 - (5) Part E — combined sewer systems.
 - (6) Part F — certification.
 - b. Form 31 — treatment agreement 542-3221.
 - c. Form 34 — open feedlots 542-4001.
 - d. Form 1 — general information for industrial, manufacturing or commercial systems 542-1376.
 - e. Form 2 — facilities which do not discharge process wastewater—industrial, manufacturing or commercial systems 542-1377.
 - f. Form 3 — facilities which discharge process wastewater existing sources—industrial, manufacturing, and commercial systems 542-1378.
 - g. Form 4 — facilities which discharge process wastewater—new sources—industrial, manufacturing or commercial systems 542-1379.
 - h. EPA Form 2F — application for NPDES individual permit to discharge storm water discharge associated with industrial activity 542-1380.
 - i. Form 5 — Certification for Industrial Facilities and Operation Permits 542-1382.
 - j. Form 6 — Operation Permit Application 542-1390.
 - k. NPDES Permit Application Supplement 542-1383.
 - l. Notice of Intent for Coverage Under Storm Water NPDES General Permit No. 1 “Storm Water Discharge Associated with Industrial Activity” or General Permit No. 2 “Storm Water Discharge Associated with Industrial Activity for Construction Activities” or General Permit No. 3 “Storm Water

Discharge Associated with Industrial Activity from Asphalt Plants, Concrete Batch Plants, Rock Crushing Plants and Construction Sand and Gravel Facilities” 542-1415.

m. Notice of Intent for Coverage Under NPDES General Permit No. 4 “Discharge from Private Sewage Treatment and Disposal Systems” 542-1541.

n. Notice of Intent for Coverage Under NPDES General Permit No. 5 “Discharge from Mining and Processing Facilities” 542-4006.

o. Notice of Discontinuation From Coverage Under General Permit No. 5 542-8038.

p. Information Required to Accompany Application for the Municipal Separate Storm Sewer System (MS4) Permit 542-8039.

q. NPDES Application Fee Invoice for Open Feedlots and Designated Confinement Feeding Operations 542-1240.

r. NPDES Application Fee Invoice 542-1251.

s. NPDES Application Fee Invoice for a New Discharger 542-1253.

t. Storm Water Discharge — NPDES General Permit #1 Notice of Discontinuation 542-8814.

u. Storm Water Discharge — NPDES General Permit #2 Notice of Discontinuation 542-8815.

v. Storm Water Discharge — NPDES General Permit #3 Notice of Discontinuation 542-8816.

w. Public Notice of Storm Water Discharge 542-8117.

x. Notice of Intent for Coverage Under NPDES General Permit No. 7, “Pesticide General Permit (PGP) for Point Source Discharges to Waters of the United States From the Application of Pesticides.”

y. Notice of Discontinuation From Coverage Under General Permit No. 7.

60.3(3) *Wastewater records of operation and other report forms.*

a. Individual operation and NPDES permit, discharge monitoring report forms as given to the permittee by the department.

b. General Permit No. 5, “Discharge from Mining and Processing Facilities,” Annual Monitoring Report 542-8035.

c. General Permit No. 6, “Iowa DNR Water Well Construction and Services Wastewater Discharge Field Office Notification Form,” 542-0018.

d. General Permit No. 7, “Pesticide General Permit (PGP) for Point Source Discharges to Waters of the United States From the Application of Pesticides,” Annual Monitoring Report.

e. “Acute Whole Effluent Toxicity Testing Report Form,” 542-1381.

f. Other forms as provided by the department, including electronic forms.

[ARC 7625B, IAB 3/11/09, effective 4/15/09; ARC 9365B, IAB 2/9/11, effective 3/30/11; ARC 2482C, IAB 4/13/16, effective 5/18/16]

567—60.4(455B,17A) **Application procedures and requirements generally.** The following procedures and requirements pertain to applications for wastewater permits. More specific and substantive requirements may be found in 567—Chapters 61 to 65.

60.4(1) *Construction permit applications.*

a. General. All applications for a construction permit pursuant to 567—64.2(455B) shall be made in accordance with the instructions for completion of application for wastewater construction permit. The instructions specify the requirements for federal grant and nongrant projects. In addition to the required engineering documents and data the appropriate application schedules (Form 28, “A” to “S”) and Sewage Treatment Agreement Form 29 as applicable shall be submitted. The applicant will be promptly notified if the application is incomplete or improperly filled out, and an application will not be reviewed until such time as a complete and proper submission is made. A wastewater construction permit will be denied when the application does not meet all requirements for issuance of a construction permit. For a system with permits conditioned by limitations on additional loads under 567—subrule 64.2(10), paragraphs “*a*,” “*b*” or “*f*,” subsequent construction permit applications must be accompanied by an accounting of connections and additional loading since the time the initial conditioned permit was issued.

b. Sewer systems. If Schedule B, “Collection System,” of the construction permit application does not provide sufficient information on which to make a determination to grant or deny a sewer system

construction permit under this subrule, additional information, such as the following, may be requested and evaluated:

- (1) Sources of extraneous flows,
- (2) Population trends and density in area to be served,
- (3) Quality and strength of wastes from industrial contributors,
- (4) Existing water used data,
- (5) Historical and experience data,
- (6) Location, capacity, and condition of existing sewer system and stormwater drainage courses,
- (7) Probability of annexation or development of adjacent areas,
- (8) Service agreements with adjacent communities,
- (9) Existence and effectiveness of industrial waste ordinance,
- (10) Drainage area limits,
- (11) Bypasses and combined sewers,
- (12) Municipal sewer map.

c. Site surveys. For new or expanded wastewater treatment facilities, an application for a site survey must be submitted, by the applicant's engineer, generally in advance of a full application for construction permit. The applicant should allow 60 days from the date of application for preliminary approvals. The following minimum information must be submitted:

(1) A preliminary engineering report or a cover letter which contains a brief description of the proposed treatment process and assurance that the project is in conformance with the long-range planning of the area.

- (2) Completed Schedule A — General Information
- (3) Completed Schedule F — Treatment Project Site Selection
- (4) Completed Schedule G — Treatment Project Design Data

If the application is incomplete it will be returned to the engineer for completion. When the application is complete it will be reviewed and if the data submitted indicates on its face that the site would be unsuitable for its intended purpose, a letter of rejection will be sent to the applicant and the engineer. Clarifications and additional data may be requested of the applicant and the engineer. When the application is complete and indicates on its face that the site may be suitable, a site survey will be conducted by department staff.

d. Modification. Persons seeking a modification to plans and specifications after having been issued a construction permit shall submit an addendum to plans and specifications, a change order, or revised plans and specifications, along with the reasons for the proposed changes, to the department. A supplemental written permit or approval will be issued when the changes submitted by the applicant meet department requirements. Construction shall not proceed until such changes have been approved.

e. Fees. Required fees shall be submitted with all applications for a construction permit as noted in 567—64.16(455B).

60.4(2) Operation and NPDES permit applications.

a. General. A person required to obtain or renew a wastewater operation permit or an Iowa NPDES permit pursuant to 567—Chapter 64, 567—Chapter 65, or 567—Chapter 69 must complete the appropriate application form as identified in subrule 60.3(2).

(1) Complete applications. A permit application is complete and approvable when all necessary questions on the application forms have been completed and the application is signed pursuant to 567—subrule 64.3(8), and when all applicable portions of the application, including the application fee and required attachments, have been submitted. The director may require the submission of additional information deemed necessary to evaluate the application. The due date for a renewal application is 180 days prior to the expiration date of the current permit, as noted in 567—64.8(455B). For a POTW, permission to submit an application at a later date may be granted by the director. The due date for a new application is 180 days prior to the date the operation is scheduled to begin, unless a shorter period is approved by the director.

(2) Incomplete applications. Incomplete applications may be returned to the applicant for completion. Authorization to discharge will be suspended if a complete application is not submitted

to the department before the expiration date of the current permit. In the case of new applications, no discharge will be allowed until an NPDES or operation permit is issued. In the case of existing discharges, if a permit application is incomplete or has not been submitted, the department shall notify the permittee of a violation of this rule and may proceed administratively on the violation or may request that the commission refer the matter to the attorney general for legal action.

(3) Other information. If a permittee becomes aware that it failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application, the permittee shall promptly submit such facts or information.

b. Amendments. A permittee seeking an amendment to its operation permit shall make a written request in the form of a detailed letter to the department which shall include the nature of and the reasons supporting the requested amendment. A variance or amendment to the terms and conditions of a general permit shall not be granted. If a variance or amendment to a general permit is desired, the applicant must apply for an individual permit following the procedures in 567—paragraph 64.3(4)“a.”

(1) Schedules of compliance. Requests to amend a permit schedule of compliance shall be made at least 30 days prior to the next scheduled compliance date which the permittee contends it is unable to meet. The request shall include any proposed changes in the existing schedule of compliance, and any supporting documentation for the time extension. An extension may be granted by the department for cause. Cause may include unusually adverse weather conditions, equipment shortages, labor strikes, federal grant regulation requirements, or any other extenuating circumstances beyond the control of the requesting party. Cause does not include economic hardship, profit reduction, or failure to proceed in a timely manner.

(2) Interim effluent limitations. A request to amend interim effluent limitations in an existing permit shall include the proposed amendments to existing effluent limitations and any documentation in support of the proposed limitations. The department will evaluate the request based upon the capability of the disposal system to meet interim effluent limitations, taking into account the contributions to treatment capability which can be made by good operation and maintenance of the disposal system and by minor alterations which can be made to the system to improve its capability. The department may deny a request where the inability of the disposal system to meet interim effluent limitations is due to increased waste loadings on the system over those loadings upon which the interim limitations were based.

(3) Monitoring requirements. An amendment request for a change in the minimum monitoring requirements in an existing permit is considered a variance request. A request for a variance shall include a letter and the Petition for Waiver or Variance form (542-1258). This form can be obtained from the NPDES section as noted in 60.3(455B). The requesting permittee must provide monitoring results which are frequent enough to reflect variations in actual wastewater characteristics over a period of time and are consistent in results from sample to sample. The department will evaluate the request based upon whether or not less frequent sample results accurately reflect actual wastewater characteristics and whether operational control can be maintained.

Upon receipt of a request, the department may grant, modify, or deny the request. If the request is denied, the department may notify the permittee of any violation of its permit and may proceed administratively on the violation or may request that the commission refer the matter to the attorney general for legal action.

c. Fees. Required fees shall be submitted with all permit applications as noted in 567—64.16(455B).

[ARC 7625B, IAB 3/11/09, effective 4/15/09]

These rules are intended to implement Iowa Code section 17A.3(1)“b” and chapter 455B, division III, part 1.

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¹ April 15, 2009, effective date of Item 2 of ARC 7625B delayed 70 days by the Administrative Rules Review Committee at its meeting held April 8, 2009; at its meeting held April 28, 2009, the Committee voted to lift the delay, effective April 29, 2009.

CHAPTER 61
WATER QUALITY STANDARDS

[Prior to 7/1/83, DEQ Ch 16]

[Prior to 12/3/86, Water, Air and Waste Management[900]]

WATER QUALITY STANDARDS

567—61.1 Rescinded, effective August 31, 1977.

567—61.2(455B) General considerations.

61.2(1) Policy statement. It shall be the policy of the commission to protect and enhance the quality of all the waters of the state. In the furtherance of this policy it will attempt to prevent and abate the pollution of all waters to the fullest extent possible consistent with statutory and technological limitations. This policy shall apply to all point and nonpoint sources of pollution.

These water quality standards establish selected criteria for certain present and future designated uses of the surface waters of the state. The standards establish the areas where these uses are to be protected and provide minimum criteria for waterways having nondesignated uses as well. Many surface waters are designated for more than one use. In these cases the more stringent criteria shall govern for each parameter.

Certain of the criteria are in narrative form without numeric limitations. In applying such narrative standards, decisions will be based on the U.S. Environmental Protection Agency's methodology described in "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses," (1985) and on the rationale contained in "Quality Criteria for Water," published by the U.S. Environmental Protection Agency (1977), as updated by supplemental Section 304 (of the Act) Ambient Water Quality Criteria documents. To provide human health criteria for parameters not having numerical values listed in 61.3(3) Table 1, the required criteria will be based on the rationale contained in these EPA criteria documents. The human health criterion considered will be the value associated with the consumption of fish flesh and a risk factor of 10^{-5} for carcinogenic parameters. For noncarcinogenic parameters, the recommended EPA criterion will be selected. For Class C water, the EPA criteria for fish and water consumption will be selected using the same considerations for carcinogenic and noncarcinogenic parameters as noted above.

All methods of sample collection, preservation, and analysis used in applying any of the rules in these standards shall be in accord with those prescribed in 567—Chapter 63.

61.2(2) Antidegradation policy. It is the policy of the state of Iowa that:

a. Tier 1 protection. Existing surface water uses and the level of water quality necessary to protect the existing uses will be maintained and protected.

b. Tier 2 protection. Where the quality of the waters exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water, that quality shall be maintained and protected unless the department finds, after full satisfaction of the intergovernmental coordination and public participation provisions, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation or lower water quality, the department shall ensure water quality adequate to protect existing uses fully. Further, the department shall ensure the highest statutory and regulatory requirements for all new and existing point sources and all cost-effective and reasonable best management practices for nonpoint source control before allowing any lowering of water quality.

c. Tier 2½ protection—outstanding Iowa waters. Where high quality waters constitute an outstanding state resource, such as waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected.

d. Tier 3 protection—outstanding national resource waters. Where high quality waters constitute an outstanding national resource, such as waters of national and state parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected. Any proposed activity that would result in a permanent new or expanded source of pollutants in an outstanding national resource water is prohibited.

- e.* Rescinded IAB 8/31/16, effective 8/12/16.
- f.* All unapproved facility plans for new or expanded construction permits, except for construction permits issued for nondischarging facilities, shall undergo an antidegradation review if degradation is likely in the receiving water or downstream waters following February 17, 2010.
- g.* This policy shall be applied in conjunction with water quality certification review pursuant to Section 401 of the Act. In the event that activities are specifically exempted from flood plain development permits or any other permits issued by this department in 567—Chapters 70, 71, and 72, the activity will be considered consistent with this policy. Other activities not otherwise exempted will be subject to 567—Chapters 70, 71, and 72 and this policy.

61.2(3) *Minimum treatment required.* All wastes discharged to the waters of the state must be of such quality that the discharge will not cause the narrative or numeric criteria limitations to be exceeded. Where the receiving waters provide sufficient assimilative capacity that the water quality standards are not the limiting factor, all point source wastes shall receive treatment in compliance with minimum effluent standards as adopted in rules by the department.

There are numerous parameters of water quality associated with nonpoint source runoff which are of significance to the designated water uses specified in the general and specific designations in 567—61.3(455B), but which are not delineated. It shall be the intent of these standards that the limits on such nonpoint source related parameters when adopted shall be those that can be achieved by best management practices as defined in the course of the continuing planning process from time to time. Existing water quality and nonpoint source runoff control technology will be evaluated in the course of the Iowa continuing planning process, and best management practices and limitations on specific water quality parameters will be reviewed and revised from time to time to ensure that the designated water uses and water quality enhancement goals are met.

61.2(4) *Regulatory mixing zones.* Mixing zones are recognized as being necessary for the initial assimilation of point source discharges which have received the required degree of treatment or control. Mixing zones shall not be used for, or considered as, a substitute for minimum treatment technology required by subrule 61.2(3). The objective of establishing mixing zones is to provide a means of control over the placement and emission of point source discharges so as to minimize environmental impacts. Waters within a mixing zone shall meet the general water quality criteria of subrule 61.3(2). Waters at and beyond mixing zone boundaries shall meet all applicable standards and the chronic and human health criteria of subrule 61.3(3), Tables 1 and 3, for that particular water body or segment. A zone of initial dilution may be established within the mixing zone beyond which the applicable standards and the acute criteria of subrule 61.3(3) will be met. For waters designated under subrule 61.3(5), any parameter not included in Tables 1, 2 and 3 of subrule 61.3(3), the chronic and human health criteria, and the acute criterion calculated following subrule 61.2(1), will be met at the mixing zone and zone of initial dilution boundaries, respectively.

a. Due to extreme variations in wastewater and receiving water characteristics, spatial dimensions of mixing zones shall be defined on a site-specific basis. These rules are not intended to define each individual mixing zone, but will set maximum limits which will satisfy most biological, chemical, physical and radiological considerations in defining a particular mixing zone. Additional details are noted in the “Iowa Wasteload Allocation (WLA) Procedure,” as revised on November 11, 2020, for considering unusual site-specific features such as side channels and sand bars which may influence a mixing zone. Applications for operation permits under 567—subrule 64.3(1) may be required to provide specific information related to the mixing zone characteristics below their outfall so that mixing zone boundaries can be determined.

b. For parameters included in Table 1 only (which does not include ammonia nitrogen), the dimensions of the mixing zone and the zone of initial dilution will be calculated using a mathematical model presented in the “Iowa Wasteload Allocation (WLA) Procedure,” as revised on November 11, 2020, or from instream studies of the mixing characteristics during low flow. In addition, the most restrictive of the following factors will be met:

- (1) The stream flow in the mixing zone may not exceed the most restrictive of the following:

1. Twenty-five percent of the design low stream flows noted in subrule 61.2(5) for interior streams and rivers, and the Big Sioux and Des Moines Rivers.

2. Ten percent of the design low stream flows noted in subrule 61.2(5) for the Mississippi and Missouri Rivers.

3. The stream flow contained in the mixing zone at the most restrictive of the applicable mixing zone length criteria, noted below.

(2) The length of the mixing zone below the point of discharge shall be set by the most restrictive of the following:

1. The distance to the juncture of two perennial streams.

2. The distance to a public water supply intake.

3. The distance to the upstream limits of an established recreational area, such as public beaches, and state, county and local parks.

4. The distance to the middle of a crossover point in a stream where the main current flows from one bank across to the opposite bank.

5. The distance to another mixing zone.

6. Not to exceed a distance of 2000 feet.

7. The location where the mixing zone contained the percentages of stream flow noted in 61.2(4) "b"(1).

(3) The width of the mixing zone is calculated as the portion of the stream containing the allowed mixing zone stream flow. The mixing zone width will be measured perpendicular to the basic direction of stream flow at the downstream boundary of the mixing zone. This measurement will only consider the distance of continuous water surface.

(4) The width and length of the zone of initial dilution may not exceed 10 percent of the width and length of the mixing zone.

c. The stream flow used in determining wasteload allocations to ensure compliance with the maximum contaminant level (MCL), chronic and human health criteria of Table 1 will be that value contained at the boundary of the allowed mixing zone. This stream flow may not exceed the following percentages of the design low stream flow as measured at the point of discharge:

(1) Twenty-five percent for interior streams and rivers, and the Big Sioux and Des Moines Rivers.

(2) Ten percent for the Mississippi and Missouri Rivers.

The stream flow in the zone of initial dilution used in determining effluent limits to ensure compliance with the acute criteria of Table 1 may not exceed 10 percent of the calculated flow associated with the mixing zone.

d. For toxic parameters noted in Table 1, the following exceptions apply to the mixing zone requirements:

(1) No mixing zone or zone of initial dilution will be allowed for waters designated as lakes or wetlands.

(2) No zone of initial dilution will be allowed in waters designated as cold water.

(3) The use of a diffuser device to promote rapid mixing of an effluent in a receiving stream will be considered on a case-by-case basis with its usage as a means for dischargers to comply with an acute numerical criterion.

(4) A discharger to interior streams and rivers, the Big Sioux and Des Moines Rivers, and the Mississippi or Missouri Rivers may provide to the department, for consideration, instream data which technically supports the allowance of an increased percentage of the stream flow contained in the mixing zone due to rapid and complete mixing. Any allowed increase in mixing zone flow would still be governed by the mixing zone length restrictions. The submission of data should follow the guidance provided in the "Iowa Wasteload Allocation (WLA) Procedure," as revised on November 11, 2020.

e. For ammonia criteria noted in Table 3, the dimensions of the mixing zone and the zone of initial dilution will be calculated using a mathematical model presented in the "Iowa Wasteload Allocation (WLA) Procedure," as revised on November 11, 2020, or from instream studies of the mixing characteristics during low flow. In addition, the most restrictive of the following factors will be met:

(1) The stream flow in the mixing zone may not exceed the most restrictive of the following:

1. One hundred percent of the design low stream flows noted in subrule 61.2(5) for locations where the dilution ratio is less than or equal to 2:1.

2. Fifty percent of the design low stream flows noted in subrule 61.2(5) for locations where the dilution ratio is greater than 2:1, but less than or equal to 5:1.

3. Twenty-five percent of the design low stream flows noted in subrule 61.2(5) for locations where the dilution ratio is greater than 5:1.

4. The stream flow contained in the mixing zone at the most restrictive of the applicable mixing zone length criteria, noted below.

(2) The length of the mixing zone below the point of discharge shall be set by the most restrictive of the following:

1. The distance to the juncture of two perennial streams.

2. The distance to a public water supply intake.

3. The distance to the upstream limits of an established recreational area, such as public beaches, and state, county, and local parks.

4. The distance to the middle of a crossover point in a stream where the main current flows from one bank across to the opposite bank.

5. The distance to another mixing zone.

6. Not to exceed a distance of 2000 feet.

7. The location where the mixing zone contained the percentages of stream flow noted in 61.2(4) "e"(1).

(3) The width of the mixing zone is calculated as the portion of the stream containing the allowed mixing zone stream flow. The mixing zone width will be measured perpendicular to the basic direction of stream flow at the downstream boundary of the mixing zone. This measurement will only consider the distance of continuous water surface.

(4) The width and length of the zone of initial dilution may not exceed 10 percent of the width and length of the mixing zone.

f. For ammonia criteria noted in Table 3, the stream flow used in determining wasteload allocations to ensure compliance with the chronic criteria of Table 3 will be that value contained at the boundary of the allowed mixing zone. This stream flow may not exceed the percentages of the design low stream flow noted in 61.2(4) "e"(1) as measured at the point of discharge.

The pH and temperature values at the boundary of the mixing zone used to select the chronic ammonia criteria of Table 3 will be from one of the following sources. The source of the pH and temperature data will follow the sequence listed below, if applicable data exists from the source.

(1) Specific pH and temperature data provided by the applicant gathered at their mixing zone boundary. Procedures for obtaining this data are noted in the "Iowa Wasteload Allocation (WLA) Procedure," as revised on November 11, 2020.

(2) Regional background pH and temperature data provided by the applicant gathered along the receiving stream and representative of the background conditions at the outfall. Procedures for obtaining this data are noted in the "Iowa Wasteload Allocation (WLA) Procedure," as revised on November 11, 2020.

(3) The statewide median background values as determined by the department.

The stream flow in the zone of initial dilution used in determining effluent limits to ensure compliance with the acute criteria of Table 3 may not exceed 5 percent of the calculated flow associated with the mixing zone for facilities with a dilution ratio of less than or equal to 2:1, and not exceed 10 percent of the calculated flow associated with the mixing zone for facilities with a dilution ratio of greater than 2:1. The pH and temperature values at the boundary of the zone of initial dilution used to select the acute ammonia criteria of Table 3 will be from one of the following sources and follow the sequence listed below, if applicable data exists from the source.

1. Specific effluent pH and temperature data if the dilution ratio is less than or equal to 2:1.

2. If the dilution ratio is greater than 2:1, the logarithmic average pH of the effluent and the regional or statewide pH provided in 61.2(4) "f" will be used. In addition, the flow proportioned average temperature of the effluent and the regional or statewide temperature provided in 61.2(4) "f" will be

used. The procedures for calculating these data are noted in the “Iowa Wasteload Allocation (WLA) Procedure,” as revised on November 11, 2020.

g. For ammonia criteria noted in Table 3, the following exceptions apply to the mixing zone requirements.

(1) No mixing zone or zone of initial dilution will be allowed for waters designated as lakes or wetlands.

(2) No zone of initial dilution will be allowed in waters designated as cold water.

(3) The use of a diffuser device to promote rapid mixing of an effluent in a receiving stream will be considered on a case-by-case basis with its usage as a means for dischargers to comply with an acute numerical criterion.

(4) A discharger to interior streams and rivers, the Big Sioux and Des Moines Rivers, and the Mississippi and Missouri Rivers may provide to the department, for consideration, instream data which technically supports the allowance of an increased percentage of the stream flow contained in the mixing zone due to rapid and complete mixing. Any allowed increase in mixing zone flow would still be governed by the mixing zone length restrictions. The submission of data should follow the guidance provided in the “Iowa Wasteload Allocation (WLA) Procedure,” as revised on November 11, 2020.

h. Temperature changes within mixing zones established for heat dissipation will not exceed the temperature criteria in 61.3(3)“b”(5).

i. The appropriateness of establishing a mixing zone where a substance discharged is bioaccumulative, persistent, carcinogenic, mutagenic, or teratogenic will be carefully evaluated. In such cases, effects such as potential groundwater contamination, sediment deposition, fish attraction, bioaccumulation in aquatic life, bioconcentration in the food chain, and known or predicted safe exposure levels shall be considered.

61.2(5) Implementation strategy. Numerical criteria specified in these water quality standards shall be met when the flow of the receiving stream equals or exceeds the design low flows noted below.

Type of Numerical Criteria	Design Low Flow Regime
Aquatic Life Protection (TOXICS)	
Acute	1Q ₁₀
Chronic	7Q ₁₀
Aquatic Life Protection (AMMONIA - N)	
Acute	1Q ₁₀
Chronic	30Q ₁₀
Human Health Protection & MCL	
Noncarcinogenic	30Q ₅
Carcinogenic	Harmonic mean

a. The allowable 3°C temperature increase criterion for warm water interior streams, 61.3(3)“b”(5)“1,” is based in part on the need to protect fish from cold shock due to rapid cessation of heat source and resultant return of the receiving stream temperature to natural background temperature. On low flow streams, in winter, during certain conditions of relatively cold background stream temperature and relatively warm ambient air and groundwater temperature, certain wastewater treatment plants with relatively constant flow and constant temperature discharges will cause temperature increases in the receiving stream greater than allowed in 61.3(3)“b”(5)“1.”

b. During the period November 1 to March 31, for the purpose of applying the 3°C temperature increase criterion, the minimum protected receiving stream flow rate below such discharges may be increased to not more than three times the rate of flow of the discharge, where there is reasonable assurance that the discharge is of such constant temperature and flow rate and continuous duration as to not constitute a threat of heat cessation and not cause the receiving stream temperature to vary more than 3°C per day.

c. Site-specific water quality criteria may be allowed in lieu of the specific numerical criteria listed in Tables 1 and 3 of this chapter if adequate documentation is provided to show that the proposed criteria will protect all existing or potential uses of the surface water. Site-specific water quality criteria may be appropriate where:

- (1) The types of organisms differ significantly from those used in setting the statewide criteria; or
- (2) The chemical characteristics of the surface water such as pH, temperature, and hardness differ significantly from the characteristics used in setting the statewide criteria.

Development of site-specific criteria shall include an evaluation of the chemical and biological characteristics of the water resource and an evaluation of the impact of the discharge. All evaluations for site-specific criteria modification must be coordinated through the department, and be conducted using scientifically accepted procedures approved by the department. Any site-specific criterion developed under the provisions of this subrule is subject to the review and approval of the U.S. Environmental Protection Agency. All criteria approved under the provisions of this subrule will be published periodically by the department. Guidelines for establishing site-specific water quality criteria can be found in "Water Quality Standards Handbook," published by the U.S. Environmental Protection Agency, December 1983.

d. A wastewater treatment facility may submit to the department technically valid instream data which provides additional information to be used in the calculations of their wasteload allocations and effluent limitations. This information would be in association with the low flow characteristics, width, length and time of travel associated with the mixing zone or decay rates of various effluent parameters. The wasteload allocation will be calculated considering the applicable data and consistent with the provisions and restrictions in the rules.

e. The department may perform use assessment and related use attainability analyses on water bodies where uses may not be known or adequately documented. The preparation of use attainability analysis documents will consider available U.S. Environmental Protection Agency guidance or other applicable guidance. Credible data and documentation will be used to assist in the preparation of use assessments and use attainability analysis reports.

61.2(6) State water quality certification. This subrule describes the procedures the department will follow when processing certification requests for state water quality certification (certification) of federally issued licenses and permits pursuant to Section 401 of the Act, including but not limited to permits issued by the United States Corps of Engineers (Corps) pursuant to Section 404 of the Act.

a. General. The department shall receive, consider, and process certification requests in accordance with Section 401 of the Act.

b. Certification requests. Certification requests shall be made on the department's Section 401 Water Quality Certification Request form. This form is available on the department's website. Individual permits or licenses issued by federal agencies require submission of a prefiling meeting request and certification request to obtain certification. The prefiling meeting request must be submitted to the department at least 30 days prior to submitting the certification request.

c. Public notice. The department shall issue a public notice of a certification request. The public notice may be a joint public notice issued by a federal agency on behalf of the department. When there is no joint public notice issued by the federal agency, a public notice issued by the department will be provided on its website. The public notice shall solicit comments from the public regarding whether the proposed project complies with state water quality requirements in accordance with Section 401 of the Act. The public notice shall specify the procedure and time frame for submitting comments on the proposed project.

d. Public notice for new or renewed nationwide or regional permits. The department shall provide additional notice to the public of certification of new or renewed nationwide or regional permits issued by the Corps pursuant to Section 404 of the Act. The department shall provide such notice on its website. The public notice shall solicit comments from the public regarding whether the proposed permit complies with state water quality requirements in accordance with Section 401 of the Act. The public notice shall specify the procedure and time frame for submitting comments on the proposed certification.

e. Department action on certification request. After the close of the public comment period and consideration of comments received, the department may issue a certification letter which may include conditions necessary to ensure compliance with state water quality requirements, waive issuance of the certification, or deny certification in accordance with Section 401 of the Act.

f. Certification of federal permits or licenses may require conditions, which may include one or more of the following, to ensure water quality requirements are met:

(1) During construction and upon completion of the project, actions must be taken to prevent pollution affecting public health, fish, shellfish, wildlife, and recreation due to turbidity, pH, nutrients, suspended solids, floating debris, visible oil and grease, or other pollutants entering waters of the state;

(2) Equipment used in waters of the state shall be cleaned of all hazardous materials, pesticides, fuels, lubricants, oils, hydraulic fluids, or other construction-related, potentially hazardous substances before arriving on site. Wash water shall not be discharged into a water of the state;

(3) All cleared vegetative material shall be properly managed in such a manner that it cannot enter a water of the state and cause a violation of water quality requirements;

(4) All construction debris shall be properly managed in such a manner that it cannot enter a water of the state;

(5) Erosion shall be managed so that sediment is not discharged to a water of the state in a manner that causes a violation of water quality requirements;

(6) Riprap, treated lumber products, and temporary structures shall consist of clean material free of coatings of potentially hazardous substances. No asphalt or petroleum-based material shall be used as or included in material placed in any water of the state or within the high-water table;

(7) Stockpiled dredged materials on the shore shall be managed so that sediment is not discharged in a manner that causes a violation of water quality requirements;

(8) Water quality monitoring will be required for Federal Energy Regulatory Commission hydropower projects at the baseline, construction and operational phases of the project;

(9) Hydraulically dredged material shall be managed to ensure the return water meets water quality requirements.

g. Duration of certification. The department's certification shall remain in effect until the expiration date of the applicable permit or license.

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567—61.3(455B) Surface water quality criteria.

61.3(1) Surface water classification. All waters of the state are classified for protection of beneficial uses. These classified waters include general use segments and designated use segments.

a. General use segments. These are intermittent watercourses and those watercourses which typically flow only for short periods of time following precipitation and whose channels are normally above the water table. These waters do not support a viable aquatic community during low flow and do not maintain pooled conditions during periods of no flow.

The general use segments are to be protected for livestock and wildlife watering, aquatic life, noncontact recreation, crop irrigation, and industrial, agricultural, domestic and other incidental water withdrawal uses.

b. Designated use segments. These are water bodies which maintain flow throughout the year or contain sufficient pooled areas during intermittent flow periods to maintain a viable aquatic community.

All perennial rivers and streams as identified by the U.S. Geological Survey 1:100,000 DLG Hydrography Data Map (published July 1993) or intermittent streams with perennial pools in Iowa not specifically listed in the surface water classification of 61.3(5) are designated as Class B(WW-1) waters.

All perennial rivers and streams as identified by the U.S. Geological Survey 1:100,000 DLG Hydrography Data Map (published July 1993) or intermittent streams with perennial pools in Iowa are designated as Class A1 waters.

Designated uses of segments may change based on a use attainability analysis consistent with 61.2(5)“e.” Designated use changes will be specifically listed in the surface water classification of 61.3(5).

Designated use waters are to be protected for all uses of general use segments in addition to the specific uses assigned. Designated use segments include:

(1) Primary contact recreational use (Class “A1”). Waters in which recreational or other uses may result in prolonged and direct contact with the water, involving considerable risk of ingesting water in quantities sufficient to pose a health hazard. Such activities would include, but not be limited to, swimming, diving, water skiing, and water contact recreational canoeing.

(2) Secondary contact recreational use (Class “A2”). Waters in which recreational or other uses may result in contact with the water that is either incidental or accidental. During the recreational use, the probability of ingesting appreciable quantities of water is minimal. Class A2 uses include fishing, commercial and recreational boating, any limited contact incidental to shoreline activities and activities in which users do not swim or float in the water body while on a boating activity.

(3) Children’s recreational use (Class “A3”). Waters in which recreational uses by children are common. Class A3 waters are water bodies having definite banks and bed with visible evidence of the flow or occurrence of water. This type of use would primarily occur in urban or residential areas.

(4) Cold water aquatic life—Type 1 (Class “B(CW1)”). Waters in which the temperature and flow are suitable for the maintenance of a variety of cold water species, including reproducing and nonreproducing populations of trout (*Salmonidae* family) and associated aquatic communities.

(5) Cold water aquatic life—Type 2 (Class “B(CW2)”). Waters that include small, channeled streams, headwaters, and spring runs that possess natural cold water attributes of temperature and flow. These waters usually do not support consistent populations of trout (*Salmonidae* family), but may support associated vertebrate and invertebrate organisms.

(6) Warm water—Type 1 (Class “B(WW-1)”). Waters in which temperature, flow and other habitat characteristics are suitable to maintain warm water game fish populations along with a resident aquatic community that includes a variety of native nongame fish and invertebrate species. These waters generally include border rivers, large interior rivers, and the lower segments of medium-size tributary streams.

(7) Warm water—Type 2 (Class “B(WW-2)”). Waters in which flow or other physical characteristics are capable of supporting a resident aquatic community that includes a variety of native nongame fish and invertebrate species. The flow and other physical characteristics limit the maintenance of warm water game fish populations. These waters generally consist of small perennially flowing streams.

(8) Warm water—Type 3 (Class “B(WW-3)”). Waters in which flow persists during periods when antecedent soil moisture and groundwater discharge levels are adequate; however, aquatic habitat typically consists of nonflowing pools during dry periods of the year. These waters generally include small streams of marginally perennial aquatic habitat status. Such waters support a limited variety of native fish and invertebrate species that are adapted to survive in relatively harsh aquatic conditions.

(9) Lakes and wetlands (Class “B(LW)”). These are artificial and natural impoundments with hydraulic retention times and other physical and chemical characteristics suitable to maintain a balanced community normally associated with lake-like conditions.

(10) Human health (Class “HH”). Waters in which fish are routinely harvested for human consumption or waters both designated as a drinking water supply and in which fish are routinely harvested for human consumption.

(11) Drinking water supply (Class “C”). Waters which are used as a raw water source of potable water supply.

61.3(2) General water quality criteria. The following criteria are applicable to all surface waters including general use and designated use waters, at all places and at all times for the uses described in 61.3(1)“a.”

a. Such waters shall be free from substances attributable to point source wastewater discharges that will settle to form sludge deposits.

- b. Such waters shall be free from floating debris, oil, grease, scum and other floating materials attributable to wastewater discharges or agricultural practices in amounts sufficient to create a nuisance.
- c. Such waters shall be free from materials attributable to wastewater discharges or agricultural practices producing objectionable color, odor or other aesthetically objectionable conditions.
- d. Such waters shall be free from substances attributable to wastewater discharges or agricultural practices in concentrations or combinations which are acutely toxic to human, animal, or plant life.
- e. Such waters shall be free from substances, attributable to wastewater discharges or agricultural practices, in quantities which would produce undesirable or nuisance aquatic life.
- f. The turbidity of the receiving water shall not be increased by more than 25 Nephelometric turbidity units by any point source discharge.
- g. Cations and anions guideline values to protect livestock watering may be found in the “Iowa Wasteload Allocation (WLA) Procedure,” as revised on November 11, 2020.
- h. The *Escherichia coli* (*E. coli*) content of water which enters a sinkhole or losing stream segment, regardless of the water body’s designated use, shall not exceed a Geometric Mean value of 126 organisms/100 ml or a sample maximum value of 235 organisms/100 ml. No new wastewater discharges will be allowed on watercourses which directly or indirectly enter sinkholes or losing stream segments.

61.3(3) Specific water quality criteria.

a. *Class “A” waters.* Waters which are designated as Class “A1,” “A2,” or “A3” in subrule 61.3(5) are to be protected for primary contact, secondary contact, and children’s recreational uses. The general criteria of subrule 61.3(2) and the following specific criteria apply to all Class “A” waters.

(1) The *Escherichia coli* (*E. coli*) content shall not exceed the levels noted in the Bacteria Criteria Table when the Class “A1,” “A2,” or “A3” uses can reasonably be expected to occur.

Bacteria Criteria Table (organisms/100 ml of water)

Use or Category	Geometric Mean	Sample Maximum
Class A1		
3/15 – 11/15	126	235
11/16 – 3/14	Does not apply	Does not apply
Class A2 (Only)		
3/15 – 11/15	630	2880
11/16 – 3/14	Does not apply	Does not apply
[Class A2 and B(CW)] or OIW or ONRW		
Year-Round	630	2880
Class A3		
3/15 – 11/15	126	235
11/16 – 3/14	Does not apply	Does not apply
Class A1 - Primary Contact Recreational Use Class A2 - Secondary Contact Recreational Use Class A3 - Children’s Recreational Use		

When a water body is designated for more than one of the recreational uses, the most stringent criteria for the appropriate season shall apply.

(2) The pH shall not be less than 6.5 nor greater than 9.0. The maximum change permitted as a result of a waste discharge shall not exceed 0.5 pH units.

b. *Class “B” waters.* All waters which are designated as Class B(CW1), B(CW2), B(WW-1), B(WW-2), B(WW-3) or B(LW) are to be protected for wildlife, fish, aquatic, and semiaquatic life. The following criteria shall apply to all Class “B” waters designated in subrule 61.3(5).

(1) Dissolved oxygen. Dissolved oxygen shall not be less than the values shown in Table 2 of this subrule.

(2) pH. The pH shall not be less than 6.5 nor greater than 9.0. The maximum change permitted as a result of a waste discharge shall not exceed 0.5 pH units.

(3) General chemical constituents. The specific numerical criteria shown in Tables 1, 2, and 3 of this subrule apply to all waters designated in subrule 61.3(5). The sole determinant of compliance with these criteria will be established by the department on a case-by-case basis. Effluent monitoring or instream monitoring, or both, will be the required approach to determine compliance.

1. The acute criteria represent the level of protection necessary to prevent acute toxicity to aquatic life. Instream concentrations above the acute criteria will be allowed only within the boundaries of the zone of initial dilution.

2. The chronic criteria represent the level of protection necessary to prevent chronic toxicity to aquatic life. Excursions above the chronic criteria will be allowed only inside of mixing zones or only for short-term periods outside of mixing zones; however, these excursions cannot exceed the acute criteria shown in Tables 1 and 3. The chronic criteria will be met as short-term average conditions at all times the flow equals or exceeds either the design flows noted in subrule 61.2(5) or any site-specific low flow established under the provisions of subrule 61.2(5).

3. Rescinded IAB 2/15/06, effective 3/22/06.

(4) Rescinded IAB 2/15/06, effective 3/22/06.

(5) Temperature.

1. No heat shall be added to interior streams or the Big Sioux River that would cause an increase of more than 3°C. The rate of temperature change shall not exceed 1°C per hour. In no case shall heat be added in excess of that amount that would raise the stream temperature above 32°C.

2. No heat shall be added to streams designated as cold water fisheries that would cause an increase of more than 2°C. The rate of temperature change shall not exceed 1°C per hour. In no case shall heat be added in excess of that amount that would raise the stream temperature above 20°C.

3. No heat shall be added to lakes and reservoirs that would cause an increase of more than 2°C. The rate of temperature change shall not exceed 1°C per hour. In no case shall heat be added in excess of that amount that would raise the temperature of the lake or reservoirs above 32°C.

4. No heat shall be added to the Missouri River that would cause an increase of more than 3°C. The rate of temperature change shall not exceed 1°C per hour. In no case shall heat be added that would raise the stream temperature above 32°C.

5. No heat shall be added to the Mississippi River that would cause an increase of more than 3°C. The rate of temperature change shall not exceed 1°C per hour. In addition, the water temperature at representative locations in the Mississippi River shall not exceed the maximum limits in the table below during more than 1 percent of the hours in the 12-month period ending with any month. Moreover, at no time shall the water temperature at such locations exceed the maximum limits in the table below by more than 2°C.

Zone II—Iowa-Minnesota state line to the northern Illinois border (Mile Point 1534.6).

Zone III—Northern Illinois border (Mile Point 1534.6) to Iowa-Missouri state line.

Month	Zone II	Zone III
January	4°C	7°C
February	4°C	7°C
March	12°C	14°C
April	18°C	20°C
May	24°C	26°C
June	29°C	29°C

Month	Zone II	Zone III
July	29°C	30°C
August	29°C	30°C
September	28°C	29°C
October	23°C	24°C
November	14°C	18°C
December	9°C	11°C

(6) Early life stage for each use designation. The following seasons will be used in applying the early life stage present chronic criteria noted in Table 3b, “Chronic Criterion for Ammonia in Iowa Streams - Early Life Stages Present.”

1. For all Class B(CW1) waters, the early life stage will be year-round.
2. For all Class B(CW2) waters, the early life stage will begin on April 1 and last through September 30.
3. For all Class B(WW-1) waters, the early life stage will begin in March and last through September, except as follows:
 - For the following, the early life stage will begin in February and last through September:
 - The entire length of the Mississippi and Missouri Rivers,
 - The lower reach of the Des Moines River south of the Ottumwa dam, and
 - The lower reach of the Iowa River below the Cedar River.
 - For the following, the early life stage will begin in April and last through September:
 - All Class B(WW-1) waters in the Southern Iowa River Basin,
 - All of the Class B(WW-1) reach of the Skunk River, the North Skunk River and the South Skunk River south of Indian Creek (Jasper County), and the Class B(WW-1) tributaries to these reaches, and the entire Class B(WW-1) reach of the English River.
4. For all Class B(WW-2) and Class B(WW-3) waters, the early life stage will begin in April and last through September.
5. For all Class B(LW) lake and wetland waters, the early life stage will begin in March and last through September except for the Class B(LW) waters in the southern two tiers of Iowa counties which will have the early life stage of April through September.

c. Class “C” waters. Waters which are designated as Class “C” are to be protected as a raw water source of potable water supply. The following criteria shall apply to all Class “C” waters designated in subrule 61.3(5).

- (1) Radioactive substances.
 1. The combined radium-226 and radium-228 shall not exceed 5 picocuries per liter at the point of withdrawal.
 2. Gross alpha particle activity (including radium-226 but excluding radon and uranium) shall not exceed 15 picocuries per liter at the point of withdrawal.
 3. The average annual concentration at the point of withdrawal of beta particle and photon radioactivity from man-made radionuclides other than tritium and strontium-90 shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem/year.
 4. The average annual concentration of tritium shall not exceed 20,000 picocuries per liter at the point of withdrawal; the average annual concentration of strontium-90 shall not exceed 8 picocuries per liter at the point of withdrawal.
- (2) All substances toxic or detrimental to humans or detrimental to treatment process shall be limited to nontoxic or nondetrimental concentrations in the surface water.
- (3) The pH shall not be less than 6.5 nor greater than 9.0.

d. Class “HH” waters. Waters which are designated as Class HH shall contain no substances in concentrations which will make fish or shellfish inedible due to undesirable tastes or cause a hazard to humans after consumption.

(1) The human health criteria represent the level of protection necessary, in the case of noncarcinogens, to prevent adverse health effects in humans and, in the case of carcinogens, to prevent a level of incremental cancer risk not exceeding 1 in 100,000. Instream concentrations in excess of the human health criteria will be allowed only within the boundaries of the mixing zone.

(2) Reserved.

TABLE 1. Criteria for Chemical Constituents

(all values as micrograms per liter as total recoverable unless noted otherwise)

Human health criteria for carcinogenic parameters noted below were based on the prevention of an incremental cancer risk of 1 in 100,000. For parameters not having a noted human health criterion, the U.S. Environmental Protection Agency has not developed final national human health guideline values. For noncarcinogenic parameters, the recommended EPA criterion was selected. For Class C waters, the EPA criteria for fish and water consumption were selected using the same considerations for carcinogenic and noncarcinogenic parameters as noted above. For Class C waters for which no EPA human health criteria were available, the EPA MCL value was selected.

Parameter		Use Designations							
		B(CW1)	B(CW2)	B(WW-1)	B(WW-2)	B(WW-3)	B(LW)	C	HH
Alachlor	MCL	—	—	—	—	—	—	2	—
Aldrin	Acute	—	—	3	3	3	—	—	—
	Human Health — Fish	—	—	—	—	—	—	—	.00050 ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	.00049 ^(f)
Aluminum	Chronic ^(r)	890 ^(o)	—	890 ^(o)	890 ^(o)	890 ^(o)	890 ^(o)	—	—
	Acute ^(r)	2,500 ^(o)	—	2,500 ^(o)	2,500 ^(o)	2,500 ^(o)	2,500 ^(o)	—	—
Antimony	Human Health — Fish	—	—	—	—	—	—	—	640 ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	5.6 ^(f)
Arsenic (III)	Chronic ^(p)	150	—	150	150	150	150	—	—
	Acute ^(p)	340	—	340	340	340	340	—	—
	Human Health — Fish	—	—	—	—	—	—	—	50 ^{(e)(g)}
	Human Health — F & W	—	—	—	—	—	—	—	.18 ^{(f)(g)}
Asbestos	Human Health — F & W	—	—	—	—	—	—	—	7 ^{(a)(f)}
Atrazine	MCL	—	—	—	—	—	—	3	—
Barium	Human Health + — F & W	—	—	—	—	—	—	—	1000 ^(f)
Benzene	Human Health — F & W	—	—	—	—	—	—	—	22 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	510 ^(e)
Benzo(a)Pyrene	Human Health — F & W	—	—	—	—	—	—	—	.038 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	.18 ^(e)
Beryllium	MCL	—	—	—	—	—	—	4	—
Bromoform	Human Health — F & W	—	—	—	—	—	—	—	43 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	1400 ^(e)
Cadmium	Chronic ^(p)	1.2 ^(h)	—	1.2 ^(h)	1.2 ^(h)	1.2 ^(h)	1.2 ^(h)	—	—

Parameter		Use Designations							C	HH
		B(CW1)	B(CW2)	B(WW-1)	B(WW-2)	B(WW-3)	B(LW)			
para-Dichlorobenzene	Human Health + — F & W	—	—	—	—	—	—	—	—	63 ^(f)
	Human Health + — Fish	—	—	—	—	—	—	—	—	190 ^(e)
3,3-Dichlorobenzidine	Human Health — Fish	—	—	—	—	—	—	—	—	.28 ^(e)
	Human Health — F & W	—	—	—	—	—	—	—	—	.21 ^(f)
Dichlorobromomethane	Human Health — F & W	—	—	—	—	—	—	—	—	5.5 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	—	170 ^(e)
1,2-Dichloroethane	Human Health — F & W	—	—	—	—	—	—	—	—	3.8 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	—	370 ^(e)
1,1-Dichloroethylene	Human Health — F & W	—	—	—	—	—	—	—	—	330 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	—	7.1* ^(e)
cis-1,2-Dichloroethylene	MCL	—	—	—	—	—	—	—	70	—
1,2-trans-Dichloroethylene	Human Health + — F & W	—	—	—	—	—	—	—	—	10* ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	—	140 ^(e)
Dichloromethane	MCL	—	—	—	—	—	—	—	5	—
1,2-Dichloropropane	Human Health — F & W	—	—	—	—	—	—	—	—	5.0 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	—	150 ^(e)
Dieldrin	Chronic	.056	—	.056	.056	.056	.056	—	—	—
	Acute	.24	—	.24	.24	.24	.24	—	—	—
	Human Health — Fish	—	—	—	—	—	—	—	—	.00054 ^(e)
	Human Health — F & W	—	—	—	—	—	—	—	—	.00052 ^(f)
Dinoseb	MCL	—	—	—	—	—	—	—	7	—
2,3,7,8-TCDD (Dioxin)	Human Health — F & W	—	—	—	—	—	—	—	—	5.0-8 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	—	5.1-8 ^(e)
Diquat	MCL	—	—	—	—	—	—	—	20	—
2,4-D	Human Health + — F & W	—	—	—	—	—	—	—	—	100 ^(f)
Endosulfan ^(b)	Chronic	.056	—	.056	.056	.056	.15	—	—	—
	Acute	.11	—	.22	.22	.22	.3	—	—	—
	Human Health + — Fish	—	—	—	—	—	—	—	—	89 ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	—	62 ^(f)
Endothall	MCL	—	—	—	—	—	—	—	100	—
Endrin	Chronic	.05	—	.036	.036	.036	.036	—	—	—
	Acute	.12	—	.086	.086	.086	.086	—	—	—
	Human Health + — Fish	—	—	—	—	—	—	—	—	.06 ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	—	.059 ^(f)

Parameter		Use Designations							HH
		B(CW1)	B(CW2)	B(WW-1)	B(WW-2)	B(WW-3)	B(LW)	C	
Ethylbenzene	Human Health + — F & W	—	—	—	—	—	—	—	530 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	2100 ^(e)
Ethylene dibromide	MCL	—	—	—	—	—	—	.05	—
Di(2-ethylhexyl)adipate	MCL	—	—	—	—	—	—	400	—
bis(2-ethylhexyl)phthalate	Human Health — F & W	—	—	—	—	—	—	—	12 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	22 ^(e)
Fluoride	MCL	—	—	—	—	—	—	4000	—
Glyphosate	MCL	—	—	—	—	—	—	700	—
Heptachlor	Chronic	.0038	—	.0038	.0038	.0038	.0038	—	—
	Acute	.38	—	.52	.52	.52	.38	—	—
	Human Health — Fish	—	—	—	—	—	—	—	.00079 ^(e)
	Human Health — F & W	—	—	—	—	—	—	—	.00079 ^(f)
Heptachlor epoxide	Chronic	.0038	—	.0038	.0038	.0038	.0038	—	—
	Acute	.52	—	.52	.52	.52	.52	—	—
	Human Health — F & W	—	—	—	—	—	—	—	.00039 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	.00039 ^(e)
Hexachlorobenzene	Human Health — F & W	—	—	—	—	—	—	—	.0028 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	.0029 ^(e)
Hexachlorocyclopentadiene	Human Health — F & W	—	—	—	—	—	—	—	40 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	1100 ^(e)
Lead	Chronic ^(p)	5.3 ⁽ⁱ⁾	—	5.3 ⁽ⁱ⁾	5.3 ⁽ⁱ⁾	5.3 ⁽ⁱ⁾	5.3 ⁽ⁱ⁾	—	—
	Acute ^(p)	136 ⁽ⁱ⁾	—	136 ⁽ⁱ⁾	136 ⁽ⁱ⁾	136 ⁽ⁱ⁾	136 ⁽ⁱ⁾	—	—
	MCL	—	—	—	—	—	—	50	—
gamma-BHC (Lindane)	Chronic	N/A	—	N/A	N/A	N/A	N/A	—	—
	Acute	.95	—	.95	.95	.95	.95	—	—
	Human Health + — Fish	—	—	—	—	—	—	—	1.8 ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	.98 ^(f)
Mercury (II)	Chronic ^(p)	0.77	—	0.77	0.77	0.77	0.77	—	—
	Acute ^(p)	1.4	—	1.4	1.4	1.4	1.4	—	—
	Human Health + — Fish	—	—	—	—	—	—	—	.15 ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	.05 ^(f)
Methoxychlor	Human Health + — F & W	—	—	—	—	—	—	—	100 ^(f)
Nickel	Chronic ^(p)	93 ^(k)	—	93 ^(k)	93 ^(k)	93 ^(k)	93 ^(k)	—	—
	Acute ^(p)	840 ^(k)	—	840 ^(k)	840 ^(k)	840 ^(k)	840 ^(k)	—	—
	Human Health + — Fish	—	—	—	—	—	—	—	4600 ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	610 ^(f)

Parameter		Use Designations							HH
		B(CW1)	B(CW2)	B(WW-1)	B(WW-2)	B(WW-3)	B(LW)	C	
Tetrachlorethylene	Human Health — F & W	—	—	—	—	—	—	—	6.9 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	33 ^(e)
Thallium	Human Health + — F & W	—	—	—	—	—	—	—	.24 ^(f)
	Human Health + — Fish	—	—	—	—	—	—	—	.47 ^(e)
Toluene	Chronic	50	—	50	150	150	50	—	—
	Acute	2500	—	2500	7500	7500	2500	—	—
	Human Health + — Fish	—	—	—	—	—	—	—	15* ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	1300 ^(f)
Total Residual Chlorine (TRC)	Chronic	10	—	11	11	11	10	—	—
	Acute	35	—	19	19	19	20	—	—
Toxaphene	Chronic	.037	—	.002	.002	.002	.037	—	—
	Acute	.73	—	.73	.73	.73	.73	—	—
	Human Health — Fish	—	—	—	—	—	—	—	.0028 ^(e)
	Human Health — F & W	—	—	—	—	—	—	—	.0028 ^(f)
1,2,4-Trichlorobenzene	MCL	—	—	—	—	—	—	70	—
1,1,1-Trichlorethane	MCL	—	—	—	—	—	—	200	—
	Human Health + — Fish	—	—	—	—	—	—	—	173* ^(e)
1,1,2-Trichloroethane	Human Health — F & W	—	—	—	—	—	—	—	6 ^(f)
Trichloroethylene (TCE)	Chronic	80	—	80	80	80	80	—	—
	Acute	4000	—	4000	4000	4000	4000	—	—
	Human Health — Fish	—	—	—	—	—	—	—	300 ^(e)
	Human Health — F & W	—	—	—	—	—	—	—	25 ^(f)
Trihalomethanes (total) ^(c)	MCL	—	—	—	—	—	—	80	—
Vinyl Chloride	Human Health — F & W	—	—	—	—	—	—	—	.25 ^(f)
	Human Health — Fish	—	—	—	—	—	—	—	24 ^(e)
Xylenes (Total)	MCL	—	—	—	—	—	—	10*	—
Zinc	Chronic ^(p)	210 ^(f)	—	210 ^(f)	210 ^(f)	210 ^(f)	210 ^(f)	—	—
	Acute ^(p)	210 ^(f)	—	210 ^(f)	210 ^(f)	210 ^(f)	210 ^(f)	—	—
	Human Health + — Fish	—	—	—	—	—	—	—	26* ^(e)
	Human Health + — F & W	—	—	—	—	—	—	—	7.4* ^(f)

- * units expressed as milligrams/liter
- ** to include the sum of known and suspected carcinogenic PAHs (includes benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd)pyrene)
- † expressed as nanograms/liter
- + represents the noncarcinogenic human health parameters
- ++ The concentrations of 4,4-DDT or its metabolites; 4,4-DDE and 4,4-DDD, individually shall not exceed the human health criteria.
- (a) units expressed as million fibers/liter (longer than 10 micrometers)
- (b) includes alpha-endosulfan, beta-endosulfan, and endosulfan sulfate in combination or as individually measured
- (c) The sum of the four trihalomethanes (bromoform [tribromomethane], chlorodibromomethane, chloroform [trichloromethane], and dichlorobromomethane) may not exceed the MCL.
- (d) Class B numerical criteria for pentachlorophenol are a function of pH using the equation: Criterion ($\mu\text{g/l}$) = $e^{[1.005(\text{pH}) - x]}$, where $e = 2.71828$ and x varies according to the following table:

	B(CW1)	B(CW2)	B(WW-1)	B(WW-2)	B(WW-3)	B(LW)
Acute	3.869	—	4.869	4.869	4.869	4.869
Chronic	4.134	—	5.134	5.134	5.134	5.134

- (e) This Class HH criterion would be applicable to any Class B(LW), B(CW1), B(WW-1), B(WW-2), or B(WW-3) water body that is also designated Class HH.
- (f) This Class HH criterion would be applicable to any Class C water body that is also designated Class HH.
- (g) inorganic form only
- (h) The acute and chronic criteria listed in main table are based on a hardness of 200 mg/l (as CaCO₃ (mg/l)). Numerical criteria ($\mu\text{g/l}$) for cadmium are a function of hardness (as CaCO₃ (mg/l)) using the following equations:

	B(CW1)	B(WW-1)&B(LW)	B(WW-2)&B(WW-3)
Acute	$(1.136672 - [(\ln \text{hardness}) \times (0.041838)]) \times e^{(0.9789 \times \ln(\text{hardness}) - 3.866)}$	$(1.136672 - [(\ln \text{hardness}) \times (0.041838)]) \times e^{(0.9789 \times \ln(\text{hardness}) - 3.4210)}$	$(1.136672 - [(\ln \text{hardness}) \times (0.041838)]) \times e^{(0.9789 \times \ln(\text{hardness}) - 2.5750)}$
Chronic	$(1.101672 - [(\ln \text{hardness}) \times (0.041838)]) \times e^{0.7977 \times \ln(\text{hardness}) - 3.909}$	$(1.101672 - [(\ln \text{hardness}) \times (0.041838)]) \times e^{0.7977 \times \ln(\text{hardness}) - 3.909}$	$(1.101672 - [(\ln \text{hardness}) \times (0.041838)]) \times e^{0.7977 \times \ln(\text{hardness}) - 3.909}$

- (i) Class B(WW-1), B(WW-2), and B(WW-3) criteria listed in main table are based on a hardness of 200 mg/l (as CaCO₃ (mg/l)). Numerical criteria ($\mu\text{g/l}$) for copper are a function of hardness (CaCO₃ (mg/l)) using the equation for each use according to the following table:

	B(WW-1)	B(WW-2)	B(WW-3)
Acute	$e^{[0.9422\text{Ln}(\text{Hardness}) - 1.700]}$	$e^{[0.9422\text{Ln}(\text{Hardness}) - 1.700]}$	$e^{[0.9422\text{Ln}(\text{Hardness}) - 1.700]}$
Chronic	$e^{[0.8545\text{Ln}(\text{Hardness}) - 1.702]}$	$e^{[0.8545\text{Ln}(\text{Hardness}) - 1.702]}$	$e^{[0.8545\text{Ln}(\text{Hardness}) - 1.702]}$

- (j) The acute and chronic criteria listed in main table are based on a hardness of 200 mg/l (as CaCO₃ (mg/l)). Numerical criteria ($\mu\text{g/l}$) for lead are a function of hardness (CaCO₃ (mg/l)) using the following equations:

Acute	$(1.46203 - [(\ln \text{hardness})(0.145712)]) \times e^{[1.2731\text{Ln}(\text{Hardness}) - 1.46]}$	$e^{[1.2731\text{Ln}(\text{Hardness}) - 1.46]}$	$e^{[1.2731\text{Ln}(\text{Hardness}) - 1.46]}$
Chronic	$(1.46203 - [(\ln \text{hardness})(0.145712)]) \times e^{[1.2731\text{Ln}(\text{Hardness}) - 4.705]}$	$e^{[1.2731\text{Ln}(\text{Hardness}) - 4.705]}$	$e^{[1.2731\text{Ln}(\text{Hardness}) - 4.705]}$

- (k) The acute and chronic criteria listed in main table are based on a hardness of 200 mg/l (as CaCO₃ (mg/l)). Numerical criteria ($\mu\text{g/l}$) for nickel are a function of hardness (CaCO₃ (mg/l)) using the following equations:

Acute	$0.998 \times e^{[0.846\text{Ln}(\text{Hardness}) + 2.255]}$
Chronic	$0.997 \times e^{[0.846\text{Ln}(\text{Hardness}) + 0.0584]}$

- (l) The acute and chronic criteria listed in main table are based on a hardness of 200 mg/l (as CaCO₃ (mg/l)). Numerical criteria ($\mu\text{g/l}$) for zinc are a function of hardness (CaCO₃ (mg/l)) using the following equations:

Acute	$0.978 \times e^{[0.8473\text{Ln}(\text{Hardness}) + 0.884]}$
Chronic	$0.986 \times e^{[0.8473\text{Ln}(\text{Hardness}) + 0.884]}$

- (m) Acute and chronic criteria listed in main table are based on a hardness of 200 mg/l (as CaCO₃ (mg/l)) and a sulfate concentration of 63 mg/l. Numerical criteria ($\mu\text{g/l}$) for chloride are a function of hardness (CaCO₃ (mg/l)) and sulfate (mg/l) using the equation for each use according to the following table:

	B(CW1), B(CW2), B(WW-1), B(WW-2), B(WW-3), B(LW)
Acute	$287.8(\text{Hardness})^{0.205797}(\text{Sulfate})^{-0.07452}$
Chronic	$177.87(\text{Hardness})^{0.205797}(\text{Sulfate})^{-0.07452}$

- (n) The copper criteria in Table 1 can be adjusted by a Water-Effect Ratio (WER). The WER factor is equal to 1.0 unless an approved WER study has been conducted by a permittee for a specific point source. The WER study shall be conducted in accordance with the "Interim Guidance on Determination and Use of Water-Effect Ratios for Metals (EPA-823-B-94-001), February 22, 1994," or upon approval by the department, the "Streamlined Water-Effect Ratio Procedure for Discharges of Copper (EPA-822-R-01-005), March 2001," which are hereby adopted by reference.

The copper Biotic Ligand Model (BLM) may be used as an alternative to the copper criteria in Table 1. The copper BLM is found in the document "Aquatic Life Ambient Freshwater Quality Criteria - Copper 2007 Revision (EPA-822-R-07-001), February 2007," which is hereby adopted by reference.

- (o) The acute and chronic criteria listed in Table 1 are calculated using Aluminum Criteria Calculator V2.0 (Excel) as described in "Final Aquatic Life Ambient Water Quality Criteria for Aluminum 2018 (EPA-822-R-18-001), December 2018." The criteria were calculated using the lowest tenth percentile of individual model outputs using spatially and temporally representative model inputs from across the state. Site-specific criteria shall also be developed using this approach and the most recent version of the calculator.
- (p) The criteria are expressed as dissolved concentration.
- (q) The silver criteria listed in Table 1 are based on a hardness of 200 mg/l (as CaCO₃ (mg/l)). Numerical criteria (µg/l) for silver are a function of hardness (CaCO₃ (mg/l)) using the following equation:
Acute $0.85 \times e^{[1.72 \ln(\text{Hardness}) - 6.59]}$
- (r) The criteria are expressed as the bioavailable portion of aluminum.

TABLE 2. Criteria for Dissolved Oxygen
(all values expressed in milligrams per liter)

	B(CW1)	B(CW2)	B(WW-1)	B(WW-2)	B(WW-3)	B(LW)
Minimum value for at least 16 hours of every 24-hour period	7.0	7.0	5.0	5.0	5.0	5.0*
Minimum value at any time during every 24-hour period	5.0	5.0	5.0	4.0	4.0	5.0*

**applies only to the upper layer of stratification in lakes*

TABLE 3a. Acute Criterion for Ammonia in Iowa Streams

Acute Criterion, mg/l as N (or Criterion Maximum Concentration, CMC)		
pH	Class B(WW-1), B(WW-2), B(WW-3) & B(LW)	Class B(CW1) & B(CW2)
6.5	48.8	32.6
6.6	46.8	31.3
6.7	44.6	29.8
6.8	42.0	28.0
6.9	39.1	26.1
7.0	36.1	24.1
7.1	32.8	21.9
7.2	29.5	19.7
7.3	26.2	17.5
7.4	23.0	15.3

Acute Criterion, mg/l as N (or Criterion Maximum Concentration, CMC)		
pH	Class B(WW-1), B(WW-2), B(WW-3) & B(LW)	Class B(CW1) & B(CW2)
7.5	19.9	13.3
7.6	17.0	11.4
7.7	14.4	9.64
7.8	12.1	8.11
7.9	10.1	6.77
8.0	8.40	5.62
8.1	6.95	4.64
8.2	5.72	3.83
8.3	4.71	3.15
8.4	3.88	2.59
8.5	3.20	2.14
8.6	2.65	1.77
8.7	2.20	1.47
8.8	1.84	1.23
8.9	1.56	1.04
9.0	1.32	0.885

TABLE 3b. Chronic Criterion for Ammonia in Iowa Streams - Early Life Stages Present

Chronic Criterion - Early Life Stages Present, mg/l as N (or Criterion Continuous Concentration, CCC)										
pH	Temperature, °C									
	0	14	16	18	20	22	24	26	28	30
6.5	6.67	6.67	6.06	5.33	4.68	4.12	3.62	3.18	2.80	2.46
6.6	6.57	6.57	5.97	5.25	4.61	4.05	3.56	3.13	2.75	2.42
6.7	6.44	6.44	5.86	5.15	4.52	3.98	3.50	3.07	2.70	2.37
6.8	6.29	6.29	5.72	5.03	4.42	3.89	3.42	3.00	2.64	2.32
6.9	6.12	6.12	5.56	4.89	4.30	3.78	3.32	2.92	2.57	2.25
7.0	5.91	5.91	5.37	4.72	4.15	3.65	3.21	2.82	2.48	2.18
7.1	5.67	5.67	5.15	4.53	3.98	3.50	3.08	2.70	2.38	2.09
7.2	5.39	5.39	4.90	4.31	3.78	3.33	2.92	2.57	2.26	1.99
7.3	5.08	5.08	4.61	4.06	3.57	3.13	2.76	2.42	2.13	1.87
7.4	4.73	4.73	4.30	3.78	3.32	2.92	2.57	2.26	1.98	1.74
7.5	4.36	4.36	3.97	3.49	3.06	2.69	2.37	2.08	1.83	1.61
7.6	3.98	3.98	3.61	3.18	2.79	2.45	2.16	1.90	1.67	1.47
7.7	3.58	3.58	3.25	2.86	2.51	2.21	1.94	1.71	1.50	1.32
7.8	3.18	3.18	2.89	2.54	2.23	1.96	1.73	1.52	1.33	1.17
7.9	2.8	2.8	2.54	2.24	1.96	1.73	1.52	1.33	1.17	1.03
8.0	2.43	2.43	2.21	1.94	1.71	1.50	1.32	1.16	1.02	0.897
8.1	2.10	2.10	1.91	1.68	1.47	1.29	1.14	1.00	0.879	0.773
8.2	1.79	1.79	1.63	1.43	1.26	1.11	0.973	0.855	0.752	0.661
8.3	1.52	1.52	1.39	1.22	1.07	0.941	0.827	0.727	0.639	0.562
8.4	1.29	1.29	1.17	1.03	0.906	0.796	0.700	0.615	0.541	0.475

Chronic Criterion - Early Life Stages Present, mg/l as N (or Criterion Continuous Concentration, CCC)										
pH	Temperature, °C									
	0	14	16	18	20	22	24	26	28	30
8.5	1.09	1.09	0.990	0.870	0.765	0.672	0.591	0.520	0.457	0.401
8.6	0.920	0.920	0.836	0.735	0.646	0.568	0.499	0.439	0.386	0.339
8.7	0.778	0.778	0.707	0.622	0.547	0.480	0.422	0.371	0.326	0.287
8.8	0.661	0.661	0.601	0.528	0.464	0.408	0.359	0.315	0.277	0.244
8.9	0.565	0.565	0.513	0.451	0.397	0.349	0.306	0.269	0.237	0.208
9.0	0.486	0.486	0.442	0.389	0.342	0.300	0.264	0.232	0.204	0.179

TABLE 3c. Chronic Criterion for Ammonia in Iowa Streams - Early Life Stages Absent

Chronic Criterion - Early Life Stages Absent, mg/l as N (or Criterion Continuous Concentration, CCC)										
pH	Temperature, °C									
	0-7	8	9	10	11	12	13	14	15*	16*
6.5	10.8	10.1	9.51	8.92	8.36	7.84	7.35	6.89	6.46	6.06
6.6	10.7	9.99	9.37	8.79	8.24	7.72	7.24	6.79	6.36	5.97
6.7	10.5	9.81	9.20	8.62	8.08	7.58	7.11	6.66	6.25	5.86
6.8	10.2	9.58	8.98	8.42	7.90	7.40	6.94	6.51	6.10	5.72
6.9	9.93	9.31	8.73	8.19	7.68	7.20	6.75	6.33	5.93	5.56
7.0	9.60	9.00	8.43	7.91	7.41	6.95	6.52	6.11	5.73	5.37
7.1	9.20	8.63	8.09	7.58	7.11	6.67	6.25	5.86	5.49	5.15
7.2	8.75	8.20	7.69	7.21	6.76	6.34	5.94	5.57	5.22	4.90
7.3	8.24	7.73	7.25	6.79	6.37	5.97	5.60	5.25	4.92	4.61
7.4	7.69	7.21	6.76	6.33	5.94	5.57	5.22	4.89	4.59	4.30
7.5	7.09	6.64	6.23	5.84	5.48	5.13	4.81	4.51	4.23	3.97
7.6	6.46	6.05	5.67	5.32	4.99	4.68	4.38	4.11	3.85	3.61
7.7	5.81	5.45	5.11	4.79	4.49	4.21	3.95	3.70	3.47	3.25
7.8	5.17	4.84	4.54	4.26	3.99	3.74	3.51	3.29	3.09	2.89
7.9	4.54	4.26	3.99	3.74	3.51	3.29	3.09	2.89	2.71	2.54
8.0	3.95	3.70	3.47	3.26	3.05	2.86	2.68	2.52	2.36	2.21
8.1	3.41	3.19	2.99	2.81	2.63	2.47	2.31	2.17	2.03	1.91
8.2	2.91	2.73	2.56	2.40	2.25	2.11	1.98	1.85	1.74	1.63
8.3	2.47	2.32	2.18	2.04	1.91	1.79	1.68	1.58	1.48	1.39
8.4	2.09	1.96	1.84	1.73	1.62	1.52	1.42	1.33	1.25	1.17
8.5	1.77	1.66	1.55	1.46	1.37	1.28	1.20	1.13	1.06	0.99
8.6	1.49	1.40	1.31	1.23	1.15	1.08	1.01	0.951	0.892	0.836
8.7	1.26	1.18	1.11	1.04	0.976	0.915	0.858	0.805	0.754	0.707
8.8	1.07	1.01	0.944	0.885	0.829	0.778	0.729	0.684	0.641	0.601
8.9	0.917	0.860	0.806	0.756	0.709	0.664	0.623	0.584	0.548	0.513
9.0	0.790	0.740	0.694	0.651	0.610	0.572	0.536	0.503	0.471	0.442

*At 15°C and above, the criterion for fish early life stage (ELS) absent is the same as the criterion for fish ELS present.

TABLE 4. Aquatic Life Criteria for Sulfate for Class B Waters*(all values expressed in milligrams per liter)*

Hardness mg/l as CaCO ₃	Chloride		
	Cl ⁻ < 5 mg/l	5 ≤ Cl ⁻ < 25	25 ≤ Cl ⁻ ≤ 500
H < 100 mg/l	500	500	500
100 ≤ H ≤ 500	500	$[-57.478 + 5.79$ (hardness) + 54.163 (chloride)] × 0.65	$[1276.7 + 5.508$ (hardness) - 1.457 (chloride)] × 0.65
H > 500	500	2,000	2,000

61.3(4) *Class “C” waters.* Rescinded IAB 4/18/90, effective 5/23/90.

61.3(5) *Surface water classification.* The department hereby incorporates by reference “Surface Water Classification,” effective July 24, 2019. This document may be obtained on the department’s website at www.iowadnr.gov.

61.3(6) *Cold water use designation assessment protocol.* The department hereby incorporates by reference “Cold Water Use Designation Assessment Protocol,” effective December 15, 2004. This document may be obtained on the department’s website at www.iowadnr.gov.

61.3(7) *Warm water stream use assessment and attainability analysis protocol.* The department hereby incorporates by reference “Warm Water Stream Use Assessment and Attainability Analysis Protocol,” effective March 22, 2006. This document may be obtained on the department’s website at www.iowadnr.gov.

61.3(8) *Recreational use assessment and attainability analysis protocol.* The department hereby incorporates by reference “Recreational Use Assessment and Attainability Analysis Protocol,” effective March 19, 2008. This document may be obtained on the department’s website.

61.3(9) *Iowa wasteload allocation (WLA) procedure.* The department hereby incorporates by reference “Iowa Wasteload Allocation (WLA) Procedure,” as revised on November 11, 2020. This document may be obtained on the department’s website at www.iowadnr.gov.

61.3(10) *Implementation procedure for biotic ligand model-based copper criteria.* The department hereby incorporates by reference “Implementation Procedure for Biotic Ligand Model-Based Copper Criteria,” February 22, 2017. This document may be obtained on the department’s website.

This rule is intended to implement Iowa Code chapter 455B, division I, and division III, part 1. [ARC 8039B, IAB 8/12/09, effective 9/16/09; ARC 8214B, IAB 10/7/09, effective 11/11/09; ARC 8226B, IAB 10/7/09, effective 11/11/09; ARC 8466B, IAB 1/13/10, effective 2/17/10; ARC 9223B, IAB 11/17/10, effective 12/22/10; ARC 1988C, IAB 5/13/15, effective 6/17/15; ARC 2911C, IAB 1/18/17, effective 2/22/17; ARC 3583C, IAB 1/17/18, effective 2/21/18; ARC 4514C, IAB 6/19/19, effective 7/24/19; ARC 5226C, IAB 10/7/20, effective 11/11/20]

567—61.4 to 61.9 Reserved.

VOLUNTEER MONITORING DATA REQUIREMENTS

567—61.10(455B) Purpose. The department uses water quality monitoring data for a number of purposes, including determining compliance with effluent limits for operation permits issued under 567—Chapter 64. The department also uses water quality monitoring data to determine the relative health of a water body by comparing monitoring data to the appropriate water quality standards established in 567—Chapter 61, a process known as water body assessments. Water body assessments are performed to prepare the biennial water quality report required under Section 305(b) of the Act and the list of impaired waters under Section 303(d) of the Act.

Iowa Code sections 455B.193 to 455B.195 require that credible data, as defined in Iowa Code section 455B.171, be used for the purpose of preparing Section 303(d) lists and other water quality program functions. Data provided by a volunteer are not considered credible data unless provided by a qualified volunteer. The purpose of this chapter is to establish minimum requirements for data produced by volunteers to meet the credible data and qualified volunteer requirements.

567—61.11(455B) Monitoring plan required. Volunteer water quality monitoring data submitted to the department must have been produced in accordance with a department-approved volunteer water quality monitoring plan before the data may be used for any of the purposes listed in Iowa Code section 455B.194. Approval of a plan will establish qualified volunteer status for the personnel identified in the plan for those monitoring activities covered under the plan.

61.11(1) Submittal of the plan. Prior to initiation of volunteer water quality monitoring activities intended to produce credible data, a water quality monitoring plan must be submitted to the department for review and approval. The plan must be submitted to the Volunteer Monitoring Coordinator, Department of Natural Resources, Wallace State Office Building, Des Moines, Iowa 50319, a minimum of 90 days before planned initiation of volunteer monitoring activities. A letter transmitting the plan must specifically request formal review and approval of the plan and identify a contact person. Volunteer monitors are encouraged to communicate with the department and to attend volunteer monitoring training sessions prior to formal submittal of a plan.

61.11(2) Content of the plan. A volunteer monitoring plan must contain, at a minimum, the following to be considered an acceptable volunteer monitoring plan:

- a. A statement of the intent of the monitoring effort.
- b. The name(s) of the person or persons that will be involved in data collection or analysis, the specific responsibilities of each person or group of people, and the general qualifications of the volunteers to carry out those responsibilities. For groups, such as educational institutions, it will be acceptable to identify the persons involved by general description (e.g., tenth grade biology class) with the exception of persons in responsible charge.
- c. The name(s) of the person or persons that will oversee the monitoring plan, ensure that quality assurance and control objectives are being met, and certify the data. The person or persons in responsible charge must have training commensurate with the level of expertise to ensure that credible data is being generated.
- d. The duration of the volunteer monitoring effort. In general, the department will not approve plans of greater than three years' duration unless a longer duration is justified.
- e. Location and frequency of sample collection.
- f. Methods of data collection and analysis.
- g. Record keeping and data reporting procedures.

61.11(3) Department review of the plan. The department will review monitoring plans and normally approve or disapprove the plan within 90 days of receipt. The department will work with the contact person identified in the plan to make any necessary changes prior to taking formal action. The department will use guidelines contained in the publications EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5, 2001) and Volunteer Monitor's Guide to Quality Assurance Project Plans (1966, EPA 841-B-96-003) or equivalent updates to determine if the plans provide adequate quality assurance and quality control measures. Approval or disapproval of the plan will be in the form of a letter and approval may include conditions or limitations.

61.11(4) Changes in monitoring plans. The department must approve any changes to an approved monitoring plan. Data collected under a modified plan will not be considered credible data until such time as the department has approved the modifications. Modifications to an approved plan should be submitted at the earliest possible time to avoid interruptions in data collection and to ensure continuity of data.

61.11(5) Appeal of disapproval. If a monitoring plan submitted for approval is disapproved, the decision may be appealed by filing an appeal with the director within 30 days of disapproval. The form of the notice of appeal and appeal procedures are governed by 567—Chapter 7.

567—61.12(455B) Use of volunteer monitoring data. Data produced under an approved water quality monitoring plan will be considered credible data for the purposes listed in Iowa Code section 455B.194 if the following conditions are met.

61.12(1) Data submittal. A qualified volunteer monitor or qualified volunteer monitoring group must specifically request that data produced under an approved volunteer monitoring plan be considered

credible data. A letter identifying the specific data must be submitted along with a certification from the volunteer or the person in responsible charge for volunteer groups that the data, to the best of the volunteer's or responsible person's knowledge, was produced in accordance with the approved volunteer monitoring plan. The department shall provide a standard format on the IOWATER website for submittal of qualified volunteer data and related information. The department encourages volunteers to enter monitoring data on the IOWATER volunteer monitoring database maintained by the department, but doing so does not constitute submittal to or acceptance of the data by the department for uses requiring credible data. Volunteer data shall be labeled as such in any departmental reports, websites, or databases.

61.12(2) *Department review of submitted data.* The department must review and approve the submitted data. The person submitting the data will be informed of the department's decision either to accept or reject the data. The department will attempt to resolve any apparent inconsistencies or questionable values in the submitted data prior to making a final decision.

567—61.13(455B) Department audits of volunteer monitoring activities. The department shall conduct field audits of a statistically valid and representative sample of volunteer data collection and analysis procedures to ensure compliance with an approved plan and may conduct confirmatory monitoring tests. Volunteers shall be informed of any audit results and be provided with an opportunity to address any concerns to the extent possible. The department reserves the right to rescind approval of an approved plan if it finds substantial problems that cannot be addressed in a timely manner to ensure the quality of the data being produced.

These rules are intended to implement Iowa Code chapter 455B, division III, part 1.

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¹ Two ARCs

² February 16, 2011, effective date of 61.2(2)“g”(8) delayed 70 days by the Administrative Rules Review Committee at its meeting held February 11, 2011.

CHAPTER 106
DEER HUNTING BY RESIDENTS
[Prior to 12/31/86, Conservation Commission[290] Ch 106]

571—106.1(481A) Licenses. When hunting deer, all hunters must have in their possession a valid deer hunting license and a valid resident hunting license and must have paid the habitat fee (if normally required to have a hunting license and to pay the habitat fee to hunt). No person while hunting deer shall carry or have in possession any license or transportation tag issued to another person. No one who is issued a deer hunting license and transportation tag shall allow another person to use or possess that license or transportation tag while that person is deer hunting or tagging a deer.

106.1(1) Type of license.

a. General deer licenses. General deer licenses shall be valid for taking deer in one season selected at the time the license is purchased. General deer licenses shall be valid for taking deer of either sex except in Buena Vista, Calhoun, Cherokee, Clay, Dickinson, Emmet, Humboldt, Ida, Kossuth, Lyon, O'Brien, Osceola, Palo Alto, Plymouth, Pocahontas, Sac, and Sioux Counties during the first regular gun season when the general deer license will be valid for taking deer with at least one forked antler. Paid general deer licenses shall be valid statewide except where prohibited in deer population management zones established under 571—Chapter 105. Free general deer licenses shall be valid for taking deer of either sex only on the farm unit of an eligible landowner or tenant in the season or seasons selected at the time the license is obtained.

b. Antlerless-deer-only licenses. Antlerless-deer-only licenses shall be valid for taking deer that have no forked antler. Paid antlerless-deer-only licenses shall be valid in one county or in one deer population management zone and in one season as selected at the time the license is purchased. Free and reduced-fee antlerless-deer-only licenses shall be valid on the farm unit of an eligible landowner or tenant in the season or seasons selected at the time the license is obtained.

106.1(2) Bow season licenses. General deer and antlerless-deer-only licenses, paid or free, shall be valid in both segments of the bow season.

106.1(3) Regular gun season licenses. Paid general deer and antlerless-deer-only licenses shall be valid in either the first or the second regular gun season, as designated on the license. Free general deer licenses and antlerless-deer-only licenses shall be valid in both the first and second regular gun seasons.

106.1(4) Muzzleloader season licenses. General deer and antlerless-deer-only licenses, paid or free, shall be valid in either the early or the late muzzleloader season, as designated on the license.

106.1(5) November antlerless-deer-only licenses. Rescinded IAB 7/11/12, effective 8/15/12.

106.1(6) January antlerless-deer-only licenses. Licenses for the January antlerless-deer-only season may be issued for the following counties: Allamakee, Appanoose, Decatur, Wayne, and Winneshiek. January antlerless-deer-only licenses shall be issued for a county only when a minimum of 100 antlerless-deer-only licenses, as described in subrule 106.6(6), remain unsold in that county as of the third Monday in December. If 100 or more antlerless-deer-only licenses remain unsold for a given county as of the third Monday in December, those remaining antlerless-deer-only licenses shall be made available for the January antlerless-deer-only season in that county until the relevant antlerless-deer-only quota as described in subrule 106.6(6) is met.

106.1(7) Free and reduced-fee deer licenses for landowners and tenants. A maximum of one free general deer license, two free antlerless-deer-only licenses, and two reduced-fee antlerless-deer-only licenses may be issued to a qualifying landowner or eligible family member and a qualifying tenant or eligible family member. Eligibility for licenses is described in 571—106.12(481A). The free general deer license shall be available for one of the following seasons: the youth/disabled hunter season (if eligible), bow season, early muzzleloader season, late muzzleloader season, or first and second regular gun seasons. One free antlerless-deer-only license shall be available for one of the following seasons: youth/disabled hunter season (if eligible), bow season, early muzzleloader season, late muzzleloader season, or first and second regular gun seasons. The second free antlerless-deer-only license shall be valid only for the January antlerless-deer-only season and will be available only if a portion of the farm unit lies within a county where paid antlerless-deer-only licenses are available during that season. Each

reduced-fee antlerless-deer-only license shall be valid for one of the following seasons: youth/disabled hunter season (if eligible), bow season, early muzzleloader season, late muzzleloader season, first and second regular gun seasons, or January antlerless-deer-only season. January antlerless-deer-only licenses will be available only if a portion of the farm unit is located in a county where paid antlerless-deer-only licenses are available in that season.

106.1(8) Antlerless-deer-only crossbow licenses for senior citizens. Persons 65 years old or older may obtain one paid antlerless-deer-only license valid statewide for taking antlerless deer with a crossbow. The license will be valid only during the bow season.

106.1(9) Deer hunting licenses for nonambulatory persons. The commission shall issue licenses in conformance with Iowa Code section 483A.8C. A person applying for this license must provide a completed form obtained from the department of natural resources. The application shall be certified by the applicant's attending physician with an original signature and declare that the applicant is nonambulatory using the criteria listed in Iowa Code section 483A.8C(4). A medical statement from the applicant's attending physician that specifies criteria met shall be on 8½" × 11" letterhead stationery. The attending physician shall be a currently practicing doctor of medicine, doctor of osteopathy, physician assistant or nurse practitioner.

[ARC 7921B, IAB 7/1/09, effective 8/5/09; ARC 8255B, IAB 11/4/09, effective 12/9/09; ARC 8888B, IAB 6/30/10, effective 8/18/10; ARC 0189C, IAB 7/11/12, effective 8/15/12; ARC 1562C, IAB 8/6/14, effective 9/10/14; ARC 3831C, IAB 6/6/18, effective 7/11/18; ARC 5066C, IAB 7/1/20, effective 8/5/20; ARC 5682C, IAB 6/16/21, effective 7/21/21]

571—106.2(481A) Season dates. Deer may be taken only during the following seasons:

106.2(1) Bow season. Deer may be taken in accordance with the type of license issued from October 1 through the Friday before the first Saturday in December and from the Monday following the third Saturday in December through January 10 of the following year.

106.2(2) Regular gun seasons. Deer may be taken in accordance with the type, season and zone designated on the license from the first Saturday in December and continuing for five consecutive days (first regular gun season) or from the second Saturday in December and continuing for nine consecutive days (second regular gun season).

106.2(3) Muzzleloader seasons. Deer may be taken in accordance with the type, season and zone designated on the license from the Saturday closest to October 14 and continuing for nine consecutive days (early muzzleloader season) or from the Monday following the third Saturday in December through January 10 of the following year (late muzzleloader season).

106.2(4) November antlerless-deer-only season. Rescinded IAB 7/11/12, effective 8/15/12.

106.2(5) January antlerless-deer-only season. Deer may be taken in accordance with the type, season, and zone designated on the license from January 11 through the second Sunday following that date.

[ARC 0189C, IAB 7/11/12, effective 8/15/12; ARC 1562C, IAB 8/6/14, effective 9/10/14; ARC 3831C, IAB 6/6/18, effective 7/11/18; ARC 5066C, IAB 7/1/20, effective 8/5/20; ARC 5682C, IAB 6/16/21, effective 7/21/21]

571—106.3(481A) Shooting hours. Legal shooting hours shall be from one-half hour before sunrise to one-half hour after sunset in all seasons.

571—106.4(481A) Limits.

106.4(1) Bow season. The daily bag limit is one deer per license. The possession limit is one deer per license. A person may shoot and tag a deer only by utilizing the license and tag issued in the person's name.

106.4(2) Muzzleloader seasons. The daily bag limit is one deer per license. The possession limit is one deer per license. A person may shoot and tag a deer only by utilizing the license and tag issued in the person's name.

106.4(3) Regular gun seasons. The bag limit is one deer for each hunter in the party who has a valid deer transportation tag. The possession limit is one deer per license. "Possession" shall mean that the deer is in the possession of the person whose license number matches the number of the transportation tag on the carcass of the deer.

106.4(4) November antlerless-deer-only season. Rescinded IAB 7/11/12, effective 8/15/12.

106.4(5) *January antlerless-deer-only season.* The bag limit is one deer per license. The possession limit is one deer per license.

106.4(6) *Maximum annual possession limit.* The maximum annual possession limit for a resident deer hunter is one deer for each legal license and transportation tag obtained.

[ARC 0189C, IAB 7/11/12, effective 8/15/12; ARC 1562C, IAB 8/6/14, effective 9/10/14; ARC 3831C, IAB 6/6/18, effective 7/11/18; ARC 5066C, IAB 7/1/20, effective 8/5/20; ARC 5682C, IAB 6/16/21, effective 7/21/21]

571—106.5(481A) *Areas closed to hunting.* There shall be no open seasons for hunting deer on the county roads immediately adjacent to or through Union Slough National Wildlife Refuge, Kossuth County, where posted accordingly. There shall be no open seasons for hunting deer on all portions of rights-of-way on Interstate Highways 29, 35, 80 and 380.

571—106.6(481A) *Paid deer license quotas and restrictions.* Paid deer licenses, including antlerless-deer-only licenses, will be restricted in the type and number that may be purchased.

106.6(1) *Paid general deer licenses.* Residents may purchase no more than two paid general deer licenses, one for the bow season and one for one of the following seasons: early muzzleloader season, late muzzleloader season, first regular gun season, or second regular gun season. No more than 7,500 paid statewide general deer licenses will be sold for the early muzzleloader season. Fifty additional paid early muzzleloader season licenses will be sold through and will be valid only for the Iowa Army Ammunition Plant. There will be no quota on the number of paid general deer licenses issued in the bow season, late muzzleloader season, first regular gun season, or second regular gun season.

106.6(2) *Paid antlerless-deer-only licenses.* Paid antlerless-deer-only licenses have quotas for each county and will be sold for each county until quotas are reached.

a. Paid antlerless-deer-only licenses may be purchased for any season in counties where licenses are available, except as outlined in 106.6(2)“*b.*” A license must be used in the season, county or deer population management area selected at the time the license is purchased.

b. No one may obtain paid licenses for both the first regular gun season and second regular gun season regardless of whether the licenses are valid for any deer or antlerless deer only. Paid antlerless-deer-only licenses for the early muzzleloader season may only be purchased by hunters who have already purchased one of the 7,500 paid statewide general deer licenses. Hunters who purchase one of the 7,500 paid statewide general deer licenses for the early muzzleloader season may not obtain paid antlerless licenses for the first or second regular gun season.

c. Prior to September 15, a hunter may purchase one antlerless-deer-only license for any season for which the hunter is eligible. Beginning September 15, a hunter may purchase an unlimited number of antlerless-deer-only licenses for any season for which the hunter is eligible, as set forth in 106.6(2)“*b.*” until the county or population management area quotas are filled. Licenses purchased for deer population management areas will not count in the county quota.

106.6(3) *November antlerless-deer-only season.* Rescinded IAB 7/11/12, effective 8/15/12.

106.6(4) *January antlerless-deer-only season.* Only antlerless-deer-only licenses, paid or free, are available in counties pursuant to the conditions described in subrule 106.1(6). A license must be used during the January antlerless-deer-only season as described in subrule 106.2(5) and in the county or deer population management area selected at the time the license is purchased. Free antlerless-deer-only licenses shall be available only in the portion of the farm unit located in a county where paid antlerless-deer-only licenses are available during the January antlerless-deer-only season.

106.6(5) *Free landowner/tenant licenses.* A person obtaining a free landowner/tenant license may purchase any combination of paid bow and paid gun licenses available to persons who are not eligible for landowner/tenant licenses as described in 571—106.12(481A).

106.6(6) *Antlerless-deer-only licenses.* Paid antlerless-deer-only licenses will be available by county as follows:

County	Quota	County	Quota	County	Quota
Adair	1200	Floyd	150	Monona	750
Adams	1000	Franklin	0	Monroe	2250
Allamakee	3800	Fremont	100	Montgomery	500
Appanoose	2700	Greene	0	Muscatine	900
Audubon	0	Grundy	0	O'Brien	0
Benton	325	Guthrie	2150	Osceola	0
Black Hawk	0	Hamilton	0	Page	500
Boone	300	Hancock	0	Palo Alto	0
Bremer	300	Hardin	0	Plymouth	0
Buchanan	400	Harrison	750	Pocahontas	0
Buena Vista	0	Henry	1050	Polk	1350
Butler	200	Howard	450	Pottawattamie	750
Calhoun	0	Humboldt	0	Poweshiek	200
Carroll	0	Ida	0	Ringgold	1400
Cass	400	Iowa	450	Sac	0
Cedar	775	Jackson	1100	Scott	200
Cerro Gordo	0	Jasper	575	Shelby	0
Cherokee	0	Jefferson	1500	Sioux	0
Chickasaw	375	Johnson	950	Story	150
Clarke	2400	Jones	1100	Tama	300
Clay	0	Keokuk	500	Taylor	1500
Clayton	4000	Kossuth	0	Union	1400
Clinton	400	Lee	1700	Van Buren	2100
Crawford	0	Linn	850	Wapello	1600
Dallas	2100	Louisa	775	Warren	3000
Davis	1700	Lucas	2500	Washington	1000
Decatur	2200	Lyon	0	Wayne	2700
Delaware	950	Madison	3300	Webster	0
Des Moines	900	Mahaska	475	Winnebago	0
Dickinson	0	Marion	2050	Winneshiek	2700
Dubuque	1200	Marshall	150	Woodbury	200
Emmet	0	Mills	300	Worth	0
Fayette	2500	Mitchell	100	Wright	0

[ARC 7921B, IAB 7/1/09, effective 8/5/09; ARC 8888B, IAB 6/30/10, effective 8/18/10; ARC 0189C, IAB 7/11/12, effective 8/15/12; ARC 0830C, IAB 7/10/13, effective 8/14/13; ARC 1562C, IAB 8/6/14, effective 9/10/14; ARC 2086C, IAB 8/5/15, effective 9/9/15; ARC 2697C, IAB 8/31/16, effective 8/12/16; ARC 3098C, IAB 6/7/17, effective 7/12/17; ARC 3831C, IAB 6/6/18, effective 7/11/18; ARC 4531C, IAB 7/3/19, effective 8/7/19; ARC 5066C, IAB 7/1/20, effective 8/5/20; ARC 5682C, IAB 6/16/21, effective 7/21/21]

571—106.7(481A) Method of take. Permitted weapons and devices vary according to the type of season.

106.7(1) Bow season. Only longbow, compound, or recurve bows shooting broadhead arrows are permitted during the bow season. Arrows must be at least 18 inches long.

a. Crossbows, as described in 106.7(1) “*b*,” may be used during the bow season in the following two situations:

- (1) By persons with certain afflictions of the upper body as provided in 571—15.22(481A); and

(2) By persons over the age of 65 with an antlerless-deer-only license as provided in Iowa Code section 483A.8B.

b. Crossbow means a weapon consisting of a bow mounted transversely on a stock or frame and designed to fire a bolt, arrow, or quarrel by the release of the bow string, which is controlled by a mechanical trigger and a working safety. Crossbows equipped with pistol grips and designed to be fired with one hand are illegal for taking or attempting to take deer. All projectiles used in conjunction with a crossbow for deer hunting must be equipped with a broadhead.

c. No explosive or chemical device may be attached to any arrow, broadhead or bolt.

106.7(2) Regular gun seasons. Only the following shall be used in the regular gun season: 10-, 12-, 16-, and 20-gauge shotguns shooting single slugs; any handgun or rifle as described in Iowa Code section 481A.48; and any muzzleloaders as described in subrule 106.7(3).

106.7(3) Muzzleloader seasons. Only muzzleloading rifles, muzzleloading muskets, muzzleloading pistols, and muzzleloading revolvers will be permitted for taking deer during the early muzzleloader season. During the late muzzleloader season, deer may be taken with a muzzleloading rifle, muzzleloading musket, muzzleloading pistol, muzzleloading revolver, any handgun as defined in 106.7(2), crossbow as described in 106.7(1) “*b*,” or bow as described in 106.7(1). All muzzleloaders as described in this subrule shall only shoot a single projectile between .44 and .775 of an inch.

106.7(4) November antlerless-deer-only season. Rescinded IAB 7/11/12, effective 8/15/12.

106.7(5) January antlerless-deer-only season. Bows, crossbows, shotguns, muzzleloaders, rifles, and handguns as described in this rule may be used during the January antlerless-deer-only season.

106.7(6) Prohibited weapons and devices. The use of dogs, domestic animals, bait, firearms except as provided for in this chapter, crossbows except as provided in 106.7(1), automobiles, aircraft, or any mechanical conveyance or device, including electronic calls, is prohibited, except that paraplegics and single or double amputees of the legs may hunt from any stationary motor-driven land conveyance. “Bait” means grain, fruit, vegetables, nuts, hay, salt, mineral blocks, or any other natural food materials; commercial products containing natural food materials; or by-products of such materials transported to or placed in an area for the intent of attracting wildlife. Bait does not include food placed during normal agricultural activities. “Paraplegic” means an individual with paralysis of the lower half of the body with involvement of both legs, usually due to disease of or injury to the spinal cord. It shall be unlawful for a person, while hunting deer, to carry or have in possession a rifle except as provided in 106.7(2) or 106.7(3). A person in possession of a valid permit to carry weapons may carry a handgun while hunting. However, only handguns as described in 106.7(2) may be used to hunt deer and only when a handgun is a lawful method of take.

106.7(7) Discharge of firearms from roadway. No person shall discharge a rifle, including a muzzleloading rifle or musket, or a handgun from a highway while deer hunting. In addition, no person shall discharge a shotgun shooting slugs from a highway north of U.S. Highway 30. A “highway” means the way between property lines open to the public for vehicle traffic, including the road ditch, as defined in Iowa Code section 321.1(78).

106.7(8) Hunting from blinds. No person shall use a blind for hunting deer during the regular gun deer seasons as defined in 106.2(2), unless such blind exhibits a solid blaze orange marking which is a minimum of 144 square inches in size and is visible in all directions. Such blaze orange shall be affixed directly on or directly on top of the blind. For the purposes of this subrule, the term “blind” is defined as an enclosure used for concealment while hunting, constructed either wholly or partially from man-made materials, and used by a person who is hunting for the purpose of hiding from sight. A blind is not a naturally occurring landscape feature or an arrangement of natural or agricultural plant material that a hunter uses for concealment. In addition to the requirements in this subrule, hunters using blinds must also satisfy the requirements of wearing blaze orange as prescribed in Iowa Code section 481A.122.

[ARC 9717B, IAB 9/7/11, effective 10/12/11; ARC 0189C, IAB 7/11/12, effective 8/15/12; ARC 1562C, IAB 8/6/14, effective 9/10/14; ARC 2086C, IAB 8/5/15, effective 9/9/15; ARC 3098C, IAB 6/7/17, effective 7/12/17; ARC 3831C, IAB 6/6/18, effective 7/11/18; ARC 5601C, IAB 5/5/21, effective 6/9/21; ARC 5682C, IAB 6/16/21, effective 7/21/21]

571—106.8(481A) Procedures to obtain licenses. All resident deer hunting licenses must be obtained using the electronic licensing system for Iowa (ELSI). Licenses may be purchased from ELSI license agents, or online at www.iowadnr.com, or by calling the ELSI telephone ordering system.

106.8(1) Licenses with quotas. All paid deer hunting licenses for which a quota is established may be obtained from the ELSI system on a first-come, first-served basis beginning August 15 until the quota fills, or through the last day of the hunting period for which the license is valid.

106.8(2) Licenses without quotas. All deer hunting licenses that have no quota may be obtained from the ELSI system beginning August 15 through the last day of the hunting period for which a license is valid.

106.8(3) Providing false information.

a. Any person who provides false information about the person's identity or eligibility for any paid or free landowner/tenant deer license and tag and who attests that the information is correct by accepting and signing the license or tag shall have the person's hunting license revoked as a part of the sentencing for such criminal conviction, and the person shall not be issued a hunting license for one year pursuant to the authority of Iowa Code section 483A.24(2) "f" and rule 571—15.6(483A).

b. In addition to any legal penalties that may be imposed, the obtaining of a license in violation of this rule shall invalidate that deer license and transportation tag and any other deer hunting license and transportation tag obtained during the same year.

571—106.9(481A) Transportation tag. A transportation tag bearing the license number of the licensee, year of issuance, and date of kill properly shown shall be visibly attached to one leg of each antlerless deer or on the main beam between two points, if present, on one of the antlers of an antlered deer in such a manner that the tag cannot be removed without mutilating or destroying the tag. This tag shall be attached to the carcass of the deer within 15 minutes of the time the deer carcass is located after being taken or before the carcass is moved to be transported by any means from the place where the deer was taken, whichever occurs first. No person shall tag a deer with a transportation tag issued to another person or with a tag that was purchased after the deer was taken. During the youth/disabled hunter season, bow season, early muzzleloader season and late muzzleloader season, the hunter who killed the deer must tag the deer by using the transportation tag issued in that person's name. During the first and second regular gun seasons and the January antlerless-deer-only season, anyone present in the hunting party may tag a deer with a tag issued in that person's name. This tag shall be proof of possession and shall remain affixed to the carcass until such time as the animal is processed for consumption. The head, and antlers if any, shall remain attached to the deer while being transported by any means whatsoever from the place where taken to the processor or commercial preservation facility or until the deer has been processed for consumption.

[ARC 9717B, IAB 9/7/11, effective 10/12/11; ARC 0189C, IAB 7/11/12, effective 8/15/12]

571—106.10(481A) Youth deer and severely disabled hunts.

106.10(1) Licenses.

a. Youth deer hunt. A youth deer license may be issued to any Iowa resident who is not over 15 years old on the day the youth obtains the license. The youth license may be paid or free to persons eligible for free licenses. If the youth obtains a free landowner/tenant license, it will count as the one free general deer license for which the youth's family is eligible.

Each participating youth must be accompanied by an adult who possesses a regular hunting license and has paid the habitat fee (if the adult is normally required to have a hunting license and to pay the habitat fee to hunt). Only one adult may participate for each youth hunter. The accompanying adult must not possess a firearm or bow and must be in the direct company of the youth at all times.

A person may obtain only one youth general deer license but may also obtain any other paid or free general deer and antlerless-deer-only licenses that are available to other hunters. Antlerless-deer-only licenses must be obtained in the same manner with which other hunters obtain them, as described in 106.6(2).

b. Severely disabled hunt. Any severely disabled Iowa resident meeting the requirements of Iowa Code section 321L.1(8) may be issued one general deer license to hunt deer during the youth season. A person applying for this license must either possess a disability parking permit or provide a completed form from the department of natural resources. The form must be signed by a physician verifying that the person's disability meets the criteria defined in Iowa Code section 321L.1(8). The attending physician shall be currently practicing medicine and shall be a medical doctor, a doctor of osteopathy, a physician assistant, or a nurse practitioner. Forms are available online at www.iowadnr.gov, by visiting the DNR office at the Wallace State Office Building, Des Moines, Iowa, or any district office, or by calling (515)725-8200. A person between 16 and 65 years of age must also possess a regular hunting license and have paid the habitat fee to obtain a license (if normally required to have a hunting license and to pay the habitat fee to hunt). A severely disabled person obtaining this license may obtain any other paid and free general deer and antlerless-deer-only licenses that are available to other hunters. Antlerless-deer-only licenses must be obtained in the same manner by which other hunters obtain them, as described in 106.6(2).

106.10(2) Season dates. Deer of either sex may be taken statewide for 16 consecutive days beginning on the third Saturday in September. A person who is issued a youth deer hunting license and does not take a deer during the youth deer hunting season may use the deer hunting license and unused tag during any subsequent deer seasons. The license will be valid for the type of deer and in the area specified on the original license. The youth must follow all other rules specified in this chapter for each season, including method of take. If the tag is filled during any of the seasons, the license will not be valid in subsequent seasons.

106.10(3) Shooting hours. Legal shooting hours will be one-half hour before sunrise to one-half hour after sunset each day regardless of weapon used.

106.10(4) Limits and license quotas. An unlimited number of licenses may be issued. The daily and season bag and possession limit is one deer per license. A person may shoot and tag a deer only by utilizing the license and tag issued in the person's name.

106.10(5) Method of take and other regulations. Deer may be taken with shotguns, bows, handguns, rifles, or muzzleloaders as permitted in 571—106.7(481A). Youth hunters using a handgun must be accompanied and under direct supervision throughout the hunt by a responsible person with a valid hunting license who is at least 21 years of age, with the consent of a parent or guardian. The responsible person with a valid hunting license who is at least 21 years of age shall be responsible for the conveyance of the pistol or revolver while the pistol or revolver is not actively being used for hunting. "Direct supervision" means the same as defined in Iowa Code section 483A.27A(4). All participants must meet the deer hunters' orange apparel requirement in Iowa Code section 481A.122. All other regulations for obtaining licenses or hunting deer shall apply.

106.10(6) Procedures for obtaining licenses. Paid and free youth season licenses and licenses for severely disabled hunters may be obtained through ELSI beginning August 15 through the last day of the youth season.

[ARC 1562C, IAB 8/6/14, effective 9/10/14; ARC 2086C, IAB 8/5/15, effective 9/9/15; ARC 3098C, IAB 6/7/17, effective 7/12/17; ARC 3831C, IAB 6/6/18, effective 7/11/18; ARC 5601C, IAB 5/5/21, effective 6/9/21]

571—106.11(481A) Deer depredation management. The deer depredation management program provides assistance to producers through technical advice and additional deer licenses and permits where the localized reduction of female deer is needed to reduce damage. Upon signing a depredation management agreement with the department, producers of agricultural or high-value horticultural crops may be issued deer depredation permits to shoot deer causing excessive crop damage. If immediate action is necessary to forestall serious damage, depredation permits may be issued before an agreement is signed. Further permits will not be authorized until an agreement is signed.

106.11(1) Method of take and other regulations. Legal weapons and restrictions will be governed by 571—106.7(481A). For deer shooting permits only, there are no shooting hour restrictions; however, taking deer with an artificial light is prohibited by Iowa Code section 481A.93. The producer or designee must meet the deer hunters' orange apparel requirement in Iowa Code section 481A.122.

106.11(2) Eligibility. Producers growing typical agricultural crops (such as corn, soybeans, hay and oats and tree farms and other forestlands under a timber management program) and producers of high-value horticultural crops (such as Christmas trees, fruit or vegetable crops, nursery stock, and commercially grown nuts) shall be eligible to enter into depredation management agreements if these crops sustain excessive damage.

- a. The producer may be the landowner or a tenant, whoever has cropping rights to the land.
- b. Excessive damage is defined as crop losses exceeding \$1,000 in a single growing season, or the likelihood that damage will exceed \$1,000 if preventive action is not taken, or a documented history of at least \$1,000 of damage annually in previous years.
- c. Producers who lease their deer hunting rights are not eligible for the deer depredation management program.

106.11(3) Depredation management plans. Upon request from a producer, field employees of the wildlife bureau will inspect and identify the type and amount of crop damage sustained from deer. If damage is not excessive, technical advice will be given to the producer on methods to reduce or prevent future damage. If damage is excessive and the producer agrees to participate, a written depredation management plan will be developed by depredation biologists in consultation with the producer.

a. The goal of the management plan will be to reduce damage to below excessive levels within a specified time period through a combination of producer-initiated preventive measures and the issuance of deer depredation permits.

(1) Depredation plans written for producers of typical agricultural crops may require preventive measures such as harassment of deer with pyrotechnics and cannons, guard dogs, and temporary fencing, as well as allowing more hunters, increasing the take of antlerless deer, and other measures that may prove effective.

(2) Depredation plans written for producers of high-value horticultural crops may include all of the measures in (1) above, plus permanent fencing where necessary. Fencing will not be required if the cost of a fence exceeds \$1,000.

(3) Depredation permits to shoot deer may be issued to Iowa residents to reduce deer numbers until long-term preventive measures become effective. Depredation permits will not be used as a long-term solution to deer damage problems.

b. Depredation management plans will normally be written for a three-year period with progress reviewed annually by the department and the producer.

- (1) The plan will become effective when signed by the depredation biologist and the producer.
- (2) Plans may be modified or extended if mutually agreed upon by the department and the producer.
- (3) Depredation permits will not be issued after the initial term of the management plan if the producer fails to implement preventive measures outlined in the plan.

106.11(4) Depredation permits. Two types of permits may be issued under a depredation management plan.

a. Deer depredation licenses. Deer depredation licenses may be sold to resident hunters only for the regular deer license fee for use during one or more legal hunting seasons. Depredation licenses will be available to producers of agricultural and horticultural crops.

- (1) Depredation licenses will be issued up to the number specified in the management plan.
- (2) The landowner or an eligible family member, which shall include the landowner's spouse or domestic partner and juvenile children, may obtain one depredation license for each season established by the commission. No other individual may initially obtain more than three depredation licenses per management plan. When a deer is reported harvested on one of these licenses, then another license may be obtained.

(3) Depredation licenses will be valid only for hunting antlerless deer, regardless of restrictions that may be imposed on regular deer hunting licenses in that county.

- (4) Hunters may keep any deer legally tagged with a depredation license.
- (5) All other regulations for the hunting season specified on the license will apply.
- (6) Depredation licenses will be valid only on the land where damage is occurring and the immediately adjacent property unless the land is within a designated block hunt area as described in

subparagraph (7). Other parcels of land in the farm unit not adjacent to the parcels receiving damage will not qualify.

(7) Block hunt areas are areas designated and delineated by wildlife biologists of the wildlife bureau to facilitate herd reduction in a given area where all producers may not qualify for the depredation program or in areas of persistent deer depredation. Depredation licenses issued to producers within the block hunt area are valid on all properties within the delineated boundaries. Individual landowner permission is required for hunters utilizing depredation licenses within the block hunt area boundaries. Creation of a given block hunt area does not authorize trespass.

b. Deer shooting permits. Permits for shooting deer outside an established hunting season may be issued to producers of high-value horticultural crops when damage cannot be controlled in a timely manner during the hunting seasons (such as late summer buck rubs in an orchard and winter browsing in a Christmas tree plantation) and to other agricultural producers who have an approved DNR deer depredation plan, and on areas such as airports where public safety may be an issue.

(1) Deer shooting permits will be issued at no cost to the applicant.

(2) The applicant or one or more designees approved by the department may take all the deer specified on the permit.

(3) Permits available to producers of high-value horticultural crops or agricultural crops may be valid for taking deer outside of a hunting season depending on the nature of the damage. The number and type of deer to be killed will be determined by a department depredation biologist and will be part of the deer depredation management plan.

(4) Permits issued due to public safety concerns may be used for taking any deer, as necessary, to address unpredictable intrusion which could jeopardize public safety. Permits may be issued for an entire year (January 1 through December 31) if the facility involved signs an agreement with the department.

(5) All deer killed must be recovered and processed for human consumption.

(6) The times, dates, place and other restrictions on the shooting of deer will be specified on the permit.

(7) Antlers from all deer recovered must be turned over to the conservation officer within 48 hours. Antlers will be disposed of according to department rules.

(8) For out-of-season shooting permits, there are no shooting hour restrictions; however, taking deer with an artificial light is prohibited by Iowa Code section 481A.93.

c. Depredation licenses and shooting permits will be issued in addition to any other licenses for which the hunters may be eligible.

d. Depredation licenses and shooting permits will not be issued if the producer restricts the legal take of deer from the property sustaining damage by limiting hunter numbers below levels required to control the deer herd. This restriction does not apply in situations where shooting permits are issued for public safety concerns.

e. A person who receives a depredation permit pursuant to this paragraph shall pay a \$1 fee for each license that shall be used and is appropriated for the purpose of deer herd population management, including assisting with the cost of processing deer donated to the help us stop hunger (HUSH) program administered by the commission and a \$1 writing fee for each license to the license agent.

106.11(5) Disposal. Rescinded IAB 7/16/08, effective 8/20/08.
[ARC 7921B, IAB 7/1/09, effective 8/5/09]

571—106.12(481A) Eligibility for free landowner/tenant deer licenses.

106.12(1) Who qualifies for free deer hunting licenses.

a. Owners and tenants of a farm unit and the spouse and juvenile child of an owner or tenant who reside with the owner or tenant are eligible for free deer licenses. The owner or tenant does not have to reside on the farm unit but must be actively engaged in farming it. Nonresident landowners do not qualify.

b. Juvenile child defined. “Juvenile child” means a person less than 18 years of age or a person who is 18 or 19 years of age and is in full-time attendance at an accredited school pursuing a course of

study leading to a high school diploma or a high school equivalency diploma. A person 18 years of age or older who has received a high school diploma or high school equivalency diploma does not qualify.

106.12(2) *Who qualifies as a tenant.* A “tenant” is a person other than the landowner who is actively engaged in the operation of the farm. The tenant may be a member of the landowner’s family, including in some circumstances the landowner’s spouse or child, or a third party who is not a family member. The tenant does not have to reside on the farm unit.

106.12(3) *What “actively engaged in farming” means.* Landowners and tenants are “actively engaged in farming” if they personally participate in decisions about farm operations and those decisions, along with external factors such as weather and market prices, determine their profit or loss for the products they produce. Tenants qualify if they farm land owned by another and pay rent in cash or in kind. A farm manager or other third party who operates a farm for a fee or a laborer who works on the farm for a wage and is not a family member does not qualify as a tenant.

106.12(4) *Landowners who qualify as active farmers.* These landowners:

- a. Are the sole operator of a farm unit (along with immediate family members), or
- b. Make all decisions about farm operations, but contract for custom farming or hire labor to do some or all of the work, or
- c. Participate annually in decisions about farm operations such as negotiations with federal farm agencies or negotiations about cropping practices on specific fields that are rented to a tenant, or
- d. Raise specialty crops from operations such as orchards, nurseries, or tree farms that do not necessarily produce annual income but require annual operating decisions about maintenance or improvements, or
- e. May have portions of the farm enrolled in a long-term land retirement program such as the Conservation Reserve Program (CRP) as long as other farm operations occur annually, or
- f. Place their entire cropland in the CRP or other long-term land retirement program with no other active farming operation occurring on the farm.

106.12(5) *Landowners who do not qualify.* These landowners:

- a. Use a farm manager or other third party to operate the farm, or
- b. Cash rent the entire farm to a tenant who is responsible for all farm operations including following preapproved operations plans.

106.12(6) *Where free licenses are valid.* A free license is valid only on that portion of the farm unit that is in a zone open to deer hunting. “Farm unit” means all parcels of land in tracts of two or more contiguous acres that are operated as a unit for agricultural purposes and are under lawful control of the landowner or tenant regardless of how that land is subdivided for business purposes. Individual parcels of land do not need to be adjacent to one another to be included in the farm unit. “Agricultural purposes” includes but is not limited to field crops, livestock, horticultural crops (e.g., from nurseries, orchards, truck farms, or Christmas tree plantations), and land managed for timber production.

106.12(7) *Registration of landowners and tenants.* Landowners and tenants and their eligible family members who want to obtain free deer hunting licenses must register with the department before the free licenses will be issued. Procedures for registering are described in 571—95.2(481A).

571—106.13(481A) Harvest reporting. Each hunter who bags a deer must report that kill according to procedures described in 571—95.1(481A).

571—106.14(481A) Extension to the regular gun seasons. Rescinded IAB 7/16/08, effective 8/20/08.

These rules are intended to implement Iowa Code sections 481A.38, 481A.39, 481A.48, 483A.8, 483A.8B, 483A.8C, 483A.24 and 483A.24B.

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CHAPTER 108
MINK, MUSKRAT, RACCOON, BADGER, OPOSSUM, WEASEL,
STRIPED SKUNK, FOX (RED AND GRAY), BEAVER, COYOTE, RIVER OTTER,
BOBCAT, GRAY (TIMBER) WOLF AND SPOTTED SKUNK SEASONS

[Prior to 12/31/86, Conservation Commission[290] Ch 104]

571—108.1(481A) Mink, muskrat and weasel. Open season for the taking of mink, muskrat and weasel shall be from 8 a.m. on the first Saturday in November through January 31 of succeeding year. Entire state open. No bag or possession limit.

108.1(1) *Molesting or disturbing muskrat houses.* Any department of natural resources officer, natural resource biologist, or county conservation board director may permit trappers to molest or disturb muskrat houses on specific state or county game management areas as provided in Iowa Code section 481A.90, after finding that muskrats are causing excessive damage by destroying the vegetation essential to the welfare of a marsh and after so posting the area.

108.1(2) *Game management areas.* Open season for taking muskrats on certain state game management areas, certain federal national wildlife refuges, and certain county conservation board areas, only where approved by the wildlife bureau and posted accordingly, shall be from 8 a.m. the day after the regular muskrat trapping season ends until April 1. The use of leg-hold traps during this season is prohibited unless each trap is placed completely inside a muskrat house. No bag or possession limit. [ARC 7933B, IAB 7/1/09, effective 8/5/09]

571—108.2(481A) Raccoon, badger, opossum and striped skunk. Open season for the taking of raccoon, badger, opossum, and striped skunk shall be from 8 a.m. on the first Saturday in November through January 31 of succeeding year. Entire state open. No bag or possession limit.

571—108.3(481A) Red and gray fox. Open season for the taking of red and gray fox shall be from 8 a.m. on the first Saturday in November through January 31 of succeeding year. Entire state open. No bag or possession limit.

571—108.4(481A) Beaver. Open season for the taking of beaver shall be from 8 a.m. on the first Saturday in November through April 15 of succeeding year. No bag or possession limit. [ARC 9654B, IAB 8/10/11, effective 9/14/11]

571—108.5(481A) Coyote.

108.5(1) *Hunting.* Continuous open season. Entire state open. No bag or possession limit.

108.5(2) *Trapping.* Open season for trapping coyote shall be 8 a.m. on the first Saturday in November through January 31 of succeeding year. Entire state open. No bag or possession limit. Any conservation officer or wildlife biologist may authorize a landowner, tenant or designee to trap coyotes causing damage outside the established trapping season dates.

571—108.6(481A) Gray (timber) wolf and spotted skunk. Continuous closed season.

571—108.7(481A) River otter and bobcat.

108.7(1) *License requirements.* Each person who takes river otters or bobcats shall have a valid fur harvester license and pay the habitat fee if normally required to have a license to hunt or trap.

108.7(2) *Open area.* River otters may be taken statewide. Bobcats may be taken in the following counties: Adair, Adams, Appanoose, Audubon, Boone, Cass, Cedar, Cherokee, Clarke, Clinton, Crawford, Dallas, Davis, Decatur, Delaware, Des Moines, Fremont, Guthrie, Harrison, Henry, Iowa, Jackson, Jasper, Jefferson, Johnson, Jones, Keokuk, Lee, Louisa, Lucas, Lyon, Madison, Mahaska, Marion, Mills, Monona, Monroe, Montgomery, Muscatine, Page, Plymouth, Polk, Pottawattamie, Poweshiek, Ringgold, Scott, Shelby, Sioux, Taylor, Union, Van Buren, Wapello, Warren, Washington, Wayne, Webster, and Woodbury.

108.7(3) *Seasonal bag limit.*

a. The seasonal bag limit for river otters is 3 river otters per person.

b. The seasonal bag limit for bobcats is 1 bobcat per person in the following counties: Audubon, Boone, Cedar, Cherokee, Clinton, Crawford, Dallas, Delaware, Guthrie, Harrison, Iowa, Jackson, Jasper, Johnson, Jones, Lyon, Monona, Muscatine, Plymouth, Polk, Poweshiek, Scott, Shelby, Sioux, Webster, and Woodbury.

c. The seasonal bag limit for bobcats is 3 bobcats per person in the following counties: Adair, Adams, Appanoose, Cass, Clarke, Davis, Decatur, Des Moines, Fremont, Henry, Jefferson, Keokuk, Lee, Louisa, Lucas, Madison, Mahaska, Marion, Mills, Monroe, Montgomery, Page, Pottawattamie, Ringgold, Taylor, Union, Van Buren, Wapello, Warren, Washington, and Wayne.

d. No more than 3 bobcats total can be legally harvested by a fur harvester in a season. River otters or bobcats trapped in excess of the seasonal bag limit or in a closed area must be turned over to the department; the fur harvester shall not be penalized.

108.7(4) *Season dates.* The season for taking river otters and bobcats opens on the first Saturday in November and closes on January 31 of the following year.

108.7(5) *Reporting requirements.* Anyone, including a landowner or tenant not required to have a fur harvester license, who takes a river otter or bobcat must report the harvest and arrange to receive a CITES tag from the officer or designated DNR employee within seven days of harvest. The river otter or bobcat shall be skinned and its lower jaw or skull turned over to the DNR conservation officer or designated DNR employee at the time the CITES tag is issued. If the specimen is to be kept whole for taxidermy purposes, a cut shall be made by the trapper between the gum line and eye so the CITES tag can be attached to the skin.

108.7(6) *Tagging requirements.* Every river otter or bobcat that may legally be kept must have a CITES tag attached. Tags will be supplied by the conservation officer or designated DNR employee. The tag must remain with the pelt until the pelt is sold or used for other purposes that render it no longer available for sale. Persons displaying river otters or bobcats as taxidermy mounts or as other decorative items must keep the tags in their possession as proof of legal harvest.

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571—108.8(481A) *Accidental capture of a river otter or bobcat during a closed season.* A person who accidentally captures a river otter or bobcat during a closed season or in a closed area or after the person's individual bag limit has been reached shall not be penalized provided that:

1. The river otter or bobcat is captured during a legal trapping season or as part of a legal depredation control process; and
2. A conservation officer is contacted within 24 hours and the river otter or bobcat and all parts thereof are turned over to a conservation officer as soon as practical.

571—108.9(481A) *Trapping restrictions.* Trapping for all furbearers will be restricted as follows:

108.9(1) *Exposed bait.* No person shall set or maintain any leghold, body-clasping trap, or snare within 20 feet of exposed bait on land anywhere in the state or over water in the following areas:

- a.* Mississippi River corridor—Allamakee, Clayton, Dubuque, Jackson, Clinton, Scott, Muscatine, Louisa, Des Moines and Lee Counties.
- b.* Missouri River corridor—Those portions of Woodbury, Monona, Harrison, Pottawattamie, Mills and Fremont Counties west of Interstate 29.
- c.* Des Moines River corridor—Boone, Dallas, Polk, Marion, Mahaska, Wapello and Van Buren Counties.

Exposed bait means meat or viscera or any animal, bird, fish, amphibian, or reptile with or without skin, hide, or feathers visible to soaring birds.

108.9(2) *Trapping near beaver lodges and dens.* Rescinded IAB 7/16/08, effective 8/20/08.

These rules are intended to implement Iowa Code sections 481A.6, 481A.38, 481A.39, 481A.87, and 481A.90.

These rules are based on the best biological data available as determined by research conducted by the department of natural resources.

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641—41.1(136C) X-rays in the healing arts.

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine.

a. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of May 16, 2018.

41.1(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapters 38 and 40 may also apply. The following are specific to 641—Chapter 41.

“*Accessible surface*” means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

“*Added filtration*” means any filtration which is in addition to the inherent filtration.

“*Aluminum equivalent*” means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

“*Attenuation block*” means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

“*Automatic exposure control (AEC)*” means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also “Phototimer”). (Includes devices such as phototimers and ion chambers.)

“*Base density*” means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

“*Base plus fog density*” means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

“*Beam monitoring system*” means a system designed to detect and measure the radiation present in the useful beam.

“*C-arm X-ray system*” means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

“*Cassette*” means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

“*Cephalometric device*” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

“*Certified components*” means components of X-ray systems which are subject to regulations promulgated under Public Law 90-602, the “Radiation Control for Health and Safety Act of 1968,” the Food and Drug Administration.

“*Certified system*” means any X-ray system which has one or more certified component(s).

“*Coefficient of variation*” or “*C*” means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\sum_{i=1}^n \frac{(x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:

\bar{s} = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample.

“*Computed tomography*” means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

“*Control chart*” means a chart used to record (and control) the results of quality control testing as a function of time.

“*Control limit*” means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

“*Control panel*” (see X-ray control panel).

“*Cooling curve*” means the graphical relationship between heat units stored and cooling time.

“*CT*” (see “*Computed tomography*”).

“*Dead-man switch*” means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

“*Dedicated mammography equipment*” means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

“*Densitometer*” means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

“*Detents*” means mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system.

“*Developer*” means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

“*Developer replenishment*” means the process, occurring as film travels past a certain point in the processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

“*Diagnostic mammography*” means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

“*Diagnostic source assembly*” means the tube housing assembly with a beam-limiting device attached.

“*Direct scattered radiation*” means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see “*Scattered radiation*”).

“*Entrance exposure rate*” means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

“*Equipment*” (see “X-ray equipment”).

“*Field emission equipment*” means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

“*Filter*” means material placed in the useful beam to preferentially absorb selected radiations.

“*Fixer*” means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

“*Fixer retention*” means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

“*Fluoroscopic imaging assembly*” means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical

interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

“Focal spot (actual)” means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

“Focal spot size” means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

“Fog” means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, chemical, or heat exposure during storage, handling, and processing.

“General purpose radiographic X-ray system” means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

“Gonad shield” means a protective barrier for the testes or ovaries.

“Healing arts screening” means the use of radiation on human beings for the detection or evaluation of health indicators for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under 41.1(3)“a”(7), or
2. An individual licensed as a physician in Iowa and listed as an authorized user on an NRC or agreement state radioactive materials license.

“Heat unit” means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., $kVp \times mA \times \text{second}$.

“Image contrast” means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attenuation difference or light exposure difference.

“Image intensifier” means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

“Image noise” See “Radiographic noise.”

“Image quality” means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

“Image receptor” means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

“Image sharpness” means the overall impression of detail and clarity in a radiographic image.

“Inherent filtration” means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

“Kilovolts peak” (see “Peak tube potential”).

“kVp” (see “Peak tube potential”).

“kWs” means kilowatt second.

“Leakage technique factors” means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

“*Linear attenuation coefficient*” or “ μ ” means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

“*Line-voltage regulation*” means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where

V_n = No-load line potential and

V_l = Load line potential.

“*mAs*” means milliamperere second.

“*Maximum line current*” means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

“*Mobile X-ray equipment*” (see “X-ray equipment”).

“*PBL*” (see “Positive beam limitation”).

“*Phototimer*” means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see “Automatic exposure control”).

“*PID*” (see “Position indicating device”).

“*Portable X-ray equipment*” (see “X-ray equipment”).

“*Position indicating device*” means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

“*Positive beam limitation*” means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

“*Processor*” means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur.

“*Protective apron*” means an apron made of radiation-absorbing materials used to reduce radiation exposure.

“*Protective glove*” means a glove made of radiation-absorbing materials used to reduce radiation exposure.

“*Quality assurance*” means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

“*Quality control*” means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

“*Radiation therapy simulation system*” means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

“*Radiograph*” means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

“*Radiographic contrast*” means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amount of X-ray or visible light exposure.

“*Radiographic noise*” means unwanted fluctuations in optical density on the screen-film image.

“*Rating*” means the operating limits as specified by the component manufacturer.

“*Recording*” means producing a permanent form of an image resulting from X-ray photons.

“*Repeat (or reject) analysis*” means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

“*Replenishment rate*” means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

“*Response time*” means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

“*Safelight*” means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

“*Screen*” means microscopic phosphor crystals on a plastic support used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X-radiation, creating a latent image on X-ray film.

“*Screen-film combination*” means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

“*Screen-film contact*” means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

“*Sensitometer*” means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

“*Sensitometric strip*” means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

“*Sensitometry*” means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

“*SID*” (see “*Source-image receptor distance*”).

“*Source*” means the focal spot of the X-ray tube.

“*Source-image receptor distance*” means the distance from the source to the center of the input surface of the image receptor.

“*Spot check*” means a procedure which is performed to ensure that a previous calibration continues to be valid.

“*Spot film*” means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

“*Spot-film device*” means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

“*Stationary X-ray equipment*” (see “*X-ray equipment*”).

“*Technique factors*” means the following conditions of operation:

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

“*Tomogram*” means the depiction of the X-ray attenuation properties of a section through the body.

“*Tube rating chart*” means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

“*Useful beam*” means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

“Variable-aperture beam-limiting device” means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

“Viewbox” means a device by which a uniform field of white light is transmitted through an X-ray so that the image on the film may be seen.

“Visible area” means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

“X-ray control panel” means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.

“X-ray equipment” means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. *“Mobile X-ray equipment”* means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. *“Portable X-ray equipment”* means X-ray equipment designed to be hand-carried but used with a tripod or other stabilization mechanism so the operator is not holding the equipment during exposure.

c. *“Stationary X-ray equipment”* means X-ray equipment which is installed in a fixed location.

d. *“Handheld X-ray equipment”* means X-ray equipment designed by the manufacturer to be handheld by the operator during the exposure. X-ray equipment designed without a backscatter shield is prohibited.

“X-ray exposure control” means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

“X-ray field” means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

“X-ray high-voltage generator” means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

“X-ray system” means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

“X-ray table” means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

41.1(3) Administrative controls.

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant’s administrative control, for ensuring that the requirements of these rules are met in the operation of the X-ray system(s), and for having the following minimum tests performed by a registered service facility according to the following schedule:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6) every two years.

2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7) every four years.

3. Fluoroscopic: entrance exposure rate (41.1(5) “c”), and minimum SSD (41.1(5) “f”) annually.

4. Veterinary systems are exempt from the above testing requirements.

All service and installation shall be performed by persons registered under 641—subrule 39.3(3). The registrant or the registrant’s agent shall ensure that the requirements of these rules are met in the operation of the X-ray system(s).

(1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

1. Operators in medical facilities shall meet the requirements of 641—Chapter 42, as applicable, and shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the appropriate technique and guidance for employing available dose reduction methods and technologies across all patient sizes and clinical indications. The following information shall be included:

1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;

2. Type and size of the film or film-screen combination to be used;

3. Type and focal distance of the grid to be used, if any; and

4. Source to image receptor distance to be used, except for dental intraoral radiography.

(4) Written safety procedures shall be provided to each individual operating X-ray equipment, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

2. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with X-ray operations.

(7) Individuals shall not be exposed to the useful beam unless (1) the radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and (2) such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3) "a"(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)“a”(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3)“a”(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 41.1(3)“a”(5)“2”;

4. No individual shall be used routinely to hold film or patients; and

5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X-ray equipment shall be used only for examinations, excluding intraoral dental imaging, where it is impractical to transfer the patient(s) to a stationary X-ray installation. Handheld mobile X-ray equipment may be used for routine intraoral dental imaging in place of stationary equipment. Handheld X-ray equipment shall be used only for intraoral dental radiography.

4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule 40.36(4) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program in the state of Iowa without prior written approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. The agency shall not approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened. If any information submitted to the agency becomes invalid or outdated, the applicant shall notify the agency in writing within five calendar days.

b. Information and maintenance record and associated information. Records in 41.1(3)“b”(1) and (3) below shall be maintained until the X-ray system is removed from the facility. There shall be two cycles of records on file for items in 41.1(3)“b”(2) below. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

- (1) User’s manual for the X-ray system;

(2) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;

(3) A copy of all correspondence with this agency regarding that X-ray system.

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient's name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. These records shall be kept until the facility is inspected by this agency or until all films listed on the utilization log have been purged.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X-ray film processing facilities and practices (except for mammography). Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion-resistant material; and

2. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom. Deviations from the manufacturer's recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer.

2. Processing deviations from the requirements of 41.1(3)“f” shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

3. All processing equipment shall be in good mechanical working order.

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom

for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records shall be maintained to verify that the items in 41.1(3) "f" are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

g. Retention of films. Record retention of films shall be seven years for patients 18 years of age or older and seven years plus the difference between the patient's age and 18 for minors.

(1) If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period.

(2) If the facility is currently utilizing computer media and also storing images in a hard-copy format, it may continue to use this method of retention throughout the retention period. If the images are also on computer media, the data should be backed up, or refreshed, at appropriate intervals as defined by the facility.

(3) If the facility is solely utilizing computer media to store study information for which a report is generated, the recording media is to be stored in conditions that will ensure that deterioration will not occur for the period required by this policy. The facility must maintain either retrieval or access or both to the stored images.

(4) If a patient's medical images are identified as being involved in a legal case, the records should immediately be coded appropriately, and maintained for the required time frame defined in this paragraph. At the time the records have reached the end of the appropriate time frame for retention, the previously identified responsible individuals involved in the legal action should be contacted for further instruction.

(5) If records are temporarily transferred to any party, appropriate information relating to location, date of release, and individual having custody of the records should be maintained.

(6) A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal.

41.1(4) General requirements for all diagnostic X-ray systems. In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 $\mu\text{C}/\text{kg}$) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

e. Beam quality.

(1) Half-value layer.

1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. and 3. Reserved.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)“e” shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)“e”(1)“1” is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)“h”(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator’s position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer’s standards.

41.1(5) Fluoroscopic X-ray systems except for computed tomography X-ray systems. All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5)“a”(2)“1” apply.

4. Other requirements for fluoroscopic beam limitation:

- Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;

- All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;

- If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;

- For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

- For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices

manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X-ray field size adjustments required in 41.1(5) "a"(2) and 41.1(5) "a"(3), that means:

1. Shall be designed for use only in the event of system failure;
2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
3. Shall have a clear and durable label as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except

- During recording of fluoroscopic images; or
- When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls

shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

3. Compliance with the requirements of 41.1(5)“c” shall be determined as follows:

- If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle;

- If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

- All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

- For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

4. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or

- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

5. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 5 roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 10 roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high level control is activated.

6. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

- The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)“c”(1)“3”;

- The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

- The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of 41.1(5)“c”(1)“3.”

(2) Reserved.

d. Barrier transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 μ C/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

f. Source-to-skin distance. The SSD shall not be less than:

- (1) 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974,
 - (2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974,
 - (3) 30 centimeters on all mobile fluoroscopes, and
 - (4) 20 centimeters for mobile fluoroscopes used for specific surgical application.
- (5) The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in 41.1(3)“a”(4).

g. Fluoroscopic timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

h. Control of scattered radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or
2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)“a”(5).

(3) The agency may grant exemptions to 41.1(5)“h”(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

i. Spot-film exposure reproducibility. Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements of 41.1(6)“d” when operating in the spot-film mode.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)“a,” “c,” “d,” and “g” provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of 41.1(5)“g” are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

k. Dose-area-product monitor requirements.

(1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (e.g., pacemaker implantation, diagnostic cardiac procedures (catheterization), and therapeutic cardiac

procedures (angioplasty-balloon; stent; directional coronary atherectomy; rotational atherectomy; laser atherectomy; radio frequency ablation; and intravascular brachytherapy)) shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used. Equipment used and installed prior to July 1, 2002, shall be retrofitted with the radiation exposure device by January 1, 2004.

(2) Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for agency review the patient radiation exposure received per procedure. Adult doses that exceed 300 rad and doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee. The review must document the reason why a dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If a facility does not have a radiation safety committee, the facility must provide the agency, within 30 days of the event, documentation stating why the patient's dose exceeded 300 rad for adults or 100 rad for children. Also, if the patient doses noted above are exceeded, the patient's physician must do a follow-up examination of the patient to determine if there is any evidence of dose recorded reaction and to ensure that proper treatment is rendered.

(3) All fluoroscopic radiation detection devices in this subrule shall be calibrated annually or after repair or replacement.

l. Equipment operation.

(1) All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

(2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(3) Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

m. Additional requirements for stationary fluoroscopic systems used for cardiac catheterization procedures.

(1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s). If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

(2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient). Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22(136C).

n. Supervision of fluoroscopy. The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner, a radiologist assistant or an advanced registered nurse practitioner (ARNP), pursuant to 655—subrule 7.2(2), for the purpose of localization to obtain images for diagnostic or therapeutic purposes.

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, veterinary, or computed tomography X-ray systems.*

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of 41.1(6) "h"(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X-ray systems and veterinarian systems (other than portable) installed after July 1, 1998.

1. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X-ray field.

- Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.

- The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)“a”(1)“1” and “2” provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with 41.1(6)“a”(1)“1” and “2”; and the purpose of 41.1(6)“a”(1)“1” and “2” will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)“a”(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:

1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Reserved.

(5) X-ray systems other than those described in 41.1(6)“a”(1), (2), and (3), and veterinary systems installed prior to July 1, 1998, and all portable veterinary X-ray systems.

1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

3. 41.1(6)“a”(5)“1” and “2” may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)“a”(1) or, when alignment means are also provided, may be met with either:

- An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

- A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

(1) Timers.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(2) X-ray control.

1. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures; and mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6) "b"(2) "2"; or

- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure. Stationary podiatric systems which do not meet the above requirements shall be provided with a 9-foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

3. The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic exposure controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

3. The minimum exposure time for all equipment other than that specified in 41.1(6) "b"(3) "2" shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

4. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

5. A visible signal shall indicate when an exposure has been terminated at the limits required by 41.1(6) "b"(3) "4," and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when four timer tests are performed:

$$\bar{T} \geq 5 (T_{\max} - T_{\min})$$

(5) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of $C\text{ kg}^{-1}\text{s}^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average $C\text{ kg}^{-1}\text{s}^{-1}$ (mR/s) values.

c. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters except for veterinary systems.

d. Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens ($0.516\ \mu\text{C}/\text{kg}$) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliamperere-seconds product ($C\text{ kg}^{-1}\text{mAs}^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of mR/mAs (or $C\text{ kg}^{-1}\text{mAs}^{-1}$), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

h. Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam limitation for stationary and mobile general purpose X-ray systems.

1. There shall be provided a means of stepless adjustment of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(2) Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of X-rays when

- Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by 41.1(6) "h" (3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

- The sum of the length and width differences as stated in 41.1(6) "h" (2) "1" above without regard to sign exceeds 4 percent of the SID;

2. Compliance with 41.1(6) "h" (2) "1" shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

4. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 41.1(6) "h" (2) "1," then any change of image receptor size or SID must cause the automatic return.

(3) Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of 41.1(6) "a" or 41.1(6) "h" (2).

i. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be handheld during exposures.

j. Systems used in a clinical (nonsurgical) setting shall be restricted to one room within a location or suite which meets the requirements of 41.1(3) "d."

41.1(7) Intraoral dental radiographic systems. In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used. Additional requirements specific to handheld dental X-ray equipment are outlined in 41.1(7) "i."

a. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

b. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(3) The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements of 41.1(4)“c.”

c. Exposure control.

(1) Exposure initiation.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

2. It shall not be possible to make an exposure when the timer is set to a “zero” or “off” position if either position is provided.

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator’s protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in X-ray systems that cannot be altered to meet this requirement.

(3) Exposure termination.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

2. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero.”

3. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half ($\frac{1}{2}$) second or less.

(4) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of $C\ kg^{-2}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

(5) Each X-ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the equipment while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3)“a”(4) must instruct the operator to remain in the protected area during the entire exposure.

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7)“c”(5)“1.”

- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 6 feet (1.8 meters) from the tube housing assembly while making exposure.

3. Portable dental X-ray systems designed with a backscatter shield may be used without an additional protective barrier, but the operator must stand directly behind the equipment to allow the shield to function as designed.

d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

e. mA/mS linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliamperere-seconds product, in units of $C\text{ kg}^{-1}\text{ mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliamperere-seconds product, in units of $C\text{ kg}^{-1}\text{ mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. kVp limitations. Dental X-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. Administrative controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID for stationary or mobile systems shall not be held by the operator during an exposure.

(3) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7) "b"(1).

(4) Dental fluoroscopy without image intensification shall not be used.

i. Handheld dental X-ray systems. Only equipment specifically designed by the manufacturer to be held by the operator for intraoral dental X-ray exposures is allowed to be operated pursuant to this subrule.

(1) Operators shall be specifically trained to operate the equipment. Records of training shall be kept at the facility until the operator is no longer an employee or until the equipment is removed from the facility.

(2) Protective aprons of not less than 0.25 millimeter lead equivalent shall be provided for operators to wear while operating the equipment.

(3) Dosimetry shall be provided for operators who are expected to exceed 10 percent of the annual occupational dose limit as outlined in 641—40.84(136C).

(4) Operators shall operate the equipment according to the manufacturer's instructions.

(5) The image receptor used must be digital radiography (DR), computed radiography (CR), or intraoral film with a speed class designated as “E/F” or a film with a faster speed designation than “F” or “E/F.”

(6) No individual except the equipment operator may be within a radius of at least 6 feet from the patient during exposures.

(7) The equipment shall not be operated unless the backscatter shield is in place as designed by the manufacturer.

(8) The equipment shall not be operated in hallways, waiting rooms, or other areas where access for individuals of the general public cannot be controlled.

(9) The equipment shall be held without any motion during a patient examination. If the operator has difficulty in holding the equipment stationary, the operator shall use a tube stand. The equipment shall be operated on a tube stand whenever practicable to avoid unnecessary motion and retakes.

(10) When not in use, the equipment shall be stored in a manner that would prevent inadvertent exposures or use by unauthorized individuals.

41.1(8) Reserved.

41.1(9) *Bone densitometry units.*

a. No additional shielding for the room is required.

b. Film badges, OSL devices, or TLDs must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months and another request for discontinuance submitted to the agency.

c. Reserved.

d. Specific operating procedures must be prepared and made available at the operator’s position.

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer’s specifications. Records of maintenance shall be kept for inspection by the agency.

41.1(10) *Veterinary medicine radiographic installations.*

a. *Equipment.*

(1) The protective tube housing shall be equivalent to the requirements of 41.1(4)“c.”

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. *Operator protection.*

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with 641—40.15(136C) and 641—40.21(136C) and 641—subrule 40.26(1).

(2) All stationary, mobile or portable X-ray systems shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. Operating procedures. Veterinary medicine radiographic installations are exempt from the requirements of 641—41.1(136C) except for subrules 41.1(3) and 41.1(10).

(1) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required, and

(2) The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures, or

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) Computed tomography X-ray systems.

a. Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

"*Computed tomography dose index*" means the integral from $-7T$ to $+7T$ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

$D(z)$ = Dose at position z .

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around $z = 0$ and that, for a multiple tomogram system, the scan increment between adjacent scans is nT .

"*Contrast scale*" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{\text{CS}} = \frac{\mu_x - \mu_w}{\overline{\text{CTN}}_x - \overline{\text{CTN}}_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$\overline{\text{CTN}}_x$ = of the material of interest.

$\overline{\text{CTN}}_w$ = of water.

"*CS*" (see "Contrast scale").

"*CT conditions of operation*" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

"*CTDI*" (see "Computed tomography dose index").

"*CT gantry*" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"*CTN*" (see "CT number").

“*CT number*” means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$\overline{\text{CTN}} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.)

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

“*Dose profile*” means the dose as a function of position along a line.

“*Elemental area*” means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also “*Picture element*”).

“*Multiple tomogram system*” means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

“*Noise*” means the standard deviation of the fluctuation in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{\text{CS}} \cdot s}{\mu_w}$$

where:

$\overline{\text{CS}}$ = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

“*Nominal tomographic section thickness*” means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

“*Picture element*” means an elemental area of a tomogram.

“*Reference plane*” means a plane which is displaced from and parallel to the tomographic plane.

“*Scan*” means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

“*Scan increment*” means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

“*Scan sequence*” means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

“*Scan time*” means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

“*Single tomogram system*” means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

“*Tomographic plane*” means that geometric plane which is identified as corresponding to the output tomogram.

“*Tomographic section*” means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

b. Requirements for equipment.

(1) Termination of exposure.

1. Means shall be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by 41.1(11)“b”(1)“1.”

3. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.

(2) Tomographic plane indication and alignment.

1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy 41.1(11)“b”(2)“1” or “2,” the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-on and shutter status indicators and control switches.

1. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 41.1(4)“c.”

(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

2. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

c. Facility design requirements.

(1) Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

1. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

d. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

1. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

(2) Radiation calibrations.

1. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

2. The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

3. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

4. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use: CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode; CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided; any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

5. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the CTDI^{3/4} along the two axes specified in 41.1(11)“d”(2)“4” shall be measured. (For the purpose of determining the CTDI, the manufacturer’s statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)“d”(3) shall be made.

7. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

(3) Spot checks.

1. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

2. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

3. All spot checks shall be included in the calibration required by 41.1(11)“d”(2) and at time intervals and under system conditions specified by a qualified expert.

4. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 41.1(11)“d”(2). The images shall be retained, until a new calibration is performed, in two forms as follows: photographic copies of the images obtained from the image display device; and images stored in digital form on a storage medium compatible with the CT X-ray system.

5. Written records of the spot checks performed shall be maintained for inspection by the agency.

(4) Operating procedures.

1. The CT X-ray system shall not be operated except by a licensed practitioner or an individual who has been specifically trained in its operation and holds a current permit to practice as a general radiologic technologist as defined under the provisions of 641—Chapter 42.

[ARC 8659B, IAB 4/7/10, effective 5/12/10; ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3103C, IAB 6/7/17, effective 7/12/17; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5683C, IAB 6/16/21, effective 7/21/21]

641—41.2(136C) Use of radionuclides in the healing arts.

41.2(1) Purpose and scope.

a. This rule establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, the applicable portions of 641—Chapters 38 to 40. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

41.2(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapters 38 to 40 may also apply. As used in 41.2(136C), the following definitions apply:

“*Area of use*” means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

“*Associate radiation safety officer*” means an individual who:

a. Meets the requirements of 41.2(65) and 41.2(77); and

b. Is currently identified as an associate radiation safety officer for the types of use of byproduct material for which the duties and tasks by the radiation safety officer on:

1. A specific medical use license issued by the NRC or an agreement state; or

2. A medical use permit issued by an NRC master material licensee.

“*Authorized medical physicist*” means an individual who:

a. Meets the requirements of 41.2(74) and 41.2(77); or

b. Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use license issued by this agency, the NRC, or an agreement state;

2. A medical use permit issued by an NRC master material licensee;

3. A permit issued by an NRC or agreement state broad scope medical use licensee; or

4. A permit issued by an NRC master material license broad scope medical use permittee.

“*Authorized nuclear pharmacist*” means a pharmacist who:

a. Has met the appropriate requirements of 41.2(77) and 41.2(78), or before May 3, 2006, meets the requirements in 10 CFR 35.980(a) and 10 CFR 35.59; or

b. Is identified as an authorized nuclear pharmacist on:

1. A specific license issued by the agency, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;

2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

3. A permit issued by the NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29) “j”(2)“3.” “*Authorized user*” means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67) “a,” 41.2(68) “a,” 41.2(69) “a,” 41.2(70) “a,” 41.2(72) “a,” 41.2(73) “a,” 41.2(81) “a,” or 41.2(82) “a,” or before May 3, 2006, meets the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(c), 35.940(a), 35.950(a), or 35.960(a) and 10 CFR 35.59; or who is identified on:

1. A current Iowa, NRC, or agreement state license that authorizes the medical use of radioactive material;

2. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

3. A permit issued by an NRC, agreement state, or Iowa-specific licensee of broad scope that is authorized to permit medical use of radioactive material; or

4. A permit issued by an NRC master material license broad scope permittee that is authorized to permit medical use of radioactive material.

“*Dedicated check source*” means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

“*Management*” means the chief executive officer or that individual’s designee.

“*Medical institution*” means an organization in which several medical disciplines are practiced.

“*Mobile nuclear medicine service*” means the transportation and medical use of radioactive material.

“*Ophthalmic physicist*” means an individual who:

a. Meets the requirements of 41.2(85) “a”(2) and 41.2(77); and

b. Is identified as an ophthalmic physicist on a:

1. Specific medical use license issued by an NRC or an agreement state;

2. Permit issued by an NRC or agreement state broad scope medical use licensee;

3. Medical use permit issued by an NRC master material licensee; or

4. Permit issued by an NRC master material licensee broad scope medical use permittee.

“*Output*” means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

“*Pharmacist*” means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

“*Radiation safety officer*” means an individual who, in addition to the definition in 641—38.2(136C):

a. Meets the requirements of 41.2(65) and 41.2(77); and

b. Is identified as a radiation safety officer on:

1. A specific medical use license issued by the NRC or an agreement state; or

2. A medical use permit issued by an NRC master material licensee.

“*Stereotactic radiosurgery*” means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

“*Teletherapy*” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“*Unit dosage*” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

“*Visiting authorized user*” means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) License required.

a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

c. An individual may prepare unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user as provided in 41.2(11) unless prohibited by license condition.

d. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Nothing in this subrule relieves the licensee from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

e. An applicant that satisfies the requirements of 641—paragraph 39.4(28) “b” may apply for a Type A specific license of broad scope.

41.2(4) License amendments.

a. A licensee shall apply for and receive a license amendment:

- (1) Before using byproduct material for a method or type of medical use not permitted by the license issued under this rule;
- (2) Before permitting anyone to work as an authorized user or authorized nuclear pharmacist under the license unless the individual meets “visiting” status in accordance with 41.2(12);
- (3) Before changing a radiation safety officer;
- (4) Before permitting anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;
- (5) Before receiving byproduct material in excess of the amount authorized on the license;
- (6) Before adding to or changing the address or addresses of use identified in the application or on the license; and
- (7) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

b. License amendment exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

- (1) The provision of 41.2(4) “a”(2);
- (2) The provisions of 41.2(4) “a”(6) regarding additions to or changes in the areas of use only at the addresses specified in the license.

41.2(5) Notifications.

a. A licensee shall notify the agency no later than 30 days after:

- (1) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, an associate radiation safety officer, an authorized medical physicist, or an ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;
- (2) The licensee permits an individual qualified to be a radiation safety officer under 41.2(65) and 41.2(77) to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with 41.2(10) “c”;
- (3) The licensee’s mailing address changes;
- (4) The licensee’s name changes but the name change does not constitute a transfer of control of the license as described in 641—paragraph 39.4(32) “b”; or
- (5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used.

b. Notifications requiring agency approval prior to implementation for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units include:

(1) Revisions to procedures required by 41.2(52), 41.2(59) "a," 41.2(59) "b," and 41.2(59) "c" as applicable, where such revision reduces radiation safety;

(2) Changes that could impact radiation levels in adjacent spaces, such as shielding or location of device.

c. The licensee shall mail the documents required in this subrule to the agency in accordance with 641—38.7(136C).

d. Notification exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of 41.2(5) "a"(1) for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist.

(2) The provisions of 41.2(5) "a"(5).

41.2(6) Maintenance of records.

a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.

c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6) "a" and "b."

41.2(7) ALARA program.

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(3).

b. To satisfy the requirement of 41.2(7) "a":

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9) "b"(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) Radiation safety officer.

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

1. Authorizing the purchase of radioactive material;
2. Receiving and opening packages of radioactive material;
3. Storing radioactive material;
4. Keeping an inventory record of radioactive material;
5. Using radioactive material safely;
6. Taking emergency action if control of radioactive material is lost;
7. Performing periodic radiation surveys;
8. Performing checks and calibrations of survey instruments and other safety equipment;
9. Disposing of radioactive material;
10. Training personnel who work in or frequent areas where radioactive material is used or stored;

and

11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

41.2(9) Radiation safety committee. Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) Reserved.

(4) The minutes of each radiation safety committee meeting shall include:

1. The date of the meeting;
2. Members present;
3. Members absent;
4. Summary of deliberations and discussions;
5. Recommended actions and the numerical results of all ballots; and
6. Document any reviews required in 41.2(7) "c" and 41.2(9) "b."

(5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

- (1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;
- (2) Review:
 1. Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;
 2. Review on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.
- (3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;
- (4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;
- (5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;
- (6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;
- (7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and
- (8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

41.2(10) Authority and responsibilities for the radiation protection program.

a. In addition to the radiation protection program requirements of 641—40.10(136C), a licensee's management shall approve in writing:

- (1) Requests for a license application, renewal, or amendment before submittal to this agency;
- (2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and
- (3) Radiation protection program changes that do not require a license amendment.

b. A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on the license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

c. For up to 60 days each year, a licensee may permit an individual qualified to be a radiation safety officer under 41.2(65) or 41.2(75) to function as a temporary radiation safety officer to perform the functions of radiation safety officer, as provided in 41.2(10) "g," if the licensee takes the actions required in 41.2(10) "b," "e," "g," and "h" and notifies this agency in accordance with 41.2(5).

d. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with 41.2(10) "c" if needed to ensure that the licensee has a temporary radiation safety officer who satisfies the requirements to be a radiation safety officer for each of the different types of byproduct material permitted on the license.

e. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

f. Licensees that are authorized for two or more different types of uses of radioactive materials or two or more types of units under this rule shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

g. A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

- (1) Identify radiation safety problems;
- (2) Initiate, recommend, or provide corrective solutions;
- (3) Verify implementation of corrective actions; and
- (4) Stop unsafe operations.

h. A licensee shall retain a record of actions taken under 41.2(10) in accordance with 641—40.80(136C).

41.2(11) *Supervision.*

a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules of this chapter, and license conditions appropriate to that individual's use of radioactive material;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals certified and issued a current permit to practice in accordance with 641—Chapter 42 as a nuclear medicine technologist or a radiation therapist, as applicable, or an Iowa-licensed physician and designated by the authorized user, shall be permitted to administer radionuclides (sealed sources only for radiation therapists) or radiation to patients or human research subjects. For a nuclear medicine technologist or a radiation therapist, the individual's permit to practice shall be made available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:

(1) Follow the instructions of the supervising authorized user for the medical uses of byproduct material;

(2) Follow the written radiation protection and written directive procedures established by the radiation safety officer; and

(3) Comply with these rules and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 41.2(3) "c," shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written procedures for maintaining written directives, as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

41.2(12) *Visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, and visiting authorized nuclear pharmacist.*

a. A licensee may permit any visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of the NRC or agreement state license that identifies the visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist by name for the medical use being utilized by the licensee; and

(3) Only those procedures for which the visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist is specifically authorized by an NRC or agreement state license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist to use licensed material as described in 41.2(12) "a."

c. A licensee shall retain copies of the records specified in 41.2(12) "a" for five years from the date of the last visit.

41.2(13) *Mobile nuclear medicine service administrative requirements.*

a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material and clearly delineates the authority of the licensee and client.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

e. Mobile nuclear medicine service licensees shall also perform the following:

(1) Check instruments used to measure the activity of unsealed radioactive material for proper function before use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this rule must include a constancy check;

(2) Check survey instruments for proper operation with a dedicated check source before use at each client's address;

(3) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements of 641—Chapters 40 and 41.

41.2(14) *Records and reports of reportable medical events.*

a. When a reportable medical event, as defined in 641—38.2(136C), occurs, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient's or human research subject's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the

reportable medical event. If the referring physician, patient or human research subject, or the patient's or human research subject's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient's or human research subject's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this notification requirement including remedial care as a result of the reportable medical event because of any delay in notification.

b. Written reports.

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the reportable medical event. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event, why the event occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, actions taken to prevent recurrence, whether the licensee notified the patient or the human research subject or the patient's or the human research subject's responsible relative or guardian (this individual will subsequently be referred to as "the patient or the human research subject"), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(2) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. A copy of the report that was submitted to the agency; or
2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. Reserved.

d. Each licensee shall retain a record of each reportable medical event for three years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14) "a" to 41.2(14) "d" shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify this agency by telephone no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

(4) The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

1. The written report must include:

- The licensee's name;

- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;
- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14) "f"(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:
 - Name of the pregnant individual or the nursing child who is the subject of the event; and
 - Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and
2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

41.2(15) Suppliers. A licensee shall use for medical use only:

- a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and
- b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration;
- c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

41.2(16) Quality control of imaging equipment. Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) Possession, use, calibration, and check of dose calibrators.

a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

b. A licensee shall:

- (1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on frequently used

settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at 12-month intervals thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at 3-month intervals thereafter over the range of use between 30 microcuries (1.1 megabecquerels) and the highest dosage that will be administered; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

d. A licensee shall also perform checks and tests required by 41.2(17) "b" following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by 41.2(17) for three years, except the geometry dependence test which shall be retained in accordance with 41.2(17) "b"(4). The records required by 41.2(17) "b" shall include:

(1) For 41.2(17) "b"(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For 41.2(17) "b"(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the individual performing the test, and the signature of the radiation safety officer;

(3) For 41.2(17) "b"(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer; and

(4) For 41.2(17) "b"(4), the model and serial number of the dose calibrator, the configuration calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer.

41.2(18) Calibration and check of survey instruments.

a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of 41.2(18) "a," the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18) "b," the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in 41.2(18) “*a*” for three years. The record shall include:

- (1) A description of the calibration procedure; and
- (2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18) “*a*,” “*b*,” and “*c*,” the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18) “*e*” shall be maintained by the licensee.

41.2(19) *Assay of radiopharmaceutical dosages.* A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains a photon-emitting radionuclide;

b. Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “*j*” or equivalent NRC or agreement state requirements;

c. Not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent unless otherwise directed by the authorized user; and

d. Retain a record of the assays required by 41.2(19) “*a*” for three years. To satisfy this requirement, the record shall contain the:

- (1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;
- (2) Patient’s or human research subject’s name and identification number if one has been assigned;
- (3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);
- (4) Date and time of the assay and administration; and
- (5) Initials of the individual who performed the assay.

41.2(20) *Authorization for calibration and reference sources.*

a. Any person authorized by 41.2(3) for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the NRC, agreement state or licensing state and that do not exceed 30 millicuries (1.11 GBq) each;

(2) Any byproduct material listed in 41.2(31) or 41.2(33) with a half-life of 120 days or less in individual amounts not to exceed 15 millicuries (555 MBq);

(3) Any byproduct material listed in 41.2(31) or 41.2(33) with a half-life greater than 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) or 1,000 times quantities in Appendix C of 641—Chapter 40 each; and

(4) Technetium-99m amounts as needed.

b. Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in 641—38.2(136C) except in accordance with the requirements in 41.2(41); or

(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this subrule.

c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in 41.2(20) “*a*” or “*b*” need not list these sources on a specific medical use license.

41.2(21) *Requirements for possession of sealed sources and brachytherapy sources.*

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the

agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall ensure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of 41.2(21) “*b*,” the licensee shall ensure that:

(1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the “off” position.

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, the signature of the radiation safety officer and the signature of the individual performing the leak test.

e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and

(2) File a report with the agency within five days of receiving the leak test results. The report shall describe the equipment involved, the model and serial number of the leaking source, the radionuclide and its estimated activity, the test results, the date of the test, and the action taken.

f. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; [and]

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at 6-month intervals. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, the signature of the radiation safety officer and the signature of the individual performing the physical inventory.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in 41.2(21) “*h*” for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) Syringe shields.

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

41.2(23) Syringe labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

41.2(24) Vial shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

41.2(25) Vial shield labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

41.2(26) Surveys for contamination and ambient radiation dose rate.

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by 41.2(26) "a" and "b" so as to be able to measure dose rates as low as 0.1 millirem (1 μ Sv) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26) "a" and "b" and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by 41.2(26) "e" so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26) "e" and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by 41.2(26) "a," "b," and "e" for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

i. A licensee does not need to perform the surveys required in this subrule in an area where the patient or human research subject is confined and cannot be released under 41.2(27).

41.2(27) Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

a. The licensee may authorize the release from its control of any individual who has been administered unsealed radioactive materials or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). (NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).)

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast feeding, and
- (2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

- (1) Using the retained activity rather than the activity administered,
- (2) Using an occupancy factor less than 0.25 at 1 meter,
- (3) Using the biological or effective half-life, or
- (4) Considering the shielding by tissue.

d. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). IDPH Regulatory Guide, Release of Patients Administered Radioactive Materials describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

41.2(28) Mobile nuclear medicine service technical requirements. A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in 41.2(17) "b"(1) "d" and "e" and 41.2(18) "d" and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

f. Retain a record of each survey required by 41.2(28) "e" for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) Storage of volatiles and gases.

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) Decay-in-storage.

a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

- (1) Holds radioactive material for decay a minimum of ten half-lives;
- (2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
- (3) Removes or obliterates all radiation labels; and
- (4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with 41.2(30) "a," the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial

number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

41.2(31) *Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements or from a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(31) “b”(1) or the physician who is an authorized user in 41.2(31) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(32) Reserved.

41.2(33) *Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements or a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69);

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(33) “b”(1) or the physician who is an authorized user in 41.2(33) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(34) *Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.*

a. A licensee shall not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or

(2) More than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-82 per megabecquerel rubidium-82 chloride); or more than 0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kilobecquerel strontium-85 per megabecquerel rubidium-82 chloride).

b. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with 41.2(34) “a.”

c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 41.2(34)“a.”

d. A licensee who must measure molybdenum-99, strontium-82, or strontium-85 concentration shall retain a record of each measurement for three years. The record shall include:

(1) For each elution or extraction of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

(2) For each elution or extraction of rubidium-82, the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (kilobecquerels of strontium-82 per megabecquerel of rubidium-82), microcuries of strontium-85 per millicurie of rubidium-82 (kilobecquerels of strontium-85 per millicurie of rubidium-82), the date of the test, and the initials of the individual who performed the test.

e. A licensee shall report any measurement that exceeds the limits in 41.2(34)“a” at the time of generator elution, in accordance with the following:

(1) The licensee shall notify by telephone the agency and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 41.2(34)“a” at the time of generator elution. The telephone report to the agency must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

(2) By an appropriate method listed in 641—38.7(136C), the licensee shall submit a written report to the agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee’s equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee’s breakthrough determination; and the information in the telephone report as required by 41.2(34)“a.”

41.2(35) Control of aerosols and gases.

a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—40.15(136C) and 641—40.26(136C) of these rules.

b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in 41.2(35)“a” at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

g. A copy of the calculations required in 41.2(35)“d” shall be recorded and retained for the duration of the license.

41.2(36) Reserved.

41.2(37) *Use of unsealed byproduct material for which a written directive is required.* A licensee may use any unsealed byproduct material identified in 41.2(69) “b”(1)“2,” seventh bulleted paragraph, prepared for medical use and for which a written directive is required that:

a. Is obtained from:

(1) A manufacturer or preparer licensed under 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements; or

(2) A PET radioactive drug producer licensed under 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69);

or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(37) “b”(1) or the physician who is an authorized user in 41.2(37) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with the Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

41.2(38) *Safety instruction for radiopharmaceutical therapy and hospitalization.*

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(38) “a,” the instruction shall describe the licensee’s procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control;

(5) Notification of the radiation safety officer, radiation safety officer designee, or authorized user in case of the patient’s or human research subject’s death or medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 641—40.116(136C) and adopted by reference and included herein.

c. A licensee shall maintain a record of safety instructions required by 41.2(38) for three years. The records must include a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

41.2(39) *Safety precautions for radiopharmaceutical therapy and hospitalization.*

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:

(1) Provide a private room with a private sanitary facility or a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under 41.2(27);

(2) Post the patient’s or human research subject’s door with a “Caution: Radioactive Material” sign and note on the door or on the patient’s or human research subject’s chart where and how long visitors may stay in the patient’s or human research subject’s room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.26(1) which is adopted by reference and included herein and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list

of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) Provide the patient or human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;

(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(40) Reserved.

41.2(41) *Use of sealed sources for diagnosis.*

a. A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

b. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

c. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements in 41.2(15) "a" are met.

41.2(42) Reserved.

41.2(43) *Use of sources for manual brachytherapy.* A licensee shall use only brachytherapy sources:

a. As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

b. In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(44) *Safety instruction for manual brachytherapy.*

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving manual brachytherapy and cannot be released under 41.2(27). Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(44) "a," the instruction shall describe:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
- (3) Procedures for patient or human research subject control;
- (4) Procedures for visitor control, to include routine visitation of hospitalized individuals in accordance with 641—40.26(136C) and visitation authorized in accordance with 641—40.26(136C);

(5) Procedures for notification of the radiation safety officer, radiation safety officer designee, or authorized user if the patient or human research subject dies or has a medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) as adopted by reference and included herein.

c. A licensee shall maintain a record of safety instructions required by 41.2(44) for three years. The records must include a description of the instruction, the date of instruction, the name of the attendee(s), and the name of the individual who gave the instruction for three years.

41.2(45) Safety precautions for manual brachytherapy.

a. For each patient or human research subject receiving manual brachytherapy a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—40.26(136C) as adopted by reference and included herein at a distance of 1 meter from the implant;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—40.26(136C) as adopted by reference and included herein; and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant; and

(6) Have applicable emergency response equipment available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following removal of the source applicators.

b. A licensee shall notify the radiation safety officer, radiation safety officer designee, or authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(46) Brachytherapy sources inventory.

a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use and patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in 41.2(46) "b" and "c" for three years.

e. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

41.2(47) Release of patients or human research subjects treated with temporary implants.

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed and, for remote afterloaders, returned to the safe shielded position. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 41.2(47) "a" for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

41.2(48) Reserved.

41.2(49) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.*

a. A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(2) In research involving photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) "a" are met.

b. A licensee must use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) "a" are met.

41.2(50) *Installation, maintenance, adjustment, and repair.*

a. Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), or reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

b. Except for low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

c. For low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units for three years. The record must include the date, description of the service, and the name of the individual who performed the work.

41.2(51) *Amendments.* In addition to the requirements specified in 41.2(4), a licensee shall apply for and receive a license amendment before:

a. Making any change in the treatment room shielding;

b. Making any change in the location of the teletherapy unit within the treatment room;

c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

d. Relocating the teletherapy unit; or

e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

41.2(52) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

a. A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or to remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by 41.2(52) "a"(4) must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 41.2(52) "a"(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

d. A licensee shall:

(1) Ensure that vendor operational and safety training is provided to all individuals who will operate the unit prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) Provide operational and safety instruction, initially and at least annually, to all individuals who operate the unit, appropriate to the individual's assigned duties, in:

1. The procedures identified in 41.2(52) "a"(4); and

2. The operating procedures for the unit.

e. The licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures, initially and at least annually.

f. A licensee shall retain a record for three years of individuals receiving instruction required by 41.2(52), a description of the instruction, the date of instruction, the name of the attendee(s), and the name of the individual who gave the instruction.

g. A copy of the procedures required in 41.2(52) "d"(2) shall be retained until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

41.2(53) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned “on” following an interlock interruption until all treatment room entrance doors are closed and the beam “on-off” control is reset at the console.

c. A licensee shall require any individual entering the treatment room to ensure, through the use of appropriate monitors, that radiation levels have returned to ambient levels.

d. Except for low-dose-rate remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or human research subject from the treatment console during irradiation.

e. For licensed activities where sources are placed within the patient’s or human research subject’s body, the licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

f. In addition to the requirements specified in 41.2(53) “a” through “e,” a licensee shall:

(1) For medium-dose-rate and pulsed-dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation of and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who have been trained to remove the source applicator in the event of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

(2) For high-dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this subparagraph, “physically present” means to be within hearing distance of normal voice.

(4) Notify the radiation safety officer, or the radiation safety officer designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

g. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

41.2(54) Reserved.

41.2(55) *Radiation monitoring device.*

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by 41.2(55) “d” for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a

dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55) "e."

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

41.2(56) Viewing system. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

41.2(57) Dosimetry equipment.

a. Except for low-dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system has not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57) "a." This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 41.2(57) "a."

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57) "a" and "b," the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) Full calibration measurements on teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

a. *Teletherapy units.*

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements for each teletherapy unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output of the last full calibration corrected mathematically for radioactive decay;

- Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

- Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

(2) To satisfy the requirements of 41.2(58) "a"(1), full calibration measurements must include determination of:

1. The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58) "a"(2)"1" may be made using the dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58) "a" in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58) "a"(2)"1" for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1 percent of all other radionuclides.

(6) Full calibration measurements required by 41.2(58) "a"(1) and physical decay corrections required in 41.2(58) "a"(5) must be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for both the unit and the source; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the measured timer accuracy for a typical treatment time; the calculated "on-off" error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements for each unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

- Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

- Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one quarter of a year for high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding one year for low-dose-rate remote afterloader units.

(2) To satisfy the requirements of 41.2(58) "b"(1), full calibration measurements must include, as applicable, determination of:

1. The output within ± 5 percent;

2. Source positioning accuracy to within ± 1 millimeter;

3. Source retraction with backup battery upon power failure;

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output.

(4) A licensee shall make full calibration measurements required by 41.2(58) "b"(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low-dose-rate remote afterloader units in 41.2(58) "b"(2), a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one quarter of a year.

(6) For low-dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 41.2(58)“b.”

(7) A licensee shall mathematically correct the outputs determined in 41.2(58)“b”(2)“1” for physical decay intervals consistent with 1 percent physical decay.

(8) Full calibration measurements required by 41.2(58)“b”(1) and physical decay corrections required by 41.2(58)“b”(7) must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with 41.2(58)“a”(7).

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

- Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

- Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of 41.2(58)“c”(1), full calibration measurements must include determination of:

1. The output within ± 3 percent;

2. Relative helmet factors;

3. Isocenter coincidence;

4. Timer accuracy and linearity over the range of use;

5. On-off error;

6. Trunnion centricity;

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

8. Helmet microswitches;

9. Emergency timing circuits; and

10. Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)“c”(2)“1” may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)“c”(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)“c”(2)“1” at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by 41.2(58)“c”(1) and physical decay corrections required in 41.2(58)“c”(5) must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 41.2(58)“a”(7).

41.2(59) Periodic spot checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

a. Teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy and timer linearity over the range of use;

2. On-off error;

3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57); and

6. The difference between the measurement made in 41.2(59) "a"(1) "5" and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by 41.2(59) "a"(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the result of each spot check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to ensure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the spot checks required in 41.2(59) "a"(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59) "a." The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required by 41.2(59) "a"(2) until the licensee no longer possesses the teletherapy unit.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

1. Before the first use of a high-dose-rate, medium-dose-rate, or pulsed-dose-rate remote afterloader unit on a given day;
2. Before each patient treatment with a low-dose-rate remote afterloader unit; and
3. After each source installation.

(2) A licensee shall perform the measurements required by 41.2(59)“b”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(4) To satisfy the requirements of 41.2(59)“b”(1), spot checks must, at a minimum, ensure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit’s computer; and
8. Decayed source(s) activity in the unit’s computer.

(5) If the results of the spot checks required in 41.2(59)“b”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)“b”(4). The record must include:

1. The date of the spot check;
2. The manufacturer’s name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit’s computer; and
5. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required in 41.2(59)“b”(2) until the licensee no longer possesses the remote afterloader unit.

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks for the gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

(2) A licensee shall:

1. Perform the measurements required by 41.2(59)“c”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

2. Have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(3) To satisfy the requirements of 41.2(59)“c”(1)“1,” spot checks must, at a minimum:

1. Ensure proper operation of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; helmet microswitches; emergency timing circuits; and stereotactic frames and localizing devices (trunnions).

2. Determine:

- The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57);

- The difference between the measurement made in the above bulleted point and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

- Source output against computer calculation;
- Timer accuracy and linearity over the range of use;
- On-off error; and
- Trunnion centricity.

(4) To satisfy the requirements of 41.2(59) “c”(1) “2” and “3,” spot checks must ensure proper functioning of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

(5) A licensee shall arrange as soon as possible for the repair of any system identified in 41.2(59) “c”(3) that is not operating properly.

(6) If the results of the spot checks required in 41.2(59) “c”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain for three years a record of each spot check required by 41.2(59) “c”(3) and (4). The record must include:

1. The date of the spot check;
2. The manufacturer’s name, model number, and serial number for the gamma stereotactic radiosurgery unit and the survey instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, on-off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(8) A licensee shall retain a copy of the procedures required in 41.2(59) “c”(2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

41.2(60) Radiation surveys for teletherapy facilities.

a. In addition to the survey requirements in 641—40.36(136C), a person licensed under 641—41.2(136C) shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

b. The licensee shall make the survey required in 41.2(60) “a” at installation of a new source, and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the source.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason

the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) *Safety spot checks for teletherapy facilities.*

a. A licensee shall promptly check all systems listed in 41.2(59) "g" for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61) "a" indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program, the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);

b. Perform the survey required by 41.2(60) again; and

c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62) "a," and the results of the second survey; or

d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.*

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the NRC or an agreement state.

c. A licensee shall maintain a record of the full inspection and servicing for the duration of the use of the unit. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and gamma stereotactic radiosurgery unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) *Training for radiation safety officer.* Except as provided in 41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer as provided in 41.2(8) to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in 41.2(65) "d." The names of the board certifications

that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall:

(1) Require all candidates for certification to:

1. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

3. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2) Require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two years of either full-time practical training or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an agreement state, or in clinical nuclear medicine facilities providing either diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 41.2(68), 41.2(69), or 41.2(75); and

3. Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. Has:

(1) Completed a structured educational program consisting of both:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Radiation biology; and
- Radiation dosimetry; and

2. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an NRC or agreement state license or permit issued by the NRC master material licensee that authorizes similar types of use of byproduct material. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on an NRC or agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

- Shipping, receiving, and performing related radiation surveys;
- Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- Securing and controlling byproduct material;
- Using administrative controls to avoid mistakes in the administration of byproduct material;
- Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

- Using emergency procedures to control byproduct material; and

- Disposing of byproduct material; and

(2) This individual must obtain a written attestation signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in 41.2(65) "b"(1) and 41.2(65) "d" and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; or

c. (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(74)“a,” has experience in radiation safety aspects of similar types of use of byproduct material for which the licensee is seeking the approval of the individual as a radiation safety officer or an associate radiation safety officer, and meets the requirements in 41.2(65)“d”; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an NRC or agreement state license, a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement state licensee of broad scope, or a permit issued by an NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer and meets the requirements in 41.2(65)“d”; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by an NRC master material licensee. The individual must also meet the requirements in 41.2(65)“d”; and

d. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type of use for which the licensee is seeking approval.

41.2(66) Reserved.

41.2(67) *Training for uptake, dilution, and excretion studies.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 41.2(31) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 41.2(67)“c”(1)“1” and “2”; and

(2) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(68) or 41.2(69) or meets equivalent NRC or agreement state requirements; or

c. (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(67) “c”(1) and is able to independently fulfill the radiation safety-related duties as an authorized user under 41.2(31). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69), or 41.2(75) or equivalent NRC or agreement state requirements; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69), or 41.2(75), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(67) “c”(1).

41.2(68) Training for imaging and localization studies. Except as provided in 41.2(75), the licensee shall require the authorized user of unsealed byproduct material for the uses authorized under 41.2(33) to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 41.2(68) “c”(1) “1” and “2”; and

- (2) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

- b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68) “c”(1) “2,” seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

- c. (1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use;
- Radiation biology, and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) “c”(1) “2,” seventh bulleted paragraph; 41.2(75); or equivalent NRC or agreement state requirements. An authorized nuclear pharmacist who meets the requirements in 41.2(75) or 41.2(78) may provide the supervised work experience for the seventh bulleted paragraph of 41.2(68) “c”(1) “2.” Work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and
- Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(68) "c"(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) "c"(1)"2," seventh bulleted paragraph; or 41.2(75), or equivalent NRC or agreement state requirements; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) "c"(1)"2," seventh bulleted paragraph; or 41.2(75); or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(68) "c"(1).

41.2(69) Training for use of unsealed byproduct material for which a written directive is required. Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 41.2(37) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in 41.2(69) "b"(1)"2," seventh bulleted paragraph. The names of the board certificates that have been recognized by the NRC or agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 41.2(69) "b"(1)"1" through 41.2(69) "b"(1)"2," fifth bulleted paragraph. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

b. (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use; and
- Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69) "b" must also have experience in administering dosages

in the same dosage category or categories (i.e., 41.2(69) “b”(1)“2,” seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Reserved.

● Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this bulleted paragraph. Radioactive drugs containing radionuclides in categories not included are regulated under 41.2(88). This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

- Oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required;
- Oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 (experience with at least three cases in this category also satisfies the requirement in the above category);
- Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emissions, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69) “b”(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 41.2(37) for which the individual is requesting authorized user status. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or equivalent NRC or agreement state requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75) or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(69) “b”(1).

c. For training only for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) or quantities greater than 33 millicuries (1.22 gigabecquerels), see 41.2(81) or 41.2(82).

41.2(70) Training for use of manual brachytherapy sources. Except as provided in 41.2(75), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 41.2(43) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of the board certifications that have been recognized by the NRC or agreement state must be posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate

Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

b. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements at a medical facility authorized to use byproduct materials under 41.2(43), involving:

• Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Checking survey meters for proper operation;
- Preparing, implanting, and removing brachytherapy sources;
- Maintaining running inventories of material on hand;
- Using administrative controls to prevent a medical event involving the use of radioactive material; and
- Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70) “*b*”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(70) “*b*”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 41.2(43). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(70), 41.2(75), or equivalent NRC or agreement state requirements; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(70), 41.2(75), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(70) “*b*”(1) and (2).

41.2(71) Training for ophthalmic use of strontium-90. Except as provided in 41.2(75), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under 41.2(70) or equivalent NRC or agreement state requirements; or

b. (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and
- (2) Has completed supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
 1. Examination of each individual to be treated;
 2. Calculation of the dose to be administered;
 3. Administration of the dose; and
 4. Follow-up and review of each individual's case history; and
- (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70), 41.2(71) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71) "b"(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

41.2(72) Training for use of sealed sources for diagnosis. Except as provided in 41.2(75), the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under 41.2(41) to be a physician, dentist, or podiatrist who:

- a. Is certified by a specialty board whose certification process includes all of the requirements in 41.2(72) "c" and "d" and whose certification has been recognized by the NRC or an agreement state. The names of the board certificates that have been recognized by the NRC or agreement state must be posted on the NRC's Medical Uses Licensee Toolkit web page; or
- b. Is an authorized user for uses listed in 41.2(33) or equivalent NRC or agreement state requirements; or
- c. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
- d. Has completed training in the use of the device for the uses requested.

41.2(73) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in 41.2(75), the licensee shall require an authorized user of a sealed source for a use authorized under 41.2(49) to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in 41.2(73) "c." The names of board certification that have been recognized by the NRC or agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - (1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
 - (2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or
- b. (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
 1. 200 hours of classroom and laboratory training in the following areas:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity; and
 - Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements at a medical facility that is authorized to use byproduct material in 41.2(49), involving:

- Reviewing full calibration measurements and periodic spot checks;
- Preparing treatment plans and calculating treatment doses and times;
- Using administrative controls to prevent a medical event involving the use of radioactive material;
- Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- Checking and using survey meters; and
- Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)“b”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)“b”(1) and (2) and 41.2(73)“c” and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(73), 41.2(75), or equivalent NRC or agreement state requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(73)“b”(1) and (2); and

c. Has received training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type of use for which the individual is seeking authorization.

41.2(74) Training for an authorized medical physicist. Except as provided in 41.2(75), the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(74)“c.” The names of the board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of either full-time practical training or supervised experience in medical physics:

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized under this rule by the NRC or an agreement state; or

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 41.2(70), 41.2(73), or 41.2(75); and

(3) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

b. (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;
2. Performing decay corrections;
3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and
4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74) "b"(1) and "c" and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

c. Has training for the type of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist who is authorized for the type of use for which the individual is seeking authorization.

41.2(75) Training for experienced radiation safety officer, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, authorized users and teletherapy or medical physicists.

a. (1) An individual identified on an NRC or agreement state license, on a permit issued by the NRC or agreement state broad scope licensee, on a master material license permit, or by a master material license permittee of broad scope as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before July 22, 2020, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78), respectively, except the radiation safety officers and authorized medical physicists identified in this paragraph must meet the training requirements in 41.2(65) "d" or 41.2(74) "c," as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in comprehensive health physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 41.2(65) to be identified as a radiation safety officer or as an associate radiation safety officer on an NRC or an agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 41.2(74), for those materials and uses that these individuals performed on or before October 24, 2005.

b. (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the NRC or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before July 22, 2020, who perform only those medical uses for which they were authorized before that date need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material issued by the NRC or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized on or before October 24, 2005, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89) for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

1. For uses authorized under 41.2(31) or 41.2(33), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

2. For uses authorized under 41.2(37), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

3. For uses authorized under 41.2(43) or 41.2(49), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

4. For uses authorized under 41.2(41), a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89) when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this rule.

c. Individuals who need not comply with training requirements as described in this subrule may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency license for the same uses for which these individuals are authorized.

41.2(76) Reserved.

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(78) and 41.2(81), 41.2(82), 41.2(85), and 41.2(89) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

41.2(78) *Training for an authorized nuclear pharmacist.* Except as provided in 41.2(75), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of combined training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

b. Has completed 700 hours in a structured education program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4. Using administrative controls to avoid medical events in the administration of byproduct material; and

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

c. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78) "b" and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

41.2(79) and 41.2(80) Reserved.

41.2(81) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(81) "c" (1) and (2) and whose certification process has been recognized by the NRC or an agreement state. The names of the board certifications that have been recognized by the NRC or agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page; or

b. Is an authorized user under 41.2(69) "a" or "b" for uses in the oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or 41.2(82) or equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) "a" or "b," 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69) "b" must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81) "c" (1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for medical uses authorized under 41.2(37). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements and has experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81), 41.2(82), or equivalent NRC or agreement state requirements; has experience in administering dosages orally as specified in 41.2(69) "b" (1) "2," seventh bulleted paragraph; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(81) "c" (1) and (2).

41.2(82) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee

shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(82)“c”(1) and (2), and whose certification has been recognized by the NRC or agreement state. The names of the board certifications that have been recognized by the NRC or agreement state must be posted on the NRC’s Medical Uses Licensee Toolkit web page; or

b. Is an authorized user under 41.2(69)“a” or “b” for oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or meets equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)“a” or “b,” 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b” must also have experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)“c”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for medical uses authorized in 41.2(37). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements and has experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(82), or equivalent NRC or agreement state requirements; has experience in administering dosages orally with greater than 33 millicuries of sodium iodide I-131, as specified in 41.2(69)“b”(1)“2,” seventh bulleted paragraph; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(82)“c”(1) and (2).

41.2(83) *Provisions for the protection of human research subjects.*

a. A licensee may conduct research involving human research subjects only if the licensee uses the radioactive materials authorized on its specific license for the uses authorized on its license.

b. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

d. Nothing in this subrule relieves a licensee from complying with the other requirements of these rules.

41.2(84) Calibration measurements of brachytherapy sources.

a. Before the first medical use of a brachytherapy source on or after January 1, 2003, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of 41.2(57);

(2) Determined the source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 41.2(84) "a."

b. A licensee may use measurements that are provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine and that are made in accordance with 41.2(84) "a"(1) and (2).

c. A licensee shall mathematically correct the outputs or activities determined in 41.2(84) "a" for physical decay at intervals consistent with 1 percent physical decay.

d. A licensee shall retain a record of each calibration for three years after the last use of the source. The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

41.2(85) Strontium-90 sources for ophthalmic treatment.

a. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 41.2(85) "b" are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

1. Is identified as an ophthalmic physicist on a specific medical use license issued by the NRC or an agreement state, permit issued by an NRC or agreement state broad scope medical use licensee, medical use permit issued by an NRC master material licensee, or permit issued by an NRC master material licensee broad scope medical use permittee; and

2. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

3. Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

4. Has documented training in:

- The creation, modification, and completion of written directives;
- Procedures for administrations requiring a written directive; and
- Performing the calibration measurements of brachytherapy sources as detailed in 41.2(84).

b. The individuals who are identified in 41.2(85) "a" must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(84); and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 41.2(85) "a" will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

c. A licensee shall retain a record of the activity of each strontium-90 source for the life of the source. The record must include:

(1) The date and initial activity of the source under 41.2(84); and

(2) For each decay calculation, the date and the source activity as determined under this subrule.

41.2(86) *Therapy-related computer systems.* The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance must include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine sealed source positions from radiographic images; and

e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable.

(2) The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

b. Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 microcuries of sodium iodide I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate setting per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions and total dose;

(6) For permanent implant brachytherapy:

1. Before implantation: the treatment site, the radionuclide, and the total source strength; and

2. After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or

(7) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radionuclide, and dose; and

2. After implantation but prior to completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or, equivalently, the total dose), and date;

(8) For therapeutic use of radiation machines, see 41.3(14).

c. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

d. The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives.

e. Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41.

f. Determine if a reportable medical event, as described in 641—38.2(136C), has occurred.

g. Determine, for a permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the postimplantation portion of the written directive, unless a written justification of patient unavailability is documented.

h. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable.

(2) The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

i. A copy of the written directive in auditable form shall be retained for three years after the date of administration.

41.2(88) *Other medical uses of byproduct material or radiation from byproduct material.* A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C) (e.g., Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency; and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

41.2(89) *Training for the parenteral administration of unsealed byproduct material requiring a written directive.*

a. Except as provided in 41.2(75), the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

(1) Is an authorized user under 41.2(69) for parenteral administration uses listed in 41.2(69) "b"(1)"2," seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

(2) Is an authorized user under 41.2(70) or 41.2(73) or equivalent NRC or agreement state requirements, and who meets the requirements in 41.2(89) "b"; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73) and who meets the requirements in 41.2(89) "b";

or

b. The physician:

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in 41.2(69) “b”(1)“2,” seventh bulleted paragraph. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements, in the parenteral administration listed in 41.2(69) “b”(1)“2,” seventh bulleted paragraph. A supervising authorized user who meets the requirements in 41.2(69), 41.2(89), or equivalent NRC or agreement state requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
5. Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration as specified in 41.2(69) “b”(1)“2,” seventh bulleted paragraph; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89) “b”(1) or (2), and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(89) or equivalent NRC or agreement state requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(89), or equivalent NRC or agreement state requirements; has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(89) “b”(1) and (2).

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641—41.3(136C) Therapeutic use of radiation machines.

41.3(1) Scope and applicability.

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(5).

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), the following definitions are specific to 641—41.3(136C).

“*Accessible surface*” means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

“*Added filtration*” means any filtration which is in addition to the inherent filtration.

“*Beam-limiting device*” means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

“*Beam-scattering foil*” means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

“*Bent beam linear accelerator*” means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

“*Contact therapy system*” means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than 5 centimeters.

“*Dose monitor unit (DMU)*” means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

“*External beam radiation therapy*” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“*Field flattening filter*” means a filter used to homogenize the absorbed dose rate over the radiation field.

“*Filter*” means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

“*Gantry*” means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

“*Interruption of irradiation*” means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

“*Isocenter*” means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

“*Megavolt (MV) (mega electron volt (MeV))*” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

“*Monitor unit (MU)*.” See “Dose monitor unit.”

“*Moving beam radiation therapy*” means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

“*Nominal treatment distance*” means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

“*Periodic quality assurance check*” means a procedure which is performed to ensure that a previous calibration continues to be valid.

“*Practical range of electrons*” corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in “Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25” (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, “Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV,” International Agency on Radiation Units and Measurements, September 15, 1984.

“*Radiation field.*” See “Useful beam.”

“*Radiation head*” means the structure from which the useful beam emerges.

“*Radiation therapy physicist*” means an individual qualified in accordance with 41.3(6).

“*Redundant beam monitoring system*” means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

“*Shadow tray*” means a device attached to the radiation head to support auxiliary beam blocking material.

“*Stationary beam radiation therapy*” means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

“*Target*” means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

“*Tenth-value layer (TVL)*” means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

“*Therapeutic radiation machine*” means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

“*Virtual source*” means a point from which radiation appears to originate.

41.3(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 641—39.4(136C).

41.3(4) General administrative requirements for facilities using therapeutic radiation machines.

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant’s agent shall ensure that the requirements of 641—41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

- (1) Radiology or therapeutic radiology by the American Board of Radiology; or
- (2) Radiation oncology by the American Osteopathic Board of Radiology; or
- (3) Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or
- (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5) “*b*” above, the classroom and laboratory training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of ionization radiation; and
- (4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4) “*b*” above, training shall be under the supervision of an authorized user and shall include:

- (1) Reviewing the full calibration measurements and periodic quality assurance checks;
- (2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;
- (3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Postadministration follow-up and review of case histories.

f. Notwithstanding the requirements of 41.3(5) "b," the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

g. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant.

41.3(6) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

a. Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

(5) Therapeutic medical physics; or

c. Be certified by the American Board of Medical Physics in radiation oncology physics; or

d. Be certified by the Canadian College of Physicists in Medicine; or

e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16) "a," 41.3(17) "c" and "d," and 41.3(18) "e" and "f" under the supervision of a radiation therapy physicist during the year of work experience.

41.3(7) Qualifications of operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and hold a current permit to practice in radiation therapy as a radiation therapist under the provisions of 641—Chapter 42. The permit holder shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under the following conditions:

- a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;
- b. The visiting authorized user meets the requirements of 41.3(5); and
- c. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the agency:

- a. Report of acceptance testing;
- b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 641—41.3(136C), as well as the name(s) of person(s) who performed such activities;
- c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;
- d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.
- e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) Records retention. All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 641—41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

41.3(13) Reserved.

41.3(14) Written directives. Each registrant shall meet the following:

a. A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

(4) The registrant shall retain a copy of the written directive for three years.

b. Procedures for administration. The registrant shall have written procedures that provide the following information:

(1) Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

1. Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive; and
2. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;
- (4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and
- (5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

41.3(15) Reports and notifications of misadministrations.

a. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

b. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose results in:

(1) A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin, and either:

1. The total dose delivered differs from the prescribed dose by 20 percent or more; or
2. The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

1. An administration of the wrong treatment modality;
2. An administration to the wrong individual or human research subject.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

c. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

d. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

- (1) The registrant's name;
- (2) The name of the prescribing physician;
- (3) A brief description of the event;
- (4) Why the event occurred;
- (5) The effect, if any, on the individual or individuals who received the misadministration;
- (6) Actions, if any, that have been taken, or are planned, to prevent recurrence;
- (7) Certification that the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not.

e. The report to the agency shall not contain the individual's name or any other information that could lead to the identification of the individual.

f. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the referring physician will inform the individual or that, based on medical judgment, the physician's telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that

individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

g. Aside from the notification requirement, nothing in this subrule affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to individuals' responsible relatives or guardians.

h. A copy of the record required in this subrule shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration.

i. Records of misadministrations. A registrant shall retain a record of misadministrations reported in this subrule for three years. The record must contain the following:

- (1) The registrant's name and the names of the individuals involved;
- (2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;
- (3) A brief description of the event; why it occurred; and the effect, if any, on the individual;
- (4) The actions, if any, taken or planned to prevent recurrence; and
- (5) Whether the registrant notified the individual or the individual's responsible relative or guardian, and, if not, whether such failure to notify was based on guidance from the referring physician.

41.3(16) General technical requirements for facilities using therapeutic radiation machines.

a. Protection surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.15(1); and
2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraphs 40.26(1) "a" and "b."

(2) In addition to the requirements of 41.3(16) "a"(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;
2. After making any change in the location of the therapeutic radiation machine within the treatment room;
3. After relocating the therapeutic radiation machine; or
4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(4) If the results of the surveys required by 41.3(16) "a"(1) or (2) indicate any radiation levels in excess of the respective limit specified in 41.3(16) "a"(1), the registrant shall lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

2. Until the registrant has received a specific exemption in writing from the agency.
 - b. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 41.3(16)“a” indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—paragraphs 40.26(1)“a” and “b,” before beginning the treatment program the registrant shall:
 - (1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—paragraphs 40.26(1)“a” and “b”;
 - (2) Perform the survey required by 41.3(16)“a” again; and
 - (3) Include in the report required by 41.3(16)“d” the results of the initial survey, a description of the modification made to comply with 41.3(5)“b”(1), and the results of the second survey; or
 - (4) Request and receive written authorization from the agency that authorizes radiation levels in unrestricted areas greater than those permitted by 641—paragraphs 40.26(1)“a” and “b.”
 - c. Dosimetry equipment.
 - (1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.
 1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.
 2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.
 - (2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16)“c”(1). This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16)“c”(1).
 - (3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16)“c”(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.
 - d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16)“a” and “b” to the agency within 30 days following completion of the action that initiated the record requirement.
 - 41.3(17) Therapeutic radiation machines of less than 500 kV.**
 - a. Equipment requirements.
 - (1) Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:
 1. 5-50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.
 2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.
 3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)“a”(1)“1” and 41.3(17)“a”(1)“2” for the

specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

(2) Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam-limiting devices.

1. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;

3. Means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Multiple tubes. When a control panel may energize more than one X-ray tube:

1. It shall be possible to activate only one X-ray tube at any time;
2. There shall be an indication at the control panel identifying which X-ray tube is activated; and
3. There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the treatment room shall meet the following design requirements:

(1) Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(3) Additional requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;
2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in 41.3(17) "b"(3)"3" is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

c. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(17) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
2. At intervals not exceeding one year; and
3. Before medical use under the following conditions:
 - Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
 - Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
4. Notwithstanding the requirements of 41.3(17) "c"(1):

- Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and

- If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 41.3(17) "b"(3).

(2) To satisfy the requirement of 41.3(17) "c"(1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

d. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to 41.3(17), which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 41.3(17) "d"(1), quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 41.3(17) "c"(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 41.3(17) "c"(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in 41.3(17) "c"(1);

(5) The registrant shall use the dosimetry system described in 41.3(16) "c"(2) to make the quality assurance check required in 41.3(17) "d";

(6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 41.3(17) are performed at intervals not to exceed one month;

(8) Notwithstanding the requirements of 41.3(17) "d"(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 41.3(17) "d"(6) and (7) have been performed within the 30 days prior to administration;

(9) To satisfy the requirement of 41.3(17) "d"(7), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. The "BEAM-ON" and termination switches;

3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(17) "d"(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine,

the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

e. Operating procedures.

(1) Therapeutic radiation machines shall not be left unattended unless secured by means identified in 41.3(17)“a”(9)“5”;

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—40.26(136C).

(6) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 41.3(17)“c” and “d” have been met.

f. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(17) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

41.3(18) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

a. Equipment requirements.

(1) Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 41.3(18)“a”(1)“1,” the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 41.3(18)“a”(1)“1” to “3” for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the agency.

(2) Leakage radiation through beam-limiting devices.

1. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the

area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10-centimeter by 10-centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
- A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of leakage radiation.

1. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters;

2. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector with an area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.

(4) Filters/wedges.

1. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 41.3(18)“a”(9) relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such filter or foil shall be removable only by the use of tools;

3. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

- Irradiation shall not be possible until a selection of a filter or a positive selection to use “no filter” has been made at the treatment control panel, either manually or automatically;
- An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and interchangeable beam-scattering foil(s) in use; and
- An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

(5) Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision).

(6) Beam monitors. All therapeutic radiation machines subject to 41.3(18) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated shall meet the following requirements:

- Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

- Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

- Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

3. For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that the:

- Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

- Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

4. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

- Maintain a reading until intentionally reset;

- Have only one scale and no electrical or mechanical scale multiplying factors;

- Utilize a design such that increasing dose is displayed by increasing numbers; and

- In the event of power failure, the beam monitoring information required in 41.3(18)“a”(6)“4” displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

(7) Beam symmetry.

1. Bent-beam linear accelerators with beam-flattening filter(s) subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 41.3(18)“a”(7)“1” shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

(8) Selection and display of dose monitor units.

1. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

2. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

3. For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

4. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

(9) Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 41.3(18)“a”(6) may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 41.3(18) "a"(7)"2" and "3" for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and
3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.
4. For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
2. The mode of operation shall be displayed at the treatment control panel;
3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;
4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value;
- Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;
- An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;
- An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.
- Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18)“a”(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

- Occurs during stationary beam radiation therapy; or
- Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 641—41.3(136C), the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced; and

4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1) "a" and "b," interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18) "a"(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18) "e" and protection surveys required by 41.3(16) "a";

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18) "f"(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by 41.3(18) “d” shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16) “a,” 41.3(18) “e,” and 41.3(18) “f” have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Acceptance testing, commissioning, and full calibration measurements.

(1) Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Acceptance testing and commissioning shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45, and the manufacturer’s contractual specifications and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41 and shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and

- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18) “e”(1)“3.”

(2) The registrant shall use the dosimetry system described in 41.3(16) “c” to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals as specified in Appendix D of 641—Chapter 41;

(2) To satisfy the requirement of 41.3(18)“f”(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in 41.3(16)“c”(1) to make the periodic quality assurance checks required in 41.3(18)“f”(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18)“f”(1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week or at longer intervals as recommended by the manufacturer;

(7) To satisfy the requirement of 41.3(18)“f”(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. Proper operation of the “BEAM-ON,” interrupt and termination switches;
3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
4. Viewing systems;
5. Aural systems;
6. Electrically operated treatment room door(s) from inside and outside the treatment room;
7. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(8) Reserved.

(9) The registrant shall promptly repair any system identified in 41.3(18)“f”(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)“f”(1) and 41.3(18)“f”(7) for three years. The record shall include the date of the quality assurance check, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the manufacturer’s name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) Shielding and safety design requirements.

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved

for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

41.3(20) Calibration of survey instruments.

a. The registrant shall ensure that the survey instruments used to show compliance with 641—41.3(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

b. To satisfy the requirements of 41.3(20), the registrant shall:

(1) Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full scale;

(3) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(4) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

c. The registrant shall retain a record of each calibration required in 41.3(20) for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

d. The registrant may obtain the services of individuals licensed by this agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in 41.3(20) shall be maintained by the registrant.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—41.4 and 41.5 Reserved.

641—41.6(136C) X-ray machines used for screening and diagnostic mammography.

41.6(1) Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

“*Accreditation body*” means an entity that has been approved by FDA to accredit mammography facilities.

“*Action limits*” or “*action levels*” means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

“*Adverse event*” means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;

2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

3. Use of personnel who do not meet the applicable requirements of this chapter.

“*Air kerma*” means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

“*Annually*” means within 10 to 14 months of previous occurrence.

“*Artifact*” means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

“Automatic exposure control systems” means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

“Average glandular dose” means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. For a 50 percent-50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy). See also: “Dose.”

“Breast implant” means a prosthetic device implanted in the breast.

“Calendar quarter” means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

“Category 1” means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

“Certificate” means the certificate described in 41.6(2)“a”(2).

“Certification” means the process of approval of a facility by the FDA or this agency to provide mammography services.

“Clinical image” means a mammogram.

“Compression device” means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

“Computed radiography mammography” means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

“Consumer” means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

“Contact hour” means an hour of training received through direct instruction.

“Continuing education unit” or *“continuing education credit”* means one contact hour of training.

“Craniocaudal view” means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

“Dedicated mammography equipment” means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

“Direct detector technology” means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

“Direct instruction” means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or
2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

“Direct supervision” means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient’s records; or
2. During the performance of a mammography examination or survey of the facility’s equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the

performance of the individual being supervised who is performing the examination or conducting the survey.

“*Dose*” means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

“*Exposure*” means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen= $2.58 \times 10E-4$ Coulombs of charge per kilogram of air.

“*Facility*” means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

“*FDA*” means the Food and Drug Administration.

“*First allowable time*” means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The “first allowable time” may vary with the certifying body.

“*Full field digital mammography*” means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

“*Grids*” means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

“*Image noise.*” See “Radiographic noise.”

“*Image receptor support device*” means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

“*Interpreting physician*” means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)“a.”

“*Kerma*” means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

“*Laterality*” means the designation of either the right or left breast.

“*Lead interpreting physician*” means the interpreting physician assigned the general responsibility for ensuring that a facility’s quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

“*Mammogram*” means a radiographic image produced through mammography.

“*Mammographic modality*” means a technology for radiography of the breast. Examples are screen-film mammography, xeromammography, and digital mammography.

“*Mammography*” means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or
2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or
3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

“*Mammography equipment evaluation*” means an on-site assessment of the mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

“Mammography medical outcomes audit” means a systematic collection of mammography results and the comparison of those results with outcomes data.

“Mammography unit(s)” means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

“Mean optical density” means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

“Medical physicist” means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)“c.”

“Mediolateral view” means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

“MQSA” means the Mammography Quality Standards Act of 1992.

“Multi-reading” means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

“Oblique mediolateral view” means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30-60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

“Patient” means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

“Phantom” means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

“Phantom image” means a radiographic image of a phantom.

“Physical science” means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

“Positive mammogram” means a mammogram that has an overall assessment of findings that are either “suspicious” or “highly suggestive of malignancy.”

“Provisional certification” means the six-month certification time period in which a facility has to complete the accreditation/certification process.

“Qualified instructor” means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers’ representatives.

“Quality control technologist” means an individual meeting the requirements of 41.6(5)“a”(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

“Radiographic equipment” means X-ray equipment used for the production of static X-ray images.

“*Radiologic technologist*” means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3)“b.”

“*Radiologist continuing experience*” means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

“*Reinstatement*” means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

“*Screen-film mammography*” means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

“*Screening mammography*” means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

“*Serious adverse event*” means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

“*Serious complaint*” means a report of a serious adverse event.

“*Standard breast*” means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

“*Supplier*” means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

“*Survey*” means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

“*Time cycle*” means the film development time.

“*Traceable to a national standard*” means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

“*Written report*” means interpreting physician’s technical narrative of a mammography evaluation.

“*Written statement*” means interpreting physician’s description of a mammography examination written in lay terms.

41.6(2) Registration and application standards and requirements.

a. Registration and certificates.

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for agency approval by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for agency-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional or reinstatement certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional or reinstatement certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive provisional or reinstatement certification, a facility must meet the requirements of 641—41.6(136C). Provisional or reinstatement certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for one 90-day extension.

c. Suspension, revocation, or denial of mammography certification.

(1) Mammography certification may be suspended or revoked with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the certification.

(2) The facility shall have opportunity for a hearing in connection with a denial, suspension or revocation of mammography certification in accordance with 641—Chapter 173.

(3) An emergency order suspending or revoking certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If certification is revoked, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

d. Reinstatement of mammography certification after revocation.

(1) An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions must be submitted with the application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A full certificate shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial mammography certification and at least annually thereafter.

f. The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility will:

(1) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and

3. Each mammography examination must have been interpreted as a “negative” or “benign” examination.

(2) Provide randomly, at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)“f”(1).

(3) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.

(4) Be billed the fee for the quality review process as set forth in 641—subparagraph 38.8(1)“b”(2).

(5) Be provided with a written explanation of the results of the quality review process which will accompany the returned mammograms referred to in 41.6(2)“f”(3).

g. Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.

h. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Part 900 which has an effective date of April 28, 1999. Persons certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

i. Soft copy review workstation requirements.

(1) Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two monitors that meet one of the following criteria:

1. Have 5 megapixel resolution; or
2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

(2) The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer’s quality control manual or that outlined by the image receptor manufacturer’s designated soft copy review workstation quality control manual.

41.6(3) Mammography personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. *Interpreting physicians.* All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)“a”(3)“1” applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;
2. Either:
 - Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or
 - Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)“a”; and

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, and physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 15 of the Category 1 hours shall have been acquired within the 36 months immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution;

4. Unless the exemption in 41.6(3)“a”(3)“2” applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician; and

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in

the new mammographic modality or at least 8 hours of training in the new mammographic modality provided by a vendor manufacturing the new mammographic modality equipment. An interpreting physician previously qualified to interpret a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa new mammographic modality interpretation.

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)“a”(2)“2” even if the course is taught multiple times during the previous 36 months.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)“a” or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)“a.” They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)“a”(1)“1” and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from 41.6(3)“a”(1)“4.”

(4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)“a”(2)“1” shall:

- Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

- Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician’s total to at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)“a”(4)“1” shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)“a”(2)“2” shall obtain a sufficient number of additional Category 1 continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Have qualified as a radiologic technologist under 41.6(3)“b” before April 28, 1999, or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of at least a two-year radiography program. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)“b”; and

3. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)“b”(2)“3,” the technologist shall have at least 8 hours of continuing education units in the new modality. The 8 hours may not be derived from the supervised examination of patients; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)“b”(3)“1” even if the course is taught multiple times during the previous 36 months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)“b”(3)“1” shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

(4) Continuing experience requirements.

1. Following the second anniversary date on which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

3. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review

of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)“c”(2) shall meet the following:

- (1) Initial qualifications.
 1. Be Iowa approved; and
 2. Have a master’s degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;
 3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and
 4. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or
- (2) Alternative initial qualifications.
 1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and
 2. Prior to April 28, 1999, have:
 - A bachelor’s degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics.
 - Forty contact hours of documented specialized training in conducting surveys of mammography facilities.
 - Experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.
 - At least eight hours of training in surveying units of the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.
- (3) Continuing qualifications.
 1. Continuing education. Following the third anniversary date on which the requirements of 41.6(3)“c”(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course shall be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.
 2. Continuing experience. Following the second anniversary date on which the requirements of this subrule were completed, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days shall be counted towards this requirement.
 3. Continuing qualifications must be met whenever medical physics services are provided by the medical physicist.
- (4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified

medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

41.6(4) Obtaining and preserving records.

a. The facility performing the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from other facilities, for comparison with the current mammography records.

b. The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

- (1) The date the mammography procedure was performed.
- (2) The date of the interpretation.
- (3) The name of the interpreting physician.
- (4) The name of the patient and an additional patient identifier.
- (5) A description of the procedures performed.
- (6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Assessment" with the appropriate assessment term. One of the following terms in quotations or an approved equivalent must be included in the assessment:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign": Also a negative assessment.

3. "Probably benign": Finding(s) has a high probability of being benign.

4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.

6. "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment in cases where no final assessment category can be assigned due to incomplete workup, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(10) Information on a patient's breast density, as categorized by an interpreting physician at the facility based on standards as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the breast imaging reporting and data system of the American College of Radiology.

c. Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service, as long as the patient continues consecutive mammograms. If no additional mammograms of the patient are performed, the records must be retained for at least ten years.

(3) If the facility should cease to exist before the end of the retention period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4) "e"(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

(3) The breast density information as designated in the report pursuant to 41.6(4) "b"(10) shall be included in the patient lay letter with a reference to a department-accepted site or document where the patient can obtain more information about breast density. For patients categorized as having heterogeneously dense breasts or extremely dense breasts, or an equivalent determination by another nationally recognized density gradient system, the notification to the patient shall include evidence-based information on dense breast tissue, the increased risk associated with dense breast tissue, and the effects of dense breast tissue on screening mammography and shall be stated in language appropriate for the facility's patient population.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including all of the items listed in 41.6(4) "b," to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

41.6(5) Quality assurance program.

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5) "e" through "k."

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting or training others to conduct equipment performance monitoring functions.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d. Calibration of equipment. All variable parameters of the equipment shall be calibrated:

(1) When the equipment is first installed.

(2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored for film-screen mammography shall include but not be limited to:

(1) Processor performance (through daily sensitometric-densitometric means).

(2) Half-value layer.

- (3) Output reproducibility and linearity.
- (4) Automatic exposure control reproducibility and linearity.
- (5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

- (1) Processor performance shall be accomplished daily before processing patient films.
- (2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.
- (3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results. Full field digital mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer's quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 millirad for film-screen units with no grids, 300 millirad for film-screen units with grids, or 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5) "k." If the results fall outside the acceptable range, the test shall be repeated. For film-screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted. For full field digital mammography, if any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

h. Retake analysis program—film-screen and full field digital.

- (1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.
- (2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.
- (3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up. The reviewing physician shall sign the medical audit as proof of the evaluation of the data.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

k. Quality assurance—equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be below plus 0.03 of the established operating level.
2. The mid-density shall be within plus or minus 0.15 of the established operating level.
3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.

4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

- Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3. Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

- The AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

- The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

- The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.

- At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Facilities shall evaluate focal spot condition only by determining the system resolution.

- Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

- The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.

- When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.

- When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.

- Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

- Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

- All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.
- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.
- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5) “k”(5)“6.”

(7) Use of test results.

1. After completion of the tests specified in 41.6(5) “k,” the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer’s recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside the action limits, the source of the problem shall be identified, and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5) “k.”

3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer’s quality control manual or in accordance with the appropriate FDA-approved alternative requirements.

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5) “k”(5) and (6), the weekly phantom image quality test described in 41.6(5) “k”(2) and the quarterly retake analysis results described in 41.6(5) “h.”

2. The results of all tests conducted by the facility in accordance with 41.6(5) “k”(1) through (7) for film-screen units, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey. Surveys of full field digital mammography units shall be conducted as described in the appropriate manufacturer’s quality control manual. The results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted at new installations, at disassembly, at reassembly, at the same or a new location, or when major components are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must

be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

l. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

41.6(6) Equipment standards. The equipment used to perform mammography shall meet the following standards:

a. Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

b. Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

c. Image receptor systems: Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 × 24 centimeters and 24 × 30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Light fields: For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

f. Tube-image receptor assembly:

(1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with this subrule shall not fail in the event of power interruption.

g. Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

h. Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for “spot compression”), may be provided. Such compression paddles for special purposes are not subject to 41.6(6) “i”(6) and (7).

(4) Except as provided in 41.6(6) “i”(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

j. Grids: Shall have the capability for using antiscatter grids.

k. AEC: Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

- The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

- The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

l. Control panel: Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Has manual selection of milliamperere seconds (mAs) or at least one of its component parts (milliamperere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.

m. mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

s. Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

t. Mobile units and vans—film-screen.

(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.

u. Mobile units and vans—full field digital. Appropriate manufacturer’s quality control manual procedures and criteria shall be met.

41.6(7) Safety standards for mammography equipment.

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall be monitored in accordance with 641—40.37(136C).

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

HVL	Mo/Mo Target Filter X-Ray Voltage (kVp)											W/AI Target Filter Combination	
	23	24	25	26	27	28	29	30	31	32	33		
0.23	109												
0.24	113	116											
0.25	117	120	122										
0.26	121	124	126	128									
0.27	126	128	130	132	134								
0.28	130	132	134	136	138	139							
0.29	135	137	139	141	142	143	144						
0.30	139	141	143	145	146	147	148	149					170
0.31	144	146	147	149	150	151	152	153	154				175
0.32	148	150	151	153	154	155	156	158	159	160	160		180
0.33	153	154	155	157	158	159	160	162	163	164	164		185
0.34	157	159	160	161	162	163	164	166	167	168	168		190
0.35		163	164	166	167	168	169	170	171	172	172		194
0.36			168	170	171	172	173	174	175	176	176		199
0.37				174	175	176	177	178	178	179	180		204
0.38					179	180	181	182	182	183	184		208
0.39						184	185	186	186	187	188		213
0.40							189	190	191	192	192		217
0.41								194	195	196	196		221
0.42										200	200		225
0.43											204		230
0.44													234
0.45													238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of $(0.50 \text{ R}) \times (174 \text{ mrad/R}) = 87 \text{ mrad}$ or 0.87 mGy.

*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159-175, 1991. W/AI conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.

RULE 641—41.6(136C)—APPENDIX I
Rescinded IAB 4/5/00, effective 5/10/00

RULE 641—41.6(136C)—APPENDIX II

Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure

4.5-cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

[ARC 1401C, IAB 4/2/14, effective 5/7/14; ARC 3393C, IAB 10/11/17, effective 11/15/17]

641—41.7(136C) X-ray machines used for stereotactically guided breast biopsy.

41.7(1) Definitions. In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

“*Collaborative setting*” means a setting in which a qualified radiologist and surgeon (under 41.7(3) “a” or 41.7(3) “c”) are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient’s benefit.

“*Procedure*” means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

“*Qualified training physician*” means a physician who is qualified under 41.7(3) to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

“*Stereotactically guided breast biopsy*” means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

“*Supervising physician*” means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

41.7(2) Registration and application standards and requirements.

a. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Suspension, revocation, or denial of authorization.

(1) Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial, suspension, or revocation of authorization.

(3) An emergency order suspending or revoking authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the

public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is revoked, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application. If the reinstatement is after a revocation, appropriate corrective action shall be submitted with the application.

(3) A full reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

41.7(3) Physicians. Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)“*a.*”

2. Shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in 41.7(3)“*a*”(1)“2” above and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

5. Shall be responsible for the supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year. If experience is not maintained, the physician must requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be licensed to practice medicine in Iowa.

2. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

3. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to perform stereotactic biopsy procedures according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for post-biopsy management of the patient.

5. Shall be responsible for supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)“*a.*”

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)“*c*”) performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be licensed to practice medicine in Iowa.

2. Must have evaluated at least 480 mammograms in the prior 24 months in consultation with a physician who is qualified according to 41.6(3)“*a.*”

3. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years’ experience having performed at least 36 stereotactically guided breast biopsies.

4. Must have four hours of Category 1 CME in medical radiation physics.

5. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.
8. Must be responsible for post-biopsy management of the patient.
- (2) Maintenance of proficiency and CME requirements.
 1. Continue to evaluate at least 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3)“a.”
 2. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.
 3. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.
 4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

41.7(4) Medical physicist.

- a. Must be qualified according to 41.6(3)“c.”
- b. Must have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4)“a” and 41.7(4)“b.”
- c. Maintenance of proficiency and continuing education requirements.
 - (1) Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist; and
 - (2) Following the third anniversary in which the requirements of this subrule were met, have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months.

41.7(5) Radiologic technologist.

- a. Must be qualified according to 41.6(3)“b.”
- b. Must meet the following initial requirements:
 - (1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a physician or technologist qualified under rule 641—41.7(136C).
 - (2) Three hours of continuing education in stereotactically guided breast biopsy. The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.
- c. Maintenance of proficiency and continuing education and experience requirements.
 - (1) Following the first anniversary in which the requirements of this subrule were met, have performed at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a physician or radiologic technologist qualified under 41.7(3) or 41.7(5).
 - (2) Following the third anniversary in which the requirements of this subrule were met, have at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.
 - (3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24 months during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3)“b”(4)“1.”

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

41.7(6) *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

- (1) The date of the procedure.
- (2) The name of the patient and one additional patient identifier.
- (3) The name of the radiologic technologists and physicians performing the procedure.
- (4) A description of the service provided.
- (5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. The facility shall name a supervising stereotactic biopsy physician who shall be responsible for:

- (1) Quality assurance activities including the medical audit,
- (2) Oversight of the quality control program, and
- (3) Supervision of the radiologic technologist(s) and the medical physicist.

d. Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

2. Collimation.

• Digital – X-ray field must not extend beyond the image receptor by more than 5 mm on any side.

• Film-screen – On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.

• Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

• Digital – Focal spot must not degrade from initial measurement. If reduction in lp/mm is found, focal spot must be corrected within 30 days of survey.

• Film-screen – Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.5 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.

- Digital – Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.

- Film-screen – Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.

- Failures must be corrected before further procedures are performed.

9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field must be corrected within 30 days of the survey.

10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.

11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test “lesion” in the sample chamber. Failures must be corrected before further procedures are performed.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

e. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate must be within manufacturer specifications for the intended target value. Failures must be corrected before further procedures are performed.

(2) Visual checklist (monthly). Any failed items must be corrected within 30 days.

(3) Phantom image (weekly). Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures must be corrected before further procedures are performed.

(4) Compression (semiannually). The maximum auto drive compression force shall not exceed 45 pounds. Failures must be corrected within 30 days.

(5) Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer must be completed as outlined in the quality control manual applicable to the unit.

f. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure. The program must include the number of biopsies performed, the number of cancers found, the number of benign lesions found, and the number of biopsies repeated.

g. Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist qualified under 41.7(4) or by an individual under the direct supervision of a medical physicist qualified under 41.7(4).

41.7(8) Equipment standards.

a. Be specifically designed for stereotactically guided breast biopsy.

b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) Safety standards.

- a.* Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.
- b.* Equipment operators shall wear personnel monitors to monitor their radiation exposure.
- c.* Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.
- d.* Equipment shall be shockproof and grounded to protect against electrical hazards.
- e.* Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

[ARC 1401C, IAB 4/2/14, effective 5/7/14]

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING
REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN
OPERATOR'S BOOTH1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows or mirrors.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m²).

(2) Regardless of size or shape, at least 0.09 m² (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS
PROPOSING TO CONDUCT HEALING
ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.

3. A detailed description of the X-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over age 45 or men over age 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the X-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the X-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the physician who will interpret the radiograph(s) and a copy of the physician's license to practice in Iowa.

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

14. An indication of the frequency of screening and the duration of the entire screening program.

15. Documentation justifying the reason for the screening. The applicant must submit data which supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data which will be acceptable to the department includes, but is not limited to, the following: (1) the recommendation of a nationally recognized certifying medical or government body; (2) the recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or (3) medical literature from peer-reviewed journals supporting the screening.

16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.

17. The dates of the screening to include beginning and ending dates.

18. A copy of IRB for a research project or information justifying the research project.

CHAPTER 41—APPENDIX D

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance ^a
Daily	<u>Dosimetry</u>	
	X-ray output constancy	3%
	Electron output constancy ^b	3%
	<u>Mechanical</u>	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	<u>Safety</u>	
	Door interlocks	functional
	Audiovisual monitors	functional
	Monthly	<u>Dosimetry</u>
X-ray output constancy ^c		2%
Electron output constancy ^c		2%
Backup monitor constancy		2%
X-ray central axis dosimetry parameter (PDD, TAR) constancy		2%
Electron central axis dosimetry parameter constancy (PDD)		2mm @ therapeutic depth
X-ray beam flatness constancy		2%
Electron beam flatness constancy		3%
X-ray and electron symmetry		3%
<u>Safety Interlocks</u>		
Wedge, electron cone interlocks		functional
<u>Mechanical</u>		
Light/radiation field coincidence		2mm or 1% on a side ^d
Gantry/collimator angle indicators		1 degree
Wedge position		2mm (or 2% change in transmission factor)
Tray position		2mm
Applicator position		2mm
Field size indicators		2mm
Cross-hair centering		2mm diameter
Treatment couch position indicators		2mm/1deg
Latching of wedges, blocking tray	functional	
Jaw symmetry ^e	2mm	
Field Light intensity	functional	
Annual	<u>Dosimetry</u>	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%

^a The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values \pm the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

^b All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

^c A constancy check with a field instrument using temperature pressure corrections.

^d Whichever is greater. Should also be checked after change of light field source.

^e Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

Frequency	Procedure	Tolerance ^a
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy ^f	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	<u>Safety Interlocks</u>	
	Follow manufacturer's test procedures	functional
	<u>Mechanical</u>	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

^f Most wedges' transmission factors are field size and depth dependent.

^a The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values \pm the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

CHAPTER 41—APPENDIX E

INFORMATION ON RADIATION SHIELDING REQUIRED
FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and “allowed” radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, “Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV” (1976).

B. NCRP Report 51, “Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities” (1977).

C. NCRP Report 79, “Neutron Contamination from Medical Electron Accelerator” (1984).

D. NCRP Report 144, “Radiation Protection for Particle Accelerator Facilities” (2003).

These rules are intended to implement Iowa Code chapter 136C.

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 [Filed 3/9/06, Notice 2/1/06—published 3/29/06, effective 5/3/06]
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 [Filed ARC 0577C (Notice ARC 0381C, IAB 10/3/12), IAB 2/6/13, effective 3/13/13]
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[◇] Two or more ARCs

CHAPTER 42
PERMIT TO OPERATE IONIZING RADIATION PRODUCING MACHINES
OR ADMINISTER RADIOACTIVE MATERIALS

641—42.1(136C) Purpose. The purpose of this chapter is to specify the permit requirements of individuals who operate or use ionizing radiation producing machines or administer radioactive materials on or to human patients or human research subjects for diagnostic or therapeutic purposes. This chapter establishes minimum formal education standards and examination, continuing education, and disciplinary procedures.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

641—42.2(136C) Definitions.

“*ARRT*” means the American Registry of Radiologic Technologists.

“*Authorized user*” means an Iowa-licensed physician identified on a specific radioactive materials license or a license of broad scope as defined in 641—subrule 41.2(2).

“*Body composition scan*” means the use of a low dose X-ray to generate images of a color-coded body map.

“*Bone densitometry*” means the art and science of applying ionizing radiation to the human body using a dual energy X-ray absorptiometry unit for the sole purpose of measuring bone density.

“*Category*” defines specific duties allowed in the limited radiologic technologist permit classification.

“*Classification*” means a specific class of permit that allows the permit holder to perform the duties specified for that permit class.

“*Computed tomography*” or “*CT*” means a technique for generating a series of X-ray images taken from different angles and processed with computer software.

1. “*Diagnostic computed tomography*” means the use of computed tomography to create cross-sectional images of the human body to be used for diagnosis.

2. “*Attenuation correction*” means the use of X-rays from a CT scan to construct an attenuation map of density differences throughout the body that can then be used to correct for the absorption of the photons emitted from Fluorodeoxyglucose (¹⁸F) decay during a PET/CT scan.

“*Continuing education activity*” means a learning activity that is recognized as continuing education by the ARRT or NMTCB.

“*Department*” means the Iowa department of public health.

“*Expiration date*” means 11:59 p.m. on the stated date.

“*Formal education*” means a course of classroom and clinical instruction which meets the training standards set by the department.

“*Ionizing radiation producing machine*” or “*radiation machine*” means an assemblage of components for the controlled production of X-rays. An ionizing radiation producing machine includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

“*NMTCB*” means Nuclear Medicine Technology Certification Board.

“*Nuclear medicine diagnostic computed tomography endorsement*” means a qualification that allows a nuclear medicine technologist to perform diagnostic computed tomography of the human body as ordered by an individual authorized by Iowa law to order radiography.

“*Nuclear medicine procedure*” means any procedure utilizing radiopharmaceuticals for diagnosis or treatment of disease in human beings and any duties performed by the technologist during sealed source procedures, and includes, but is not limited to:

1. Administration of any radiopharmaceutical to human beings for diagnostic purposes.
2. Administration of radioactive material to human beings for therapeutic purposes.
3. Use of radioactive material for diagnostic purposes involving transmission or excitation.
4. Quality control and quality assurance.

“*Nuclear medicine technologist*” means an individual who performs nuclear medicine procedures while under the supervision of an authorized user. The classifications are as follows:

1. “General nuclear medicine technologist” performs any nuclear medicine procedures and may perform computed tomography for attenuation correction during PET/CT or SPECT/CT only.
2. “Limited nuclear medicine technologist” performs nuclear medicine procedures only as approved by the department at the time the initial permit was issued.

“*Permit*” means the document issued to an individual by the department when the individual has met the requirements of this chapter. This document authorizes the individual to perform the duties allowed for the classification of permit issued.

“*PET/CT*” means an imaging modality that uses positron emission tomography and computed tomography in one device to combine the structural anatomic information with functional data collected during the examination.

“*Radiation therapist*” means an individual who performs radiation therapy under the supervision of a radiation oncologist licensed in Iowa.

“*Radiation therapy*” means the science and art of performing simulation radiography or applying ionizing radiation emitted from X-ray machines, particle accelerators, or radioactive materials in the form of sealed sources to human beings for therapeutic purposes.

“*Radiography*” means a technique for generating and recording an X-ray pattern for the purpose of providing the user with an image(s) during or after termination of the exposure.

“*Radiologic technologist*” means an individual, excluding X-ray equipment operators, who performs radiography of the human body as ordered by an individual authorized by Iowa law to order radiography. The classifications are as follows:

1. “General radiologic technologist” performs radiography and computed tomography of any part of the human body.
2. “Limited radiologic technologist” performs radiography for the chest, spine, extremities, shoulder or pediatrics, excluding computed tomography and fluoroscopy.
3. “Limited in-hospital radiologic technologist” performs radiography of any part of the human body as approved by the department at the time the initial permit was issued.

“*Radiologist assistant*” means an advanced-level radiologic technologist who has completed the necessary requirements in order to perform procedures as outlined in ARRT guidance while under supervision of a radiologist.

“*SPECT/CT*” means an imaging modality that uses single-photon emission computed tomography and computed tomography in one device to combine the structural anatomic information with functional data collected during the examination.

“*Student*” means an individual enrolled in and participating in formal education.

“*Therapeutic*” means a medical treatment using radiation for therapy purposes.

“*X-ray equipment operator*” means an individual performing radiography of the human body using dedicated equipment as ordered by an individual authorized by Iowa law to order radiography. These individuals do not qualify for a permit in any other classification. The classifications are as follows:

1. “Podiatric X-ray equipment operator” performs radiography of only the foot and ankle using dedicated podiatric equipment. Studies using computed tomography, fluoroscopy, or nondedicated equipment are prohibited.
2. “Bone densitometry equipment operator” performs bone densitometry using only dual energy X-ray absorptiometry equipment. Studies using computed tomography, fluoroscopy, or nondedicated equipment are prohibited.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 3239C, IAB 8/2/17, effective 9/6/17; ARC 5683C, IAB 6/16/21, effective 7/21/21]

641—42.3(136C) Exemptions.

42.3(1) The following are exempt from obtaining a permit as required by this chapter:

- a. A licensed physician.
- b. A licensed physician’s assistant.
- c. A licensed chiropractor.

- d. A licensed dentist.
- e. A licensed dental hygienist.
- f. A licensed podiatrist.
- g. An individual certified by the dental board in dental radiography.
- h. A student as a part of the student's formal education.

42.3(2) The department may, upon application or upon its own initiative, grant such exemptions from the requirements of this chapter as it determines are authorized by law and will not result in undue hazard to public health and safety. Application for exemptions should be made in accordance with 641—Chapter 178.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

PERMIT APPLICATION AND RENEWAL

641—42.4(136C) Permit application and renewal. An individual shall not operate ionizing radiation producing machines or administer radioactive materials for diagnostic or therapeutic purposes unless the individual possesses a current Iowa permit in the individual's classification of practice.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

641—42.5(136C) Permit to practice as a general radiologic technologist.

42.5(1) An individual applying for an initial permit shall:

- a. Be at least 18 years of age.
- b. Submit the appropriate completed application.
- c. Submit a nonrefundable \$100 application fee.
- d. Submit proof of a passing score on the ARRT general radiography examination.

42.5(2) An individual renewing a current permit shall:

- a. Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.
- b. Report 24.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

42.5(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable \$150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 42.5(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 24.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 4612C, IAB 8/14/19, effective 9/18/19]

641—42.6(136C) Permit to practice as a general nuclear medicine technologist.

42.6(1) An individual applying for an initial permit shall:

- a. Be at least 18 years of age.
- b. Submit the appropriate completed application.
- c. Submit a nonrefundable \$100 application fee.
- d. Submit proof of a passing score on ARRT's nuclear medicine examination or the NMTCB nuclear medicine examination.

42.6(2) An individual renewing a current permit shall:

- a. Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.
- b. Report 24.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

42.6(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable \$150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 42.6(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 24.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

42.6(4) An individual applying for a nuclear medicine diagnostic computed tomography endorsement shall:

a. Maintain an active permit to practice as a general nuclear medicine technologist. Endorsements may not be held without an active permit.

b. Submit proof of a passing score on the ARRT or NMTCB computed tomography examination. [ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 3239C, IAB 8/2/17, effective 9/6/17; ARC 4612C, IAB 8/14/19, effective 9/18/19]

641—42.7(136C) Permit to practice as a radiation therapist.

42.7(1) An individual applying for an initial permit shall:

a. Be at least 18 years of age.

b. Submit the appropriate completed application.

c. Submit a nonrefundable \$100 application fee.

d. Submit proof of a passing score on the ARRT's radiation therapy examination.

42.7(2) An individual renewing a current permit shall:

a. Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.

b. Report 24.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

42.7(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable \$150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 42.7(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 24.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 4612C, IAB 8/14/19, effective 9/18/19]

641—42.8(136C) Permit to practice as a radiologist assistant.

42.8(1) An individual applying for an initial permit shall:

a. Submit the appropriate completed application.

b. Submit a nonrefundable \$100 application fee.

c. Submit proof of completion of formal education for a radiologist assistant.

d. Submit proof of one year of experience as a general radiologic technologist.

e. Submit proof of passing score on the ARRT radiologist assistant examination or another examination that is recognized by the department.

42.8(2) An individual renewing a current permit shall:

a. Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.

b. Report 50.0 hours of continuing education obtained within the biennium indicated on the individual's permit. Radiologist assistant permit holders must obtain at least one-half of the required continuing education in subject areas specific to radiography. The remainder may be earned as physician credit hours.

42.8(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable \$150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 42.8(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 50.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 4612C, IAB 8/14/19, effective 9/18/19]

641—42.9(136C) Permit to practice as a limited radiologic technologist with categories of chest, spine, extremities, shoulder, pediatric. An individual with a limited radiologic technologist permit shall perform radiography only within the scope of the category(ies) in which the permit is issued.

42.9(1) The scope of each category is defined as follows:

a. “Chest” allows the permit holder to perform radiography of the lung fields including the cardiac shadow, as taught in the limited radiography formal education standards. Chest radiograph techniques shall not be manipulated for the evaluation of the shoulder, clavicle, scapula, ribs, thoracic spine and sternum. Limited radiologic technologists who have completed the appropriate formal education after January 1, 2009, may perform lateral decubitus chest views.

b. “Extremities” allows the permit holder to perform radiography for body parts from:

(1) The distal phalanges of the foot to the head of the femur, including its articulation with the pelvic girdle. True hip radiographs are prohibited.

(2) The distal phalanges of the hand to the head of the humerus. These projections may include the acromioclavicular or glenoid-humeral areas. The radiograph shall not include any of the views in the shoulder category unless the individual holds a limited radiologic technologist permit that includes the shoulder category.

c. “Spine” allows the permit holder to perform radiography of the spine in the approved areas only. Approved areas and limitations are described as:

(1) Cervical vertebrae.

(2) Thoracic (dorsal) vertebrae.

(3) Lumbar vertebrae to include the articulations with the sacrum and coccyx and the sacral articulation with the pelvic girdle. True pelvis radiographs or other projections performed with the image receptor positioned perpendicular to the long axis of the torso are prohibited under this category.

(4) All projections shall be performed as taught in the limited radiologic technologist formal education standards.

d. “Shoulder” allows the permit holder to perform radiography of the shoulder in the approved projections only. Approved projections and limitations are described as:

(1) AP internal and external rotation.

(2) AP neutral.

(3) Transthoracic lateral views.

(4) Scapular “Y” lateral.

(5) The image may not include the proximal end of the clavicle on any AP projection. All other shoulder views are prohibited. The permit holder must hold a limited radiologic technologist permit with a category of either chest or extremity in order to be granted the shoulder category.

e. “Pediatric” allows the permit holder to perform radiography of either chest or extremities or both as defined in paragraphs 42.9(1) “*a*” and “*b*” above for patients aged 36 months and under. The permit holder must hold a limited radiologic technologist permit with the minimum categories of chest or extremities or both in order to qualify for pediatric radiography. This designation allows permit holders to perform pediatric radiography within the permit classifications listed on their permit only. All other projections on pediatric patients by limited radiologic technologists are prohibited.

42.9(2) An individual applying for an initial permit shall:

a. Be at least 18 years of age.

- b. Submit the appropriate completed application.
- c. Submit a nonrefundable \$100 application fee.
- d. Submit proof of completion of formal education in all limited diagnostic radiography categories for which the individual is applying. In order to apply for the shoulder category, the individual must also apply for the chest or extremity category. In order to apply for the pediatric category, the individual must also apply for the chest or extremity category. Each individual making application to attend a formal education course provided by the department to fulfill the requirements of 42.9(2)“d” must submit an application and nonrefundable fee of \$200 to the department each time the individual attends a course.
- e. Submit proof of completion of testing as applicable for each permit category for which the individual is applying on the limited radiologic technologist permit. No examination is required for the categories of shoulder or pediatric.

(1) The following are passing scores:

- 1. A score of at least 70 percent on the ARRT limited scope of practice in radiography examination core section and at least 70 percent on each category; or
- 2. A score of at least 70 percent on the American Chiropractic Registry of Radiologic Technologists Limited Radiography examination; or
- 3. A score of at least 70 percent on a department-approved examination.

(2) Three failed attempts on the examination in 42.9(2)“e”(1)“1” or “3” will require the individual to repeat the formal education or complete a department-approved review program.

(3) Each individual making application to take an examination as a limited radiologic technologist in 42.9(2)“e”(1)“1” or “3” must submit an application and nonrefundable fee of \$200 to the department each time the individual takes the examination.

f. Submit proof of completion of formal education and examination in the category to be added and a nonrefundable \$40 amendment fee to add chest, extremity or spine category to an existing limited radiologic technologist permit. A score of at least 70 percent on each category is required.

g. Submit proof of completion of formal education and a nonrefundable \$40 amendment fee to add shoulder or pediatric category to an existing limited radiologic technologist permit. No examination is required.

42.9(3) An individual renewing a current permit shall:

- a. Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.
- b. Report 12.0 hours of continuing education obtained within the biennium indicated on the individual’s permit.

42.9(4) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable \$150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of rule 641—42.9(136C).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 12.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1931C, IAB 4/1/15, effective 5/6/15; ARC 4612C, IAB 8/14/19, effective 9/18/19]

641—42.10(136C) Permit to practice as an X-ray equipment operator in either podiatric radiography or bone densitometry (dual energy X-ray absorptiometry). After January 1, 2015, all individuals performing only bone densitometry or other examinations using DEXA machines must hold a bone densitometry permit.

42.10(1) An individual applying for an initial permit shall:

- a. Be at least 18 years of age.
- b. Submit the completed application.
- c. Submit a nonrefundable \$40 application fee.

d. Submit proof of completion of formal education that meets the department minimum training standards. Each individual making application to attend an X-ray equipment operator formal education course provided by the department to fulfill the requirement of 42.10(1) “*d*” must submit an application and nonrefundable fee of \$150 to the department each time the individual attends the course.

e. Submit proof of at least a 70 percent score on a department-approved examination.

(1) Three failed attempts on the examination in 42.10(1) “*e*” will require the individual to repeat the formal education or complete a department-approved review program.

(2) Each individual making application to take an examination as an X-ray equipment operator to meet the requirements of 42.10(1) “*e*” must submit an application and nonrefundable fee of \$100 to the department each time the individual takes the examination.

42.10(2) An individual renewing a current permit shall:

a. Renew annually by submitting a renewal application and a nonrefundable \$40 renewal fee.

b. Report 4.0 hours of continuing education obtained within the biennium indicated on the individual’s permit.

42.10(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable \$75 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 42.10(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 4.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 4612C, IAB 8/14/19, effective 9/18/19; ARC 5683C, IAB 6/16/21, effective 7/21/21]

641—42.11 Reserved.

641—42.12(136C) Closed classification or category permits.

42.12(1) The following classifications or categories are closed to new applicants. Permits in the following classifications or categories that are expired for more than six months are not eligible to be reinstated, and individuals shall maintain current permits as outlined below:

a. Limited in-hospital radiologic technologist shall:

(1) Perform diagnostic radiography procedures, excluding CT and fluoroscopy, in a hospital setting only for specific body parts for which the individual is qualified.

(2) Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.

(3) Report 24.0 hours of continuing education obtained within the biennium indicated on the individual’s permit.

b. Limited nuclear medicine technologist shall:

(1) Perform nuclear medicine procedures for which the individual is qualified and has been authorized by the department.

(2) Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.

(3) Report 12.0 hours of continuing education obtained within the biennium indicated on the individual’s permit.

c. Limited radiologic technologist paranasal sinus shall:

(1) Perform diagnostic radiography procedures, excluding CT and fluoroscopy, specific to paranasal sinus.

(2) Renew annually by submitting a renewal application and a nonrefundable \$75 renewal fee.

(3) Report 6.0 hours of continuing education obtained within the biennium indicated on the individual’s permit.

42.12(2) An individual renewing a permit expired less than six months shall submit the following:

a. Application to reinstate and nonrefundable \$150 application fee.

b. Any continuing education hours due at time of renewal.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 4612C, IAB 8/14/19, effective 9/18/19]

641—42.13(136C) Combining permits for an individual qualifying for permits in more than one classification.

42.13(1) An individual applying for an initial permit in more than one classification at the same time shall combine classifications on one permit by:

- a. Indicating each classification on the appropriate completed application;
- b. Submitting the required documentation for each classification as outlined in each classification section; and
- c. Submitting a nonrefundable \$150 application fee.

42.13(2) Permit holders shall add a classification to an existing permit by:

- a. Completing the appropriate application;
- b. Submitting the required documentation as outlined in the section specific to the classification to be added; and
- c. Submitting a nonrefundable \$40 fee.

42.13(3) An individual renewing a combined classification permit must submit the appropriately completed renewal application and submit a nonrefundable \$110 renewal fee.

42.13(4) An individual shall submit a total of 24.0 hours of continuing education obtained within the biennium indicated on the individual's permit. If the permit includes the radiologist assistant classification, then the individual must submit a total of 50.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

42.13(5) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and a nonrefundable \$150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 42.7(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 24.0 hours of continuing education obtained within the previous 24 months must be submitted. If the permit includes the radiologist assistant classification, then the individual must submit a total of 50.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 4612C, IAB 8/14/19, effective 9/18/19; ARC 5683C, IAB 6/16/21, effective 7/21/21]

641—42.14 to 42.17 Reserved.

PERMIT HOLDER SUBMISSION OF CONTINUING EDUCATION

641—42.18(136C) Submission of proof of completion of continuing education by permit holder to meet continuing education requirements to renew or reinstate a permit.

42.18(1) A permit holder who has a current ARRT or NMTCB registration that has been renewed within 60 days prior to the submission of the permit renewal application required by these rules shall be credited the number of hours recognized by the ARRT or NMTCB registration, or

42.18(2) A permit holder must submit proof of completion of continuing education activities recognized by ARRT or NMTCB.

a. Acceptable proof of completion must be documentation signed and dated by the continuing education provider that includes the participant's name, title of the activity, approval number for the activity, dates of attendance, number of contact hours for the activity, name of the approving organization, and signature of the sponsor or instructor or authorized representative of the sponsor or instructor.

b. Continuing education activities that are lecture presentations may not be repeated for credit in the same biennium.

c. All continuing education activities that are not lecture presentations may not be repeated for credit in the same or any subsequent biennium.

42.18(3) Podiatric X-ray equipment operator permit holders may submit activities as described in 42.18(2) or may submit activities sponsored by the American Podiatric Medical Association or the Iowa Podiatric Medical Society.

a. Acceptable proof of completion must be documentation signed and dated by the continuing education provider that includes the participant's name, title of the activity, approval number for the activity, dates of attendance, number of contact hours for the activity, the name of the approving organization, and signature of the sponsor or instructor or authorized representative of the sponsor or instructor.

b. Continuing education activities that are lecture presentations may not be repeated for credit in the same biennium.

c. All continuing education activities that are not lecture presentations may not be repeated for credit in the same or any subsequent biennium.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

641—42.19 and 42.20 Reserved.

ADMINISTRATIVE ITEMS AND GROUNDS FOR DISCIPLINARY ACTION

641—42.21(136C) Administrative items.

42.21(1) A nonrefundable \$25 fee shall be assessed for each check returned for any reason. All fees for returned checks plus original fees must be paid by certified bank check or money order.

42.21(2) A permit is valid from the date of issuance until the expiration date, unless otherwise revoked or suspended.

42.21(3) The department may at any time require further documentation to ensure compliance with these rules.

42.21(4) The permit holder shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

42.21(5) The permit holder must maintain proof of continuing education for at least three years.

42.21(6) Continuing education obtained to satisfy disciplinary or enforcement action or as part of a corrective action plan may not be reported to meet continuing education requirements.

42.21(7) All permit holders are subject to a department audit at any time.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

641—42.22(136C) Rules of conduct, self-reporting requirements, and enforcement actions for all permit holders or applicants.

42.22(1) *Rules of conduct.* These are mandatory standards of minimally acceptable professional conduct intended to promote the protection, safety, and comfort of patients. Any individual who fails to meet or allows any other individual to fail to meet the following standards may be subject to enforcement actions as outlined in subrule 42.22(3). The following shall be grounds for disciplinary action:

a. Failing to perform with reasonable skill and safety all procedures accepted under this chapter's educational guidelines and allowed under the individual's permit.

b. Operating as a permitted individual without meeting the applicable requirements of this chapter. This includes performing procedures not allowed under the individual's current permit.

c. Failing to report immediately to the department any individual who may be operating as a permit holder and who does not meet the requirements of this chapter.

d. Engaging in any practice that results in unnecessary danger to a patient's life, health, or safety. This includes delegating or accepting the delegation of any function when the delegation or acceptance could cause unnecessary danger.

e. Engaging in any action that the department determines may jeopardize the health and safety of the public, other staff or the permit holder. These actions shall include but not be limited to:

(1) A misdemeanor or felony which may impair or limit the individual's ability to perform the duties authorized by the individual's permit.

(2) Any disciplinary action brought against the individual in connection with a certificate or license issued from a certifying or licensing entity.

(3) Being found guilty of incompetence or negligence during the individual's performance as a permit holder.

f. Failing to conform to applicable state and federal statutes and rules. This includes any action that might place a facility in noncompliance with Iowa statutes and rules.

g. Practicing when there is an actual or potential inability to perform with reasonable skill and safety due to illness, use of alcohol, drugs, chemicals, or any other material, or as the result of any mental or physical condition.

h. Engaging in any unethical conduct or conduct likely to deceive, defraud, or harm the public; or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient.

i. Revealing privileged communication from or relating to former or current patients except as permitted by law.

j. Improperly managing patient records, including failing to maintain adequate records, failing to furnish records, or making, causing, or allowing anyone to make a false, deceptive, or misleading entry into a patient record.

k. Providing false or misleading information that is directly related to the care of a former or current patient.

l. Interpreting or rendering a diagnosis for a physician based on a diagnostic image or prescribing medications or therapies.

m. Failing to immediately report to a supervisor information concerning an error made in connection with imaging, treating, or caring for a patient. This includes any departure from the normal standard of care and behavior that is negligent.

n. Employing fraud or deceit to obtain, attempt to obtain or renew a permit under this chapter or in connection with a certification or license issued from a certifying or licensing entity. This includes altering documents, failing to provide complete and accurate responses or information, indicating falsely in writing that a permit is valid when that is not the case, or any form of examination subversion.

o. Failure to provide truthful, accurate, unaltered, or nondeceptive information related to continuing education activities to the department or a record keeper.

p. Assisting others to provide false, inaccurate, altered, or deceptive information related to continuing education to this department or a record keeper. This includes sharing answers, providing or using false certificates of participation, or verifying continuing education hours that have not been earned.

q. Failure to pay all fees or costs required to meet the requirements of this chapter. Penalties for working without a current permit will be considered on a case-by-case basis.

r. Failure to respond to an audit request or failure to provide proper documentation.

s. Submitting false information to a facility that might place the facility in noncompliance with any federal or state statutes or laws.

t. Engaging in any conduct that subverts or attempts to subvert a department investigation.

u. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation by the department.

v. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

w. Sexual harassment of a patient, student or supervisee. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal and physical conduct of a sexual nature.

x. Violating a statute of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, including but not limited to a crime involving dishonesty,

fraud, theft, embezzlement, controlled substances, substance abuse, assault, sexual abuse, sexual misconduct, or homicide. A copy of the record of conviction or plea of guilty is conclusive evidence of the violation.

y. Having a permit, license or certification related to the classification of the permit issued to the individual suspended or revoked or having other disciplinary action taken by a licensing or certifying authority of this state or another state, territory or country. A copy of the record or order of suspension, revocation, or disciplinary action is conclusive or prima facie evidence.

z. Failure to respond within 30 days of receipt of communication from the department.

42.22(2) Self-reporting. Each permit holder shall:

a. Submit a report to the department within five days of the final disposition of all criminal proceedings, convictions, or military court-martials involving alcohol or illegal drug use while operating as a permit holder, sex-related infractions, or patient-related infractions in any state, territory, or country.

b. Submit a written report to the department within five days of the initial charge and within five days of the final disposition of any disciplinary action brought against the individual in connection with a certificate or license issued from a certifying or licensing entity, or any disciplinary action brought against the individual by an employer or patient.

c. Report potential ethics violations (including state licensing issues and criminal charges and convictions) within 30 days of the occurrence or during the permit holder's annual renewal process, whichever comes first.

42.22(3) Enforcement actions. Enforcement actions may include, but are not limited to, denial, probation, suspension or revocation of a permit, directed corrective action, and civil penalty.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 5683C, IAB 6/16/21, effective 7/21/21]

641—42.23(136C) Procedures for demand for information, notice of proposed action, and orders for penalties, suspensions, revocations, and civil penalties for all individuals under this chapter. These actions may be imposed on any permit holder who violates any rule in this chapter.

42.23(1) Demand for information.

a. The department may issue a demand for information for the purpose of determining whether any further action shall be taken. The demand shall state the alleged violations and allow the individual 20 days from the date of the letter to file a written answer with the department.

b. The individual must file a written answer to the department. The answer shall specifically admit or deny each allegation or charge made in the demand for information and provide fact and law on which the answer relies, set forth reasons why the demand should not have been issued, and if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer, the department may institute the next level of proceeding or consider the matter closed. If no answer is filed, the department shall institute the notice of proposed action.

42.23(2) Procedures for enforcement actions.

a. *Notice of proposed action.*

(1) In response to an alleged violation of any provision of the Iowa Code, these rules, or any order issued by the department, the department may issue a written notice of proposed action. The notice of proposed action shall concisely state the alleged violation(s), the action the department is proposing, the time period in which a written response must be received, and the process for requesting a hearing.

(2) A written response must state any facts, explanations, or arguments denying the violations or must demonstrate any extenuating circumstances, error in the notice, or other reason why the proposed action should not be imposed. Responses may also request remission or mitigation of any penalty.

(3) If a request for a hearing is received within the allotted time period, the proposed action shall be suspended pending the outcome of the hearing. Prior to or at the hearing, the department may rescind the notice of proposed action upon satisfaction that the reason for the proposed action has been resolved.

(4) If no answer is filed, the department shall institute the order.

b. *Order.* An order may be issued upon response to the notice of proposed action or if no answer to the notice has been filed. The order may institute a proceeding to impose a penalty or suspend, revoke, or place on probation the individual's permit, or issue a civil penalty. An order shall concisely state the

violation(s), the action the department has imposed, the effective date of the order, the time period for written response to be received by the department, and the process for requesting a hearing. If there has been consent in writing to the notice of proposed action, no written response to the order is necessary.

(1) If a request for a hearing is received within the allotted time period, the proposed action of the order shall be suspended pending the outcome of the hearing. Prior to or at the hearing, the department may rescind the order upon satisfaction that the reason for the proposed action has been resolved.

(2) If no answer is filed, the department shall institute the order. A consent to the order shall constitute a waiver to a hearing, findings of fact and conclusions of law, and of all right to seek department and judicial review or to contest the validity of the order in any form as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the department and shall be effective as provided in the order. Failure to comply with an order either consented to or validated by a hearing officer shall result in further enforcement action.

c. Civil penalty. Before instituting any proceeding to impose a civil penalty, the department shall serve written notice of violation upon the individual charged. This notice shall be included in the notice of proposed action or order issued. The notice of proposed action or order shall specify the amount of each proposed penalty for each alleged violation. The notice or order shall state that the amount charged may be paid as specified or protested in its entirety or in part. Upon final action of a civil penalty, payment must be made within the specified time stated in the order or the department may refer the matter to the attorney general for collection.

d. Settlement and compromise. At any time after the issuance of a notice or order designating the time and place of hearing in response to an order, the department and the regulated individual may enter into a stipulation for a settlement or compromise of the notice or order. The stipulation of compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the chief administrative law judge. The presiding officer or chief administrative law judge may order such adjudication of the issued notice or order as deemed to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

641—42.24 and 42.25 Reserved.

641—42.26(136C) Rescinded **ARC 5683C**, IAB 6/16/21, effective 7/21/21.

641—42.27 to 42.29 Reserved.

FORMAL EDUCATION

641—42.30(136C) Requirements for formal education. Formal education must meet the following minimum requirements:

42.30(1) General radiologic technology formal education must be recognized by the ARRT to allow students to qualify for the general radiography examination.

42.30(2) Nuclear medicine technology formal education must be recognized by the ARRT or NMTCB to allow students to qualify for the nuclear medicine technology examination.

42.30(3) Radiation therapy formal education must be recognized by the ARRT to allow students to qualify for the radiation therapy examination.

42.30(4) Radiologist assistant formal education must provide training to allow students to qualify for a department-approved radiologist assistant examination.

42.30(5) Limited radiologic technologist formal education must meet the minimum standards specified in 641—42.31(136C).

42.30(6) X-ray equipment operator formal education must meet the minimum standards as outlined in 641—42.32(136C) or 641—42.33(136C).

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

641—42.31(136C) Standards for formal education for limited radiologic technologists.

42.31(1) The formal education may be a single offering that meets all standards of all categories, or it may be offered individually specific to the category the provider wishes to offer.

42.31(2) The following are the minimum standards:

a. A principal instructor shall:

(1) Be an Iowa-licensed chiropractor teaching spine and extremities categories only; or

(2) Be an Iowa-permitted general radiologic technologist and have at least two years of current experience in radiography; or

(3) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

b. A clinical instructor shall:

(1) Be an Iowa-licensed chiropractor teaching spine and extremities categories only; or

(2) Be an Iowa-permitted general radiologic technologist and have at least two years of current experience in radiography; or

(3) Be an Iowa-permitted limited radiologic technologist in the category of instruction and have at least two years of current experience in radiography; or

(4) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

c. Clinical instructors shall be supervised by the principal instructor.

d. A principal instructor may also act as clinical instructor, if applicable.

e. Classroom and clinical standards are listed below:

Category	Classroom Hours	Clinical Practice Projections	Clinical Competency Projections
Core: completed by all trainees	60		
Chest	20	30 PA or LAT	5 PA, 5 LAT
Upper extremity	20	30 (any projections)	10 (only 2 of any projection allowed)
Lower extremity	20	30 (any projections)	10 (only 2 of any projection allowed)
Shoulder	20	20 (any projections)	6 (only 2 of any projection allowed)
Spine	20	30 (any projections)	10 (only 2 of any projection allowed)
Pediatric: add on to chest	8 of initial pediatrics	20 (any projections)	2 PA, 2 LAT
Pediatric: add on to upper extremity	8 of initial pediatrics	20 (any projections)	10 (only 2 of any projection allowed)
Pediatric: add on to lower extremity	8 of initial pediatrics	20 (any projections)	10 (only 2 of any projection allowed)

(1) All competency testing for limited radiography shall be directly supervised by the principal or clinical instructor, can only begin after the classroom hours in a category have been completed, and cannot begin until after the clinical site has been approved by the department using the Initial Clinical Site Form.

(2) Clinical instructors shall directly supervise all students before the student's competency for a specific projection is documented and indirectly supervise after the student's competency for a specific projection is documented.

(3) Current permit holders completing formal education to add a category do not need to repeat the core curriculum.

42.31(3) Department approval is required before implementing any formal education or making any changes to a formal education offering.

42.31(4) Administrative items for all formal education:

a. The department reserves the right to audit or evaluate any aspect of the formal education or student progress.

b. The department may at any time require further documentation.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 5683C, IAB 6/16/21, effective 7/21/21]

641—42.32(136C) Standards for formal education for X-ray equipment operators in podiatric radiography.**42.32(1)** The following are the minimum standards:

a. A principal instructor shall:

- (1) Be an Iowa-licensed podiatrist; or
- (2) Be an Iowa-permitted general radiologic technologist and have at least two years of current experience in radiography; or
- (3) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

b. A clinical instructor shall:

- (1) Be an Iowa-licensed podiatrist; or
- (2) Be an Iowa-permitted limited radiologic technologist in the category of extremities and have at least two years of current experience in radiography; or
- (3) Be an Iowa-permitted X-ray equipment operator in podiatry and have at least two years of current experience in radiography; or
- (4) Be an Iowa-permitted general radiologic technologist and have at last two years of current experience in radiography; or
- (5) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

c. Clinical instructors shall be supervised by the principal instructor.

d. A principal instructor may also act as clinical instructor, if applicable.

e. The following are classroom and clinical standards:

- (1) A minimum of 8.0 hours of classroom instruction to include radiation safety, equipment operation, patient care, and anatomy.
- (2) Clinical instruction to include positioning and a minimum of 20 projections excluding the competency projections.
- (3) Clinical competency projections shall include 10 projections with only 2 of any single projection allowed to count toward the competency projections.
- (4) All competency testing shall be directly supervised by the principal or clinical instructor.
- (5) Clinical instructors shall directly supervise all students before the student's competency for the specific projection is documented and indirectly supervise after the student's competency for the specific projection is documented.

42.32(2) Department approval is required before implementing any formal education or making any changes to a formal education offering.

42.32(3) Administrative items for all formal education:

a. The department reserves the right to audit or evaluate any aspect of the formal education or student progress.

b. The department may at any time require further documentation.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

641—42.33(136C) Standards for formal education for X-ray equipment operators in bone densitometry.**42.33(1)** The following are the minimum standards:

a. A principal instructor shall have at least two years of current experience in radiography and bone densitometry and shall:

- (1) Be an Iowa-permitted general radiologic technologist; or
- (2) Hold a current ARRT registration if the clinical site is located outside of Iowa.

b. A clinical instructor shall have at least two years of current experience in radiography and bone densitometry and shall:

- (1) Be an Iowa-permitted limited radiologic technologist; or
- (2) Be an Iowa-permitted X-ray equipment operator in bone densitometry; or
- (3) Be an Iowa-permitted general radiologic technologist; or
- (4) Hold a current ARRT registration if the clinical site is located outside of Iowa.

c. Clinical instructors shall be supervised by the principal instructor.

d. A principal instructor shall also act as clinical instructor, if applicable.

e. The following are classroom and clinical standards:

(1) A minimum of 8.0 hours of classroom instruction to include radiation safety, equipment operation, quality control, patient care, and anatomy.

(2) Clinical instruction to include positioning and a minimum of 10 projections excluding the competency projections.

(3) Clinical competency projections shall include 5 projections.

(4) All competency testing shall be directly supervised by the principal or clinical instructor.

(5) Clinical instructors shall directly supervise all students before the student's competency for the specific projection is documented and indirectly supervise after the student's competency for the specific projection is documented.

42.33(2) Department approval is required before implementing any formal education or making any changes to a formal education offering.

42.33(3) Administrative items for all formal education:

a. The department reserves the right to audit or evaluate any aspect of the formal education or student progress.

b. The department may at any time require further documentation.

[ARC 0577C, IAB 2/6/13, effective 3/13/13]

These rules are intended to implement Iowa Code sections 136C.3, 136C.4, 136C.5, 136C.10, and 136C.14.

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⁰ Two or more ARCs

¹ Effective date of Ch 42 delayed 70 days by the administrative rules review committee. [Published IAC 6/23/82]
Effective date of Ch 42 delayed by the Administrative Rules Review Committee forty-five days after convening of the next General Assembly pursuant to §17A.8(9). [IAB 9/29/82]

² Subrule 42.1(4) "b"(4) is rescinded two years subsequent to the effective date of rule 42.1(136C).

CHAPTER 69
RENOVATION, REMODELING, AND REPAINTING—
LEAD HAZARD NOTIFICATION PROCESS

641—69.1(135) Applicability. This chapter applies to all persons who perform renovation, remodeling, or repainting for compensation in target housing or a child-occupied facility.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.2(135) Definitions.

“Arithmetic mean” means the algebraic sum of data values divided by the number of data values. For example, the sum of the concentration of lead in several soil samples divided by the number of samples is the arithmetic mean.

“Certificate of mailing” means certified mail with return receipt or its equivalent.

“Chewable surface” means an interior or exterior surface painted with lead-based paint that a young child can mouth or chew.

“Child-occupied facility” means a building, or portion of a building, constructed prior to 1978, that is described by all of the following: (1) The building is visited on a regular basis by the same child, who is less than six years of age, on at least two different days within any week. For purposes of this chapter, a week is a Sunday through Saturday period. (2) Each day’s visit by the child lasts at least 3 hours, and the combined annual visits total at least 60 hours. A child-occupied facility may include, but is not limited to, a child care center, preschool, or kindergarten classroom. A child-occupied facility also includes common areas that are routinely used by children who are less than six years of age, such as restrooms and cafeterias, and the exterior walls and adjoining space of the building that are immediately adjacent to the child-occupied facility or the common areas routinely used by children under the age of six years. “Child-occupied facility” also includes any building where lead-based paint activities are conducted immediately prior to or during the conversion of the building to a child-occupied facility.

“Common area” means a portion of the building that is generally accessible to all occupants. This includes, but is not limited to, hallways, stairways, laundry and recreational rooms, playgrounds, community centers, garages, and boundary fences.

“Compensation” means payment or reimbursement for services performed. Compensation is not limited to monetary considerations and includes payment of rent for rental units, receipt of a salary from the owner or manager of target housing, and receipt of a salary from the owner or operator of a child-occupied facility.

“Components” means specific design or structural elements or fixtures of a building, residential dwelling, or child-occupied facility that are distinguished from each other by form, function, and location. These include, but are not limited to, interior components such as ceilings, crown moldings, walls, chair rails, doors, door trim, floors, fireplaces, radiators and other heating units, shelves, shelf supports, stair treads, stair risers, stair stringers, newel posts, railing caps, balustrades, windows and trim (including sashes, window heads, jambs, sills or stools and troughs), built-in cabinets, columns, beams, bathroom vanities, countertops, and air conditioners; and exterior components such as painted roofing, chimneys, flashing, gutters and downspouts, ceilings, soffits, fascias, rake boards, cornerboards, bulkheads, doors and door trim, fences, floors, joists, latticework, railings and railing caps, siding, handrails, stair risers and treads, stair stringers, columns, balustrades, windowsills or stools and troughs, casing, sashes and wells, and air conditioners.

“Department” means the department of public health.

“Dripline” means the area within three feet surrounding the perimeter of a building.

“Dust-lead hazard” means surface dust in residential dwellings or child-occupied facilities that contains a mass-per-area concentration of lead equal to or exceeding 10 micrograms per square foot on floors, 100 micrograms per square foot on interior windowsills, and 400 micrograms per square foot on window troughs based on wipe samples. A dust-lead hazard is present in a residential dwelling or child-occupied facility when the weighted arithmetic mean lead loading for all single-surface or composite samples of floors and interior windowsills is equal to or greater than 10 micrograms per

square foot on floors, 100 micrograms per square foot on interior windowsills, and 400 micrograms per square foot on window troughs based on wipe samples. A dust-lead hazard is present on floors, interior windowsills, or window troughs in an unsampled residential dwelling in a multifamily dwelling if a dust-lead hazard is present on floors, interior windowsills, or window troughs, respectively, in at least one sampled residential unit on the property. A dust-lead hazard is present on floors, interior windowsills, or window troughs in an unsampled common area in a multifamily dwelling if a dust-lead hazard is present on floors, interior windowsills, or window troughs, respectively, in at least one sampled common area in the same common area group on the property.

“Dwelling unit” means a single, unified combination of rooms designed for use as a dwelling by one family.

“Emergency renovation, remodeling, or repainting” means renovation, remodeling, or repainting activities necessitated by nonroutine failures of equipment or a structure that were not planned but resulted from a sudden, unexpected event that, if not immediately attended to, presents a safety or public health hazard or threatens equipment or property with significant damage.

“Friction surface” means an interior or exterior surface that is subject to abrasion or friction including, but not limited to, certain window, floor, and stair surfaces.

“Hazardous lead-based paint” means lead-based paint that is present on a friction surface where there is evidence of abrasion or where the dust-lead level on the nearest horizontal surface underneath the friction surface (e.g., the windowsill or floor) is equal to or greater than the dust-lead hazard level, lead-based paint that is present on an impact surface that is damaged or otherwise deteriorated from impact, lead-based paint that is present on a chewable surface, or any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

“Housing for the elderly” means retirement communities or similar types of housing reserved for households composed of one or more persons 62 years of age or older or an age recognized as elderly by a specific federal housing assistance program.

“Impact surface” means an interior or exterior surface that is subject to damage by repeated sudden force such as certain parts of door frames.

“Lead-based paint” means paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram per square centimeter or more than 0.5 percent by weight.

“Lead-based paint hazard” means hazardous lead-based paint, a dust-lead hazard, or a soil-lead hazard.

“Living area” means any area of a residential dwelling used by at least one child six years of age or less including, but not limited to, living rooms, kitchen areas, dens, playrooms, and children’s bedrooms.

“Mid-yard” means an area of a residential yard approximately midway between the dripline of a residential building and the nearest property boundary or between the driplines of a residential building and another building on the same property.

“Multifamily dwelling” means a structure that contains more than one separate residential dwelling unit, which is used or occupied, or is intended to be used or occupied, in whole or in part, as the home or residence of one or more persons.

“Person” means individual, corporation, limited liability company, government or governmental subdivision or agency, business trust, estate, trust, partnership, or association, or any other legal entity.

“Play area” means an area of frequent soil contact by children of less than six years of age as indicated by, but not limited to, factors including the following: the presence of play equipment (sandboxes, swing sets, and sliding boards), toys, or other children’s possessions, observations of play patterns, or information provided by parents, residents, caregivers, or property owners.

“Regulated entity” means any individual or company that is regulated by the department by virtue of these rules, the Iowa Code, or other official regulatory promulgation.

“Renovation, remodeling, repainting” means modifying any existing structure or portion of a structure where painted surfaces are disturbed, unless the activity fits the criteria of lead abatement as defined in 641—70.2(135) and is performed by a certified lead abatement contractor as defined in 641—70.2(135). This includes, but is not limited to, removing walls, ceilings, and other painted

building components; window replacement; floor refinishing; and sanding, scraping, stripping, water blasting, or otherwise removing paint.

“Residential dwelling” means (1) a detached single-family dwelling unit, including the surrounding yard, attached structures such as porches and stoops, and detached buildings and structures including, but not limited to, garages, farm buildings, and fences, or (2) a single-family dwelling unit in a structure that contains more than one separate residential dwelling unit, which is used or occupied, or intended to be used or occupied, in whole or part, as the home or residence of one or more persons.

“Soil-lead hazard” means bare soil on residential real property or on the property of a child-occupied facility that contains total lead in excess of 400 parts per million for the dripline, mid-yard, and play areas. A soil-lead hazard is present in a dripline, mid-yard, or play area when the soil-lead concentration from a composite sample of bare soil is equal to or greater than 400 parts per million.

“Target housing” means housing constructed prior to 1978 with the exception of housing for the elderly or for persons with disabilities, unless at least one child under the age of six years resides or is expected to reside in the housing, and housing which does not contain a bedroom.

[ARC 8501B, IAB 2/10/10, effective 1/13/10; ARC 5684C, IAB 6/16/21, effective 7/21/21]

641—69.3(135) Notification required in target housing. A person who performs renovation, remodeling, or repainting of target housing for compensation, except for emergency renovation, remodeling, or repainting of target housing, and except for minor repair and maintenance activities that disrupt less than 1.0 square feet of painted surface, must do the following prior to commencing the work:

69.3(1) Provide the pamphlet, *Lead Poisoning: How to Protect Iowa Families*, or the federal pamphlet, *Renovate Right*, to the owner and adult occupant of each dwelling unit where renovation, remodeling, or repainting will be performed. The pamphlet shall be provided no more than 60 days prior to commencing the work.

69.3(2) Obtain a signed, dated acknowledgment from the owner and known adult occupant of each dwelling unit where renovation, remodeling, or repainting will be performed affirming that they have received the pamphlet prior to the start of renovation, remodeling, or repainting and are aware of the potential health hazards from remodeling, renovating, or repainting housing containing lead-based paint. The acknowledgment shall be obtained no more than 60 days prior to commencing the work.

a. The acknowledgment shall include the owner’s and occupant’s names and the address of the residential dwelling undergoing renovation, remodeling, or repainting.

b. The acknowledgment shall include the following language:

I have received the pamphlet entitled *Lead Poisoning: How to Protect Iowa Families* or the federal pamphlet, *Renovate Right*, prior to the start of renovation, remodeling, or repainting and am aware of the potential health risk associated with remodeling, renovating, or repainting housing containing lead-based paint or lead-based paint hazards.

c. Below the statement, the acknowledgment shall require the signature of the owner and occupant, along with their dates of signature.

d. If a signature cannot be obtained from an adult occupant, the person must certify in writing that the pamphlet has been delivered to the dwelling and that a written acknowledgment could not be obtained from an adult occupant. Such certification must include the address of the unit to be remodeled, renovated, or repainted, the date and method of delivery of the pamphlet, the name of the person delivering the pamphlet, the reason for lack of acknowledgment (e.g., occupant refuses to sign, no adult occupant available), the signature of the person conducting the renovation, remodeling, or repainting, and the date of signature.

e. The type shall be clear and legible.

f. The acknowledgment may be included as a separate sheet or as a part of any written contract or service agreement. The acknowledgment must be completed prior to commencing the work.

g. If the parties use a written contract or agreement which is written in a language other than English, the acknowledgment text shall be written in the same language as the text of the contract or agreement.

69.3(3) In lieu of delivering the pamphlet and written acknowledgment, the person conducting the renovation, remodeling, or repainting may obtain a certificate of mailing the pamphlet and written acknowledgment at least seven days prior to beginning the work.

69.3(4) If the general nature, location, and expected starting and ending dates of the planned renovation, remodeling, or repainting change after the initial notification has been conducted, the person conducting the renovation, remodeling, or repainting shall provide further notification to the owners and occupants providing revised information on the ongoing or planned activities. This subsequent notification must be provided before the person conducting the renovation, remodeling, or repainting initiates work beyond that which was described in the original notice.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.4(135) Notification required in multifamily housing. A person who performs renovation, remodeling, or repainting of common areas for compensation, except for emergency renovation, remodeling, or repainting of target housing, and except for minor repair and maintenance activities that disrupt less than 1.0 square feet of painted surface, must do the following prior to commencing the work:

69.4(1) Provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the owner of the multifamily target housing where renovation, remodeling, or repainting will be performed. The pamphlet shall be provided no more than 60 days prior to commencing the work.

69.4(2) Obtain a signed, dated acknowledgment from the owner of the multifamily target housing where renovation, remodeling, or repainting will be performed affirming that the owner has received the pamphlet prior to the start of renovation, remodeling, or repainting and is aware of the potential health hazards from remodeling, renovating, or repainting housing containing lead-based paint. The acknowledgment shall be obtained no more than 60 days prior to commencing the work.

a. The acknowledgment shall include the owner's name and the address of the multifamily dwelling undergoing renovation, remodeling, or repainting.

b. The acknowledgment shall include the following language:

I have received the pamphlet entitled Lead Poisoning: How to Protect Iowa Families or the federal pamphlet, Renovate Right, prior to the start of renovation, remodeling, or repainting and am aware of the potential health risk associated with remodeling, renovating, or repainting housing containing lead-based paint or lead-based paint hazards.

c. Below the statement, the acknowledgment shall require the signature of the owner, along with the date of signature.

d. The type shall be clear and legible.

e. The acknowledgment may be included as a separate sheet or as a part of any written contract or service agreement. The acknowledgment must be completed prior to commencing the work.

f. If the parties use a written contract or agreement which is written in a language other than English, the acknowledgment text shall be written in the same language as the text of the contract or agreement.

g. Notify each occupant of the multifamily housing, in writing, of the intended remodeling, repainting, or renovation, and make the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, available upon request. At a minimum, this notification shall be accomplished by distributing written notice to each occupant of the target housing. The notice shall describe:

(1) The general nature and location of the planned renovation, remodeling, or repainting activity.

(2) The expected starting and ending dates of the planned renovation, remodeling, or repainting activity.

(3) A statement of how the owners and occupants can obtain the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, at no charge from the person conducting the renovation, remodeling, or repainting activity.

h. These activities shall be conducted by the person planning to perform the renovation, remodeling, or repainting, or by the owner on behalf of this person.

i. The person planning to perform the renovation, remodeling, or repainting must prepare, sign, and date a statement describing the steps performed to notify all occupants of the intended renovation, remodeling, or repainting, and to provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, at no charge upon request. Regardless of who performs the notification activities required in this subrule, the person planning to conduct the renovation, remodeling, or repainting shall be responsible for ensuring compliance with this subrule and shall be liable for any failures to comply with the notification requirements in this subrule.

69.4(3) In lieu of delivering the pamphlet and written acknowledgment to the owner, the person conducting the renovation, remodeling, or repainting may obtain a certificate of mailing the pamphlet and written acknowledgment at least seven days prior to beginning the work.

69.4(4) If the general nature, location, and expected starting and ending dates of the planned renovation, remodeling, or repainting change after the initial notification has been conducted, the person conducting the renovation, remodeling, or repainting shall provide further notification to the owners and occupants providing revised information on the ongoing or planned activities. This subsequent notification must be provided before the person conducting the renovation, remodeling, or repainting initiates work beyond that which was described in the original notice.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.5(135) Emergency renovation, remodeling, or repainting in target housing. A person who performs emergency renovation, remodeling, or repainting of target housing for compensation, except for minor repair and maintenance activities that disrupt less than 1.0 square feet of painted surface, must do the following as soon as reasonably possible:

69.5(1) Provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the owner of the target housing where renovation, remodeling, or repainting is performed.

69.5(2) Notify each owner and occupant of the target housing, in writing, of the remodeling, repainting, or renovation, and make the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, available upon request. At a minimum, this notification shall be accomplished by distributing written notice to each owner and occupant of the target housing. The notice shall describe:

- a.* The general nature and location of the renovation, remodeling, or repainting activity.
- b.* The starting and ending dates of the renovation, remodeling, or repainting activity.
- c.* A statement of how the owners and occupants can obtain the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, at no charge from the person conducting the renovation, remodeling, or repainting activity.

69.5(3) These activities shall be conducted by the person performing the renovation, remodeling, or repainting, or by the owner on behalf of this person. The person planning to perform the renovation, remodeling, or repainting must prepare, sign, and date a statement describing the steps performed to notify all occupants of the intended renovation, remodeling, or repainting, and to provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, at no charge upon request. Regardless of who performs the notification activities required in this rule, the person conducting the renovation, remodeling, or repainting shall be responsible for ensuring compliance with this rule and shall be liable for any failures to comply with the notification requirements in this rule.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.6(135) Certification of attempted delivery in target housing. When an adult occupant is unavailable for signature or refuses to sign the acknowledgment of receipt of the pamphlet, the person conducting the renovation, remodeling, or repainting is permitted by subrule 69.3(2) to certify delivery for each instance. The certification shall include the address of the unit undergoing renovation, remodeling, or repainting, the date and method of delivery of the pamphlet, name of the person delivering the pamphlet, reason for lack of acknowledgment (e.g., occupant refuses to sign, no adult occupant available), the signature of the person conducting the renovation, remodeling, or repainting, and the date of signature.

69.6(1) Unavailable for signature.

a. If an adult occupant is unavailable for signature, the certification shall contain the following language:

I certify that I have made a good-faith effort to deliver the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the unit listed below at the dates and times indicated, and that an adult occupant was unavailable to sign the acknowledgment. I further certify that I have left a copy of the pamphlet at the unit with the occupant.

b. Below the statement, the certification shall require the printed name and signature of the person conducting the renovation, remodeling, or repainting, the address of the unit, the attempted delivery dates and times, and the date of signature.

69.6(2) Refused to sign.

a. If the occupant refuses to sign the acknowledgment, the certification shall contain the following language:

I certify that I have made a good-faith effort to deliver the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the unit listed below at the dates and times indicated, and that the occupant refused to sign the acknowledgment. I further certify that I have left a copy of the pamphlet at the unit.

b. Below the statement, the certification shall require the printed name and signature of the person conducting the renovation, remodeling, or repainting, the address of the unit, the attempted delivery dates and times, the location where the pamphlet was left at the unit (e.g., taped to the door, slipped under the door), and the date of signature.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.7(135) Notification required in child-occupied facilities. A person who performs renovation, remodeling, or repainting of child-occupied facilities for compensation, except for emergency renovation, remodeling, or repainting of child-occupied facilities, and except for minor repair and maintenance activities that disrupt less than 1.0 square feet of painted surface, must do the following prior to commencing the work:

69.7(1) Provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the owner of the building where renovation, remodeling, or repainting will be performed. The pamphlet shall be provided no more than 60 days prior to commencing the work.

69.7(2) Obtain a signed, dated acknowledgment from the owner of the building where renovation, remodeling, or repainting will be performed affirming that the owner has received the pamphlet prior to the start of renovation, remodeling, or repainting and is aware of the potential health hazards from remodeling, renovating, or repainting buildings containing lead-based paint. The acknowledgment shall be obtained no more than 60 days prior to commencing the work.

a. The acknowledgment shall include the owner's name and the address of the child-occupied facility undergoing renovation, remodeling, or repainting.

b. The acknowledgment shall include the following language:

I have received the pamphlet entitled Lead Poisoning: How to Protect Iowa Families or the federal pamphlet, Renovate Right, prior to the start of renovation, remodeling, or repainting and am aware of the potential health risk associated with remodeling, renovating, or repainting buildings containing lead-based paint or lead-based paint hazards.

c. Below the statement, the acknowledgment shall require the signature of the owner along with the date of signature.

d. If a signature cannot be obtained from the owner, the person must certify in writing that the pamphlet has been delivered to the building and that a written acknowledgment could not be obtained from an owner. Such certification must include the address of the building to be remodeled, renovated, or repainted, the date and method of delivery of the pamphlet, the name of the person delivering the

pamphlet, the reason for lack of acknowledgment (e.g., owner refuses to sign, owner not available), the signature of the person conducting the renovation, remodeling, or repainting, and the date of signature.

e. The type shall be clear and legible.

f. The acknowledgment may be included as a separate sheet or as a part of any written contract or service agreement. The acknowledgment must be completed prior to commencing the work.

g. If the parties use a written contract or agreement which is written in a language other than English, the acknowledgment text shall be written in the same language as the text of the contract or agreement.

69.7(3) In lieu of delivering the pamphlet and written acknowledgment, the person conducting the renovation, remodeling, or repainting may obtain a certificate of mailing the pamphlet and written acknowledgment to the owner at least 7 days prior to beginning the work.

69.7(4) If the general nature, location, and expected starting and ending dates of the planned renovation, remodeling, or repainting change after the initial notification has been conducted, the person conducting the renovation, remodeling, or repainting shall provide further notification to the owners providing revised information on the ongoing or planned activities. This subsequent notification must be provided before the person conducting the renovation, remodeling, or repainting initiates work beyond that which was described in the original notice.

69.7(5) If the operator of the child-occupied facility is not the owner of the building, provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the operator of the child-occupied facility where renovation, remodeling, or repainting will be performed. The pamphlet shall be provided no more than 60 days prior to commencing the work.

69.7(6) If the operator of the child-occupied facility is not the owner of the building, obtain a signed, dated acknowledgment from the operator of the child-occupied facility where renovation, remodeling, or repainting will be performed affirming that the operator has received the pamphlet prior to the start of renovation, remodeling, or repainting and is aware of the potential health hazards from remodeling, renovating, or repainting buildings containing lead-based paint. The acknowledgment shall be obtained no more than 60 days prior to commencing the work.

a. The acknowledgment shall include the name of the operator of the child-occupied facility and the address of the child-occupied facility undergoing renovation, remodeling, or repainting.

b. The acknowledgment shall include the following language:

I have received the pamphlet entitled Lead Poisoning: How to Protect Iowa Families or the federal pamphlet, Renovate Right, prior to the start of renovation, remodeling, or repainting and am aware of the potential health risk associated with remodeling, renovating, or repainting buildings containing lead-based paint or lead-based paint hazards.

c. Below the statement, the acknowledgment shall require the signature of the operator of the child-occupied facility along with the date of signature.

d. If a signature cannot be obtained from the operator of the child-occupied facility, the person must certify in writing that the pamphlet has been delivered to the building and that a written acknowledgment could not be obtained from the operator of the child-occupied facility. Such certification must include the address of the building to be remodeled, renovated, or repainted, the date and method of delivery of the pamphlet, the name of the person delivering the pamphlet, the reason for lack of acknowledgment (e.g., operator of the child-occupied facility refuses to sign, operator of the child-occupied facility not available), the signature of the person conducting the renovation, remodeling, or repainting, and the date of signature.

e. The type shall be clear and legible.

f. The acknowledgment may be included as a separate sheet or as a part of any written contract or service agreement. The acknowledgment must be completed prior to commencing the work.

g. If the parties use a written contract or agreement which is written in a language other than English, the acknowledgment text shall be written in the same language as the text of the contract or agreement.

69.7(7) In lieu of delivering the pamphlet and written acknowledgment, the person conducting the renovation, remodeling, or repainting may obtain a certificate of mailing the pamphlet and written acknowledgment to the operator of the child-occupied facility at least 7 days prior to beginning the work.

69.7(8) If the general nature, location, and expected starting and ending dates of the planned renovation, remodeling, or repainting change after the initial notification has been conducted, the person conducting the renovation, remodeling, or repainting shall provide further notification to the operator of the child-occupied facility providing revised information on the ongoing or planned activities. This subsequent notification must be provided before the person conducting the renovation, remodeling, or repainting initiates work beyond that which was described in the original notice.

69.7(9) Provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, and information regarding the general nature and locations of the renovation, remodeling, or repainting and the anticipated completion date to the parents and guardians of children using the child-occupied facility where renovation, remodeling, or repainting will be performed. The pamphlet and information shall be provided no more than 60 days prior to commencing the work. The person conducting the renovation, remodeling, or repainting shall provide this information using one of the following methods:

a. Mail or hand-deliver the pamphlet and information to each parent or guardian of each child using the child-occupied facility (the pamphlet and information may not be sent home with the child); or

b. While the renovation, remodeling, or repainting is ongoing, post informational signs describing the general nature and locations of the renovation, remodeling, or repainting and the anticipated completion date. These signs must be posted in areas where they can be seen by the parents of the children frequenting the child-occupied facility. The signs must be accompanied by a posted copy of the pamphlet or information on how interested parents or guardians can review a copy of the pamphlet or obtain a copy from the person conducting the renovation, remodeling, or repainting at no cost to the parents or guardians.

69.7(10) The activities in subrule 69.7(9) shall be conducted by the person planning to perform the renovation, remodeling, or repainting or by the owner or operator of the child-occupied facility on behalf of this person. Regardless of who performs the notification activities required in subrule 69.7(9), the person conducting the renovation, remodeling, or repainting shall be responsible for ensuring compliance with this rule and shall be liable for any failures to comply with the notification requirements in this rule.

69.7(11) The person conducting the renovation, remodeling, or repainting shall prepare, sign, and date a statement describing the steps performed to notify all parents and guardians of the intended renovation, remodeling, or repainting and to provide the pamphlet to them.

69.7(12) If the general nature, location, and expected starting and ending dates of the planned renovation, remodeling, or repainting change after the initial notification has been conducted, the person conducting the renovation, remodeling, or repainting shall provide revised information on the ongoing or planned activities to the parents and guardians of children frequenting the child-occupied facility providing revised information on the ongoing or planned activities. This subsequent notification must be provided before the person conducting the renovation, remodeling, or repainting initiates work beyond that which was described in the original notice.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.8(135) Emergency renovation, remodeling, or repainting in child-occupied facilities. A person who performs emergency renovation, remodeling, or repainting of child-occupied facilities for compensation, except for minor repair and maintenance activities that disrupt less than 1.0 square feet of painted surface, must do the following as soon as reasonably possible:

69.8(1) Provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the owner of the building where renovation, remodeling, or repainting is performed.

69.8(2) Notify each owner and, if different, the operator of the child-occupied facility, in writing, of the remodeling, repainting, or renovation, and make the pamphlet, Lead Poisoning: How to Protect

Iowa Families, or the federal pamphlet, Renovate Right, available upon request. At a minimum, this notification shall be accomplished by distributing written notice to each owner and, if different, operator of the child-occupied facility. The notice shall describe:

- a. The general nature and location of the renovation, remodeling, or repainting activity.
- b. The starting and ending dates of the renovation, remodeling, or repainting activity.
- c. A statement of how each owner and, if different, the operator of the child-occupied facility can obtain the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, at no charge from the person conducting the renovation, remodeling, or repainting activity.

69.8(3) Provide the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, and information regarding the general nature and locations of the renovation, remodeling, or repainting and the anticipated completion date to the parents and guardians of children using the child-occupied facility where renovation, remodeling, or repainting will be performed. The person conducting the renovation, remodeling, or repainting shall provide this information using one of the following methods:

- a. Mail or hand-deliver the pamphlet and information to each parent or guardian of each child using the child-occupied facility (the pamphlet and information may not be sent home with the child); or
- b. While the renovation, remodeling, or repainting is ongoing, post informational signs describing the general nature and locations of the renovation, remodeling, or repainting and the anticipated completion date. These signs must be posted in areas where they can be seen by the parents or guardians of the children frequenting the child-occupied facility. The signs must be accompanied by a posted copy of the pamphlet or information on how interested parents or guardians can review a copy of the pamphlet or obtain a copy from the person conducting the renovation, remodeling, or repainting at no cost to the parents or guardians.

69.8(4) The activities in subrule 69.8(3) shall be conducted by the person planning to perform the renovation, remodeling, or repainting or by the owner or operator of the child-occupied facility on behalf of this person. Regardless of who performs the notification activities required in subrule 69.8(3), the person conducting the renovation, remodeling, or repainting shall be responsible for ensuring compliance with this rule and shall be liable for any failures to comply with the notification requirements in this rule. [ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.9(135) Certification of attempted delivery for child-occupied facilities. When the owner and, if different, operator of a child-occupied facility are unavailable for signature or refuse to sign the acknowledgment of receipt of the pamphlet, the person conducting the renovation, remodeling, or repainting is permitted by subrule 69.3(2) to certify delivery for each instance. The certification shall include the address of the child-occupied facility undergoing renovation, remodeling, or repainting, the date and method of delivery of the pamphlet, name of the person delivering the pamphlet, reason for lack of acknowledgment (e.g., owner and, if different, operator refuse to sign), the signature of the individual conducting the renovation, remodeling, or repainting, and the date of signature.

69.9(1) Unavailable for signature.

- a. If the owner and, if different, operator of the child-occupied facility are unavailable for signature, the certification shall contain the following language:

I certify that I have made a good-faith effort to deliver the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the child-occupied facility listed below at the dates and times indicated, and that the owner and, if different, operator of the child-occupied facility were unavailable to sign the acknowledgment. I further certify that I have left a copy of the pamphlet at the child-occupied facility with the owner and, if different, operator.

- b. Below the statement, the certification shall require the printed name and signature of the person conducting the renovation, remodeling, or repainting, the address of the child-occupied facility, the attempted delivery dates and times, and the date of signature.

69.9(2) Refused to sign.

a. If the owner and, if different, operator refuse to sign the acknowledgment, the certification shall contain the following language:

I certify that I have made a good-faith effort to deliver the pamphlet, Lead Poisoning: How to Protect Iowa Families, or the federal pamphlet, Renovate Right, to the child-occupied facility listed below at the dates and times indicated, and that the owner and, if different, operator refused to sign the acknowledgment. I further certify that I have left a copy of the pamphlet at the child-occupied facility.

b. Below the statement, the certification shall require the printed name and signature of the person conducting the renovation, remodeling, or repainting, the address of the child-occupied facility, the attempted delivery dates and times, the location where the pamphlet was left at the child-occupied facility (e.g., taped to the door, slipped under the door), and the date of signature.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.10(135) Subcontracts. In cases where renovation, remodeling, or repainting activities involve subcontracts, it is the responsibility of the person receiving the compensation from the property owner, or other party on behalf of the property owner, to provide the notification(s) described in 641—69.3(135), 641—69.4(135), 641—69.5(135), and 641—69.6(135) of this chapter.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.11(135) Exemption. Renovation, remodeling, or repainting in target housing or a child-occupied facility in which a lead inspector/risk assessor or elevated blood lead (EBL) inspector/risk assessor certified pursuant to 641—Chapter 70 has made a written determination that the components affected by the renovation are free of lead-based paint and where the person conducting the renovation, remodeling, or repainting has obtained a copy of the written determination is exempt from the provisions of 641—Chapter 69.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.12(135) Record-keeping requirements. A person who conducts renovation, remodeling, or repainting for compensation in target housing or a child-occupied facility shall retain all records necessary to demonstrate compliance with this chapter for a minimum of three years following completion of the renovation, remodeling, or repainting. The records shall include:

69.12(1) The address or location of the target housing or child-occupied facility where remodeling, renovation, or repainting was conducted.

69.12(2) A list of all known occupants of the dwelling units where renovation, remodeling, or repainting was conducted at the commencement of the work.

69.12(3) Copies of signed, dated acknowledgments as required by subrule 69.3(2) from each owner and occupant of a dwelling unit where renovation, remodeling, or repainting was conducted.

69.12(4) Copies of signed, dated acknowledgments as required by subrule 69.4(2) from each owner of multifamily target housing where renovation, remodeling, or repainting was conducted in common areas.

69.12(5) Copies of all signed, dated statements of notification, as well as copies of all notification materials given to all owners and occupants and acknowledgments as required by subrule 69.4(2) from each owner and occupant of multifamily target housing where renovation, remodeling, or repainting was conducted in common areas.

69.12(6) Copies of signed, dated acknowledgments as required by 641—69.7(135) from the owner and, if different, operator of a child-occupied facility where renovation, remodeling, or repainting was conducted.

69.12(7) Copies of all notification materials given to the parents or guardians of children using a child-occupied facility or the signs posted in areas where the signs can be seen by the parents or guardians of children using the child-occupied facility as required by subrule 69.7(9).

69.12(8) Reports showing that a lead inspector/risk assessor or elevated blood level (EBL) inspector/risk assessor certified pursuant to 641—Chapter 70 has made a written determination that the components affected by the renovation are free of lead-based paint.

69.12(9) Certifications of attempted delivery as described in 641—69.6(135).

69.12(10) Certificates of mailing as described in subrules 69.3(3) and 69.4(3).

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.13(135) Compliance inspections. The department may enter the place of business of a person who conducts renovation, remodeling, or repainting for the purpose of enforcing the notification required by this chapter.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.14(135) Enforcement.

69.14(1) The department may impose a civil penalty pursuant to Iowa Code section 135.105C and this rule and may refer the case to the office of the county attorney for possible criminal penalties pursuant to Iowa Code section 135.38 when it finds that a person has committed any of the following acts:

- a.* Failed or refused to comply with any requirements of this chapter.
- b.* Failed or refused to establish, maintain, provide, copy, or permit access to records or reports as required by this chapter.
- c.* Failed or refused to permit entry or inspection as described in subrule 69.14(1).
- d.* Falsified reports and records required by this chapter.
- e.* Failed to comply with the terms of a department order or the terms of a settlement agreement or consent order.
- f.* Failed to respond within 20 days of receipt of communication sent by the department by registered or certified mail.
- g.* Engaged in any conduct that subverts or attempts to subvert a department investigation.
- h.* Failed to comply with a subpoena issued by the department or failed to cooperate with a department investigation.
- i.* Failed to pay costs assessed in any disciplinary action.

69.14(2) Complaints and other requests for action under this rule. Complaints regarding a person who performs renovation, remodeling, or repainting for compensation in target housing or a child-occupied facility shall be submitted in writing to the Iowa Department of Public Health, Lead Poisoning Prevention Program, 321 East 12th Street, Des Moines, Iowa 50319-0075. The complainant shall provide the name of the person who performs renovation, remodeling, or repainting for compensation in target housing or a child-occupied facility and the specific details of the person's action(s) that did not comply with the rules.

69.14(3) Civil penalties.

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 135.105C, the department shall serve a written notice of violation upon the person charged. The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the department, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action pursuant to Iowa Code section 135.105C.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

c. If the person charged with a violation fails to answer within the time specified in paragraph 69.14(3) "b," an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in paragraph 69.14(3) "a."

d. If the person charged with a violation files an answer to the notice of violation, the department, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with a violation requests a hearing, the department will issue an order designating the time and place of hearing. The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10, Iowa Administrative Code.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the department dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The department may compromise any civil penalty. If the civil penalty is not compromised or is not remitted by the presiding officer or the department or if the time for requesting a hearing described in paragraph 69.14(3) “*d*” has expired, the department may refer the matter to the attorney general for collection.

h. Except when payment is made after compromise or mitigation by the department of justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties imposed under Iowa Code section 135.105C shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

69.14(4) Appeals.

a. Notice of the civil penalty shall be sent to the affected person by certified mail, return receipt requested, or by personal service. The affected person shall have a right to appeal the civil penalty.

b. An appeal of a civil penalty shall be submitted by certified mail, return receipt requested, to the Iowa Department of Public Health, Lead Poisoning Prevention Program, 321 East 12th Street, Des Moines, Iowa 50319-0075, within 20 days of receipt of the department’s notice. If such a request is made within the 20-day time period, the notice of civil penalty shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the civil penalty has been or will be removed. After the hearing, or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the civil penalty. If no appeal is submitted within 20 days, the civil penalty shall become the department’s final agency action.

c. Upon receipt of an appeal that meets contested case status, the appeal shall be transmitted to the department of inspections and appeals within 5 working days of receipt pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the civil penalty is based shall be provided to the department of inspections and appeals.

d. The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10, Iowa Administrative Code.

e. When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. The proposed decision and order then becomes the department’s final agency action without further proceedings 10 days after it is received by the aggrieved party unless an appeal to the director is taken as provided in paragraph 69.14(4) “*f*.”

f. Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within 10 days after the receipt of the administrative law judge’s proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for appeal shall state the reason for appeal.

g. Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing or submission to the director. The record shall include the following:

- (1) All pleadings, motions, and rulings.
- (2) All evidence received or considered and all other submissions by recording or transcript.
- (3) A statement of all matters officially noticed.
- (4) All questions and offers of proof, objection, and rulings thereon.
- (5) All proposed findings and exceptions.
- (6) The proposed findings and order of the administrative law judge.

h. The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

i. It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

j. Any petition for judicial review of a decision and order shall be filed in the district court within 20 days after the decision and order becomes final. A copy of the notice of appeal shall be sent by certified mail, return receipt requested, or by personal service to the Iowa Department of Public Health, Lead Poisoning Prevention Program, 321 East 12th Street, Des Moines, Iowa 50319-0075.

k. The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

[ARC 8501B, IAB 2/10/10, effective 1/13/10]

641—69.15(135) Waivers. Rules in this chapter are not subject to waiver pursuant to 641—Chapter 178 or any other provision of law.

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PROFESSIONAL LICENSURE DIVISION[645]

Created within the Department of Public Health[641] by 1986 Iowa Acts, chapter 1245.
Prior to 7/29/87, for Chs. 20 to 22 see Health Department[470] Chs. 152 to 154.

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[Prior to 7/29/87, Health Department[470] Ch 152]
[Prior to 2/20/02, see 645—Chapter 20]

645—21.1(158) Definitions. For purposes of these rules, the following definitions shall apply:

“Active license” means a license that is current and has not expired.

“Apprentice” means any person, other than a helper, journeyperson, or master, who is working under the supervision of either a master or a journeyperson and is progressing toward completion of a barbering apprenticeship training program registered by the Office of Apprenticeship of the United States Department of Labor while learning and assisting in the practice of barbering.

“Board” means the board of barbering.

“Examination” means any of the tests used by the board to determine minimum competency prior to the issuance of a barber or barber instructor license.

“Grace period” means the 30-day period following expiration of a license when the license is still considered to be active. In order to renew a license during the grace period, a licensee is required to pay a late fee.

“Inactive license” means a license that has expired because it was not renewed by the end of the grace period. The category of “inactive license” may include licenses formerly known as lapsed, inactive, delinquent, closed, or retired.

“Licensee” means any person licensed to practice as a barber in the state of Iowa.

“License expiration date” means June 30 of even-numbered years.

“Licensure by endorsement” means the issuance of an Iowa license to practice as a barber to an applicant who is or has been licensed in another state.

“NIC” means the National-Interstate Council of State Boards of Cosmetology, Inc.

“Reactivate” or *“reactivation”* means the process as outlined in rule 645—21.16(17A,147,272C) by which an inactive license is restored to active status.

“Reciprocal license” means the issuance of an Iowa license to practice barbering to an applicant who is currently licensed in another state and which state has a mutual agreement to license persons who have the same or similar qualifications to those required in Iowa.

“Reinstatement” means the process as outlined in 645—11.31(272C) by which a licensee who has had a license suspended or revoked or who has voluntarily surrendered a license may apply to have the license reinstated, with or without conditions. Once the license is reinstated, the licensee may apply for active status.

“Testing service” means a national testing service selected by the board.

[ARC 8349B, IAB 12/2/09, effective 1/6/10; ARC 5039C, IAB 5/6/20, effective 6/10/20]

645—21.2(158) Requirements for licensure.

21.2(1) The following criteria shall apply to licensure:

a. Applicants shall complete a board-approved application form. Application forms may be obtained from the board’s website (www.idph.iowa.gov/licensure) or directly from the board office. The application and licensure fees shall be sent to the Board of Barbering, Professional Licensure Division, Fifth Floor, Lucas State Office Building, Des Moines, Iowa 50319-0075.

b. Applicants shall present proof of completion of the tenth grade or equivalent education. In the event the applicant is a refugee or immigrant from a country where high school records no longer exist, the applicant shall be considered to have met this requirement when the applicant submits an affidavit attesting to the fact that the applicant has met the tenth-grade requirement.

c. Applicants shall provide an official copy of the transcript or diploma sent directly from the school to the board showing proof of completion of training at a barber school licensed by the board. If the applicant graduated from a school that is not licensed by the board, the applicant shall direct the school to provide an official transcript showing completion of a course of study that meets the requirements of rule 645—23.8(158). If the applicant completed a barbering apprenticeship training program registered by the Office of Apprenticeship of the United States Department of Labor while committed to the custody of the director of the department of corrections, the applicant shall request the department of corrections to provide an official transcript showing completion of the apprentice program.

d. Applicants shall pass both the NIC theory examination and the NIC practical examination with a score of 70 percent or better on each examination.

e. An applicant shall provide verification of license(s) from every state in which the applicant has been licensed as a barber, sent directly from the state(s) to the Iowa board of barbering office.

f. Applications for a barber license must be received in the board office a minimum of five business days prior to the NIC practical examination.

g. Licensees who were issued their licenses within six months prior to renewal shall not be required to renew their licenses until the renewal month two years later.

h. Incomplete applications that have been on file in the board office for more than two years shall be:

- (1) Considered invalid and shall be destroyed; or
- (2) Maintained upon written request of the applicant. The applicant is responsible for requesting that the file be maintained.

21.2(2) Foreign-trained barbers shall:

a. Provide an equivalency evaluation of their educational credentials by one of the following: International Educational Research Foundation, Inc., Credentials Evaluation Service, P.O. Box 3665, Culver City, CA 90231-3665, telephone (310)258-9451, website www.ierf.org or email at info@ierf.org; or World Education Services (WES) at (212)966-6311, electronically at www.wes.org or by writing to WES, P.O. Box 745, Old Chelsea Station, New York, NY 10113-0745. The professional curriculum must be equivalent to that stated in these rules. An applicant shall bear the expense of the curriculum evaluation.

b. Provide a notarized copy of the certificate or diploma awarded to the applicant from a barber school in the country in which the applicant was educated.

c. Receive a final determination from the board regarding the application for licensure.

21.2(3) Requirements for an instructor's license. Applicants shall:

- a.* Complete all requirements stated in subrule 21.2(1), paragraphs "*a*" and "*d*";
- b.* Present proof of graduation from an accredited high school or the equivalent thereof;
- c.* Be licensed in the state of Iowa as a barber for not less than two years; and
- d.* Pass both the NIC instructor theory examination and the NIC instructor practical examination with a score of 70 percent or better on each examination.

21.2(4) Instructors who were issued their licenses within six months prior to renewal shall not be required to renew their licenses until the renewal month two years later.

21.2(5) Incomplete applications that have been on file in the board office for more than two years shall be:

- a.* Considered invalid and shall be destroyed; or
- b.* Maintained upon written request of the applicant. The applicant is responsible for requesting that the file be maintained.

21.2(6) An applicant who meets the requirements for an instructor's license except for the instructor examinations may apply for a temporary permit to be an instructor. The temporary permit shall be valid for a maximum of six months from the issue date of the permit and shall not be renewable.

[ARC 7578B, IAB 2/25/09, effective 4/1/09; ARC 8349B, IAB 12/2/09, effective 1/6/10; ARC 5039C, IAB 5/6/20, effective 6/10/20]

645—21.3(158) Examination requirements for barbers and barber instructors.

21.3(1) *Theory examination.* Applicants shall contact the testing service directly to schedule the computer-based NIC theory examination. The fee for scheduling the written theory examination shall be paid directly to the testing service. This fee is not included in the licensure fee and practical examination fee identified in 645—subrules 5.2(1) and 5.2(4).

21.3(2) *Practical examination.* Applicants who have completed the application process and passed the NIC theory examination with a score of 70 percent or better shall be eligible to sit for the NIC practical examination administered by the board.

a. Application, supporting documentation, and licensure and practical examination fees required by the board shall be received in the board office at least five days prior to the scheduled NIC practical examination date.

b. The board shall send a notice of the date and time of the practical examination to the address on record.

c. Applicants are required to receive a passing score of 70 percent on the practical examination to be eligible for licensure.

d. Applicants shall be notified in writing of the result of the practical examination.

e. Applicants who fail to appear for the practical examination must request in writing or by telephone to reschedule the examination. Examination fees are not refundable, but the rescheduled examination fee may be waived upon the applicant's showing of good cause for missing the previously scheduled examination. Proof of good cause shall be submitted to the board office with the request to reschedule the examination. The applicant shall be required to pay the reexamination fee if the applicant does not appear for the subsequent examination.

f. Persons who do not attain the passing score may reapply to take the practical examination. The examination fee cannot be refunded, and the applicant shall be required to pay the reexamination fee.

[ARC 7578B, IAB 2/25/09, effective 4/1/09; ARC 8349B, IAB 12/2/09, effective 1/6/10]

645—21.4(158) Educational qualifications. Rescinded IAB 2/25/09, effective 4/1/09.

645—21.5(158) Licensure by endorsement. The board may issue a license by endorsement to any applicant from the District of Columbia or another state, territory, province or foreign country who has held an active license under the laws of another jurisdiction for at least 12 months during the past 24 months and who:

21.5(1) Submits to the board a completed application and pays the licensure fee specified in 645—subrule 5.2(1).

21.5(2) Provides verification of license(s) from every state in which the applicant has been licensed as a barber, sent directly from the state(s) to the Iowa board of barbering office. Web-based verification may be substituted for verification direct from the jurisdiction's board office if the verification provides:

a. Licensee's name;

b. Date of initial licensure;

c. Current licensure status; and

d. Any disciplinary action taken against the license.

21.5(3) Beginning August 1, 2010, completes one hour of Iowa barbering laws and administrative rules and sanitation.

21.5(4) Passes a national written and practical examination.

[ARC 7578B, IAB 2/25/09, effective 4/1/09; ARC 8349B, IAB 12/2/09, effective 1/6/10]

645—21.6(158) Licensure by reciprocal agreement. Rescinded IAB 2/25/09, effective 4/1/09.

645—21.7(158) Temporary permits to practice barbering. An applicant must meet the following requirements:

1. The applicant is applying for initial licensure and is not licensed in another state.
2. The applicant has met the requirements for licensure except for passing the examinations required by the board. The temporary permit is valid from the date the application is approved for a maximum of six months and shall not be renewable.

[ARC 8349B, IAB 12/2/09, effective 1/6/10]

645—21.8(158) Demonstrator's permit. The board may issue a demonstrator's permit to a licensed barber for the purpose of demonstrating barbering to the public. The following criteria apply to the demonstrator's permit:

1. A demonstrator's permit shall be valid for a barbershop, person or an event. The location, purpose and duration shall be stated on the permit.
2. A demonstrator's permit shall be valid for no more than 10 days.
3. A completed application shall be submitted on a form provided by the board at least 30 days in advance of the intended use dates.
4. An application fee shall be submitted as set forth in these rules.
5. No more than four permits shall be issued to any applicant during a calendar year.

645—21.9(158) License renewal.

21.9(1) The biennial license renewal period for a license to practice barbering shall begin on July 1 of each even-numbered year and end on June 30 of each even-numbered year. All licensees shall renew on a biennial basis. The licensee is responsible for renewing the license prior to its expiration. Failure of the licensee to receive notice from the board does not relieve the licensee of the responsibility for renewing the license.

21.9(2) A licensee seeking renewal shall:

- a. Meet the continuing education requirements of rule 645—24.2(158). A licensee whose license was reactivated during the current renewal compliance period may use continuing education credit earned during the compliance period for the first renewal following reactivation; and
- b. Submit the completed renewal application and renewal fee before the license expiration date.
- c. Persons licensed to practice as barbers shall keep their renewal licenses displayed in a conspicuous public place at the primary site of practice.
- d. Individuals who were issued a license within six months of the license renewal date will not be required to renew their licenses until the next renewal two years later.

21.9(3) Late renewal. The license shall become late when the license has not been renewed by the expiration date on the wallet card. The licensee shall be assessed a late fee as specified in 645—subrule 5.2(10). To renew a late license, the licensee shall complete the renewal requirements and submit the late fee within the grace period.

21.9(4) Upon receiving the information required by this rule and the required fee, board staff shall administratively issue a two-year license and shall send the licensee a wallet card by regular mail. In the event the board receives adverse information on the renewal application, the board shall issue the renewal license but may refer the adverse information for further consideration or disciplinary investigation.

21.9(5) Inactive license. A licensee who fails to renew the license by the end of the grace period has an inactive license. A licensee whose license is inactive continues to hold the privilege of licensure in Iowa, but may not practice as a barber in Iowa until the license is reactivated. A licensee who practices as a barber in the state of Iowa with an inactive license may be subject to disciplinary action by the board, injunctive action pursuant to Iowa Code section 147.83, criminal sanctions pursuant to Iowa Code section 147.86, and other available legal remedies.

[ARC 7578B, IAB 2/25/09, effective 4/1/09; ARC 1680C, IAB 10/15/14, effective 11/19/14]

645—21.10(272C) Exemptions for inactive practitioners. Rescinded IAB 8/17/05, effective 9/21/05.

645—21.11(158) Requirements for a barbershop license.

21.11(1) A barbershop shall not operate unless the owner of the barbershop possesses a current barbershop license issued by the board. The following criteria shall apply to licensure:

a. The owner shall complete a board-approved application form. Application forms may be obtained from the board's website (www.idph.iowa.gov/licensure), or directly from the board office. The application and fee shall be submitted to the Board of Barbering, Professional Licensure Division, Fifth Floor, Lucas State Office Building, Des Moines, Iowa 50319-0075.

b. The barbershop shall meet the requirements for sanitary conditions established in 645—Chapter 22.

c. A barbershop license may be for a stationary barbershop or a mobile barbershop.

(1) Stationary barbershop. A stationary barbershop license shall be issued for a specific location. A change in location or site of a stationary barbershop shall result in the cancellation of the existing license and necessitate application for a new license and payment of the fee required by 645—subrule 5.2(8). A change of address without change of actual location shall not be construed as a new site.

(2) Mobile barbershop. A mobile barbershop license shall be issued for a permanent physical address. The licensee is required to provide a permanent physical address for board correspondence. A mobile barbershop may operate in a legal parking spot or on private property, with the permission of the owner or the owner's designee, anywhere in the state of Iowa provided the mobile barbershop is operating in compliance with applicable federal and state transportation, environmental, and sanitary regulations, including those herein.

(3) Barbershop owner's contact information. The listed owner of either a stationary or mobile barbershop must update the board within 30 days of a change in contact information, which includes telephone number, email address, and mailing address.

d. A barbershop license is not transferable. A change in ownership of a barbershop shall result in the cancellation of the existing license and necessitate application for a new license and payment of the fee required by 645—subrule 5.2(8).

e. A change in the name of a barbershop shall be reported to the board within 30 days of the name change.

f. Upon closure of a barbershop, the barbershop license shall be submitted to the board office within 30 days.

g. A barbershop that was issued a license within six months prior to renewal shall not be required to renew the license until the renewal month two years later.

21.11(2) Incomplete applications that have been on file in the board office for more than two years shall be:

a. Considered invalid and shall be destroyed; or

b. Maintained upon written request of the candidate. The candidate is responsible for requesting that the file be maintained.

[ARC 7578B, IAB 2/25/09, effective 4/1/09; ARC 5686C, IAB 6/16/21, effective 7/21/21]

645—21.12(158) Barbershop license renewal.

21.12(1) The biennial license renewal period for a barbershop license shall begin on July 1 of each even-numbered year and end on June 30 of the next even-numbered year.

21.12(2) Failure to receive the renewal application from the board shall not relieve the barbershop of the obligation to pay the biennial renewal fee on or before the renewal date.

21.12(3) The completed application and renewal fee shall be submitted to the board office before the license expiration date.

21.12(4) The barbershop shall be in full compliance with this chapter and 645—Chapter 22 to be eligible for license renewal.

21.12(5) When all requirements for license renewal are met, a license wallet card will be sent by regular mail.

21.12(6) A barbershop that is issued an initial license within six months prior to the renewal date will not be required to renew the license until the next renewal two years later.

21.12(7) Barbershop license late renewal. If the renewal fee and renewal application are received within 30 days after the license renewal expiration date, the late fee for failure to renew before expiration shall be charged.

21.12(8) Inactive barbershop license. If the renewal application and fee are not postmarked within 30 days after the license expiration date, the barbershop license is inactive. To reactivate a barbershop license, the reactivation application and fee shall be submitted to the board office.

[ARC 7578B, IAB 2/25/09, effective 4/1/09; ARC 1680C, IAB 10/15/14, effective 11/19/14]

645—21.13(147) Duplicate certificate or wallet card. Rescinded IAB 2/25/09, effective 4/1/09.

645—21.14(147) Reissued certificate or wallet card. Rescinded IAB 2/25/09, effective 4/1/09.

645—21.15(272C) License denial. Rescinded IAB 2/25/09, effective 4/1/09.

645—21.16(17A,147,272C) License reactivation. To apply for reactivation of an inactive license, a licensee shall:

21.16(1) Submit a reactivation application on a form provided by the board.

21.16(2) Pay the reactivation fee that is due as specified in 645—subrule 5.2(11).

21.16(3) Provide verification of current competence to practice as a barber by satisfying one of the following criteria:

a. If the license has been on inactive status for five years or less, an applicant must provide the following:

(1) Verification of the license(s) from every jurisdiction in which the applicant is or has been licensed and is or has been practicing during the time period the Iowa license was inactive, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification from a jurisdiction's board office if the verification includes:

1. Licensee's name;
2. Date of initial licensure;
3. Current licensure status; and
4. Any disciplinary action taken against the license; and

(2) Verification of completion of three hours of continuing education that meet the continuing education standards defined in rule 645—24.3(158,272C) within two years of application for reactivation.

b. If the license has been on inactive status for more than five years, an applicant must provide the following:

(1) Verification of the license(s) from every jurisdiction in which the applicant is or has been licensed and is or has been practicing during the time period the Iowa license was inactive, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification from a jurisdiction's board office if the verification includes:

1. Licensee's name;
2. Date of initial licensure;
3. Current licensure status; and
4. Any disciplinary action taken against the license; and

(2) Verification of completion of three hours of continuing education that meet the continuing education standards defined in rule 645—24.3(158,272C) within two years of application for reactivation; and

(3) Verification of passing the examinations required by the board within one year immediately prior to reactivation if the applicant does not have a current license and has not been in active practice in the United States during the past five years.

21.16(4) Licensees who are barber instructors shall obtain an additional four hours of continuing education in teaching methodology.

[ARC 7578B, IAB 2/25/09, effective 4/1/09; ARC 8349B, IAB 12/2/09, effective 1/6/10; ARC 2722C, IAB 9/28/16, effective 11/2/16]

645—21.17(17A,147,272C) Reactivation of a barbershop license. To apply for reactivation of an inactive license, a licensee shall:

21.17(1) Submit a reactivation application on a form provided by the board.

21.17(2) Pay the reactivation fee that is due as specified in 645—subrule 5.2(12).

21.17(3) Meet the requirements for sanitary conditions established in 645—Chapter 22.

[ARC 7578B, IAB 2/25/09, effective 4/1/09]

645—21.18(17A,147,272C) License reinstatement. A licensee whose license has been revoked, suspended, or voluntarily surrendered must apply for and receive reinstatement of the license in accordance with 645—11.31(272C) and must apply for and be granted reactivation of the license in accordance with 645—21.16(17A,147,272C) prior to practicing as a barber in this state.

[ARC 7578B, IAB 2/25/09, effective 4/1/09]

645—21.19(158) Mobile barbershops. A mobile home, motor home, trailer, or other recreational vehicle may be used as a mobile barbershop if it complies with the following:

21.19(1) The owner shall possess a current mobile barbershop license issued by the board.

21.19(2) The owner shall complete a board-approved application.

21.19(3) The mobile barbershop's owner's telephone number, email address, and permanent address must be included on the mobile barbershop's application for licensure and must be updated and accurate.

21.19(4) No service may be performed on a client in a moving vehicle. Services shall be performed in a mobile barbershop that is parked in a legal parking spot.

21.19(5) Mobile barbershops must provide:

a. A supply of hot and cold water;

b. Adequate lighting;

c. A floor surface in the service area that is nonabsorbent and easily cleanable;

d. Work surfaces that are easily cleaned;

e. Cabinets secured with safety catches wherein all chemicals shall be stored when the vehicle is moving;

f. A first-aid kit that includes adhesive dressing, gauze and antiseptic, tape, triple antibiotics, eyewash, and gloves.

21.19(6) Mobile barbershops must comply with all rules in 645—Chapter 22, Infection Control for Barbershops and Barber Schools, except rules 645—22.5(158) through 645—22.7(158).

[ARC 5686C, IAB 6/16/21, effective 7/21/21]

These rules are intended to implement Iowa Code chapters 272C and 158.

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[◇] Two or more ARCs

¹ See Public Health Department[641], IAB

² Effective date of rule 567—20.10(158) delayed 70 days by the Administrative Rules Review Committee at its meeting held December 11, 1991; delayed until adjournment of the 1992 General Assembly at the Committee's meeting held February 3, 1992.

CHAPTER 83
IOWA SEX OFFENDER REGISTRY
[Prior to 2/16/05, see 661—8.301 to 8.305]

661—83.1(692A) Sex offender registry established. The Iowa sex offender registry, as authorized by Iowa Code chapter 692A, is hereby established in the division of criminal investigation.

661—83.2(692A) Definitions. The following definitions apply to rules 661—83.1(692A) to 661—83.5(692A).

“Aggravated offense” means a conviction for any of the following offenses:

1. Sexual abuse in the first degree in violation of Iowa Code section 709.2.
2. Sexual abuse in the second degree in violation of Iowa Code section 709.3.
3. Sexual abuse in the third degree in violation of Iowa Code section 709.4(1)“a.”
4. Lascivious acts with a child in violation of Iowa Code section 709.8(1)“a” or “b.”
5. Assault with intent to commit sexual abuse in violation of Iowa Code section 709.11.
6. Burglary in the first degree in violation of Iowa Code section 713.3(1)“d.”
7. Kidnapping, if sexual abuse as defined in Iowa Code section 709.1 is committed during the commission of the offense.
8. Murder in violation of Iowa Code section 707.2 or 707.3, if sexual abuse as defined in Iowa Code section 709.1 is committed during the offense.
9. Continuous sexual abuse of a child in violation of Iowa Code section 709.23.
10. Any conviction for an offense specified in the laws of another jurisdiction or any conviction for an offense prosecuted in a federal, military, or foreign court that is comparable to an offense listed in paragraphs “1” through “9” shall be considered an aggravated offense for purposes of registering under this chapter.

“Aggravated offense against a minor” means a conviction for any of the following offenses, if such offense was committed against a minor or otherwise involves a minor:

1. Sexual abuse in the first degree in violation of Iowa Code section 709.2.
2. Sexual abuse in the second degree in violation of Iowa Code section 709.3.
3. Sexual abuse in the third degree in violation of Iowa Code section 709.4, except for a violation of Iowa Code section 709.4(1)“b”(3)(d).
4. Continuous sexual abuse of a child in violation of Iowa Code section 709.23.
5. Any offense specified in the laws of another jurisdiction or prosecuted in a federal, military, or foreign court that is comparable to an offense listed in paragraphs “1” through “4” shall be considered an aggravated offense against a minor if such an offense was committed against a minor or otherwise involves a minor.

“Appearance” means to appear in person at a sheriff’s office.

“Business day” means every day except Saturday, Sunday, or any paid holiday for county employees in the applicable county.

“Change” means to add, begin, or terminate.

“Child care facility” means the same as defined in Iowa Code section 237A.1.

“Convicted” means found guilty of, pleads guilty to, or is sentenced or adjudicated delinquent for an act which is an indictable offense in this state or in another jurisdiction including in a federal, military, tribal, or foreign court, including but not limited to a juvenile who has been adjudicated delinquent but whose juvenile court records have been sealed under Iowa Code section 232.150, and a person who has received a deferred sentence or a deferred judgment or has been acquitted by reason of insanity. “Convicted” includes the conviction of a juvenile prosecuted as an adult. “Convicted” also includes a conviction for an attempt or conspiracy to commit an offense. “Convicted” does not mean a plea, sentence, adjudication, deferred sentence, or deferred judgment which has been reversed or otherwise set aside.

“Criminal or juvenile justice agency” means an agency or department of any level of government or an entity wholly owned, financed, or controlled by one or more such agencies or departments

which performs as its principal function the apprehension, prosecution, adjudication, incarceration, or rehabilitation of criminal or juvenile offenders.

“Department” means the department of public safety.

“Employee” means an offender who is self-employed, employed by another, and includes a person working under contract or acting or serving as a volunteer, regardless of whether the self-employment, employment by another, or volunteerism is performed for compensation.

“Employment” means acting as an employee.

“Foreign court” means a court of a foreign nation that is recognized by the United States Department of State that enforces the right to a fair trial during the period in which a conviction occurred.

“Habitually lives” means living in a place with some regularity, and with reference to where the sex offender actually lives, which could be some place other than a mailing address or primary address but would entail a place where the sex offender lives on an intermittent basis.

“Incarcerated” means to be imprisoned by placing a person in a jail, prison, penitentiary, juvenile facility, or other correctional institution or facility or a place or condition of confinement or forcible restraint regardless of the nature of the institution in which the person serves a sentence for a conviction.

“Internet identifier” means an electronic mail address, instant message address or identifier, or any other designation or moniker used for self-identification during Internet communication or posting, including all designations used for the purpose of routing or self-identification in Internet communications or postings.

“Jurisdiction” means any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Northern Mariana Islands, the United States Virgin Islands, or a federally recognized Indian tribe.

“Loiter” means remaining in a place or circulating around a place under circumstances that would warrant a reasonable person to believe that the purpose or effect of the behavior is to enable a sex offender to become familiar with a location where a potential victim may be found, or to satisfy an unlawful sexual desire, or to locate, lure, or harass a potential victim.

“Military offense” means a sex offense specified by the U.S. Secretary of Defense under 10 U.S.C. Section 951.

“Minor” means a person under 18 years of age.

“Principal residence” for a sex offender means:

1. The residence of the offender, if the offender has only one residence in this state.
2. The residence at which the offender resides, sleeps, or habitually lives for more days per year than another residence in this state, if the offender has more than one residence in this state.
3. The place of employment or attendance as a student, or both, if the sex offender does not have a residence in this state.

“Professional licensing information” means the name or other description, number, if applicable, and issuing authority or agency of any license, certification, or registration required by law to engage in a profession or occupation held by a sex offender who is required at the time of the initial requirement to register under this chapter, or any such license, certification, or registration that was issued to an offender within the five-year period prior to conviction for a sex offense that requires registration under this chapter, or any such license, certification, or registration that is issued to an offender at any time during the duration of the registration requirement.

“Public library” means any library that receives financial support from a city or county pursuant to Iowa Code section 256.69.

“Registrant” means a person who is currently registered with the Iowa sex offender registry.

“Relevant information” means the following information with respect to a sex offender:

1. Criminal history, including warrants, articles, status of parole, probation, or supervised release, date of arrest, date of conviction, and registration status.
2. Date of birth.
3. Passport and immigration documents.
4. Government-issued driver's license or identification card.
5. DNA sample.

6. Educational institutions attended as a student, including the name and address of such institutions.

7. Employment information, including name and address of employer.

8. Fingerprints.

9. Internet identifiers.

10. Names, nicknames, aliases, or ethnic or tribal names, and, if applicable, the real names of an offender protected under 18 U.S.C. Section 3521.

11. Palm prints.

12. Photographs.

13. Physical description, including scars, marks, or tattoos.

14. Professional licensing information.

15. Residence.

16. Social security number.

17. Telephone numbers, including any landline or wireless numbers.

18. Temporary lodging information, including dates when residing in temporary lodging.

19. Statutory citation and text of offense committed that requires registration under this chapter.

20. Vehicle information for a vehicle owned or operated by an offender, including license plate number, registration number, or other identifying number, vehicle description, and the permanent or frequent locations where the vehicle is parked, docked, or otherwise kept.

21. The name, gender, and date of birth of each person residing in the residence.

EXCEPTION: "Relevant information" does not include relevant information in paragraphs "1" and "19," when a sex offender is required to provide relevant information pursuant to this chapter.

"Residence" means each dwelling or other place where a sex offender resides, sleeps, or habitually lives, or will reside, sleep, or habitually live, including a shelter or group home. If a sex offender does not reside, sleep, or habitually live in a fixed place, "residence" means a description of the locations where the offender is stationed regularly, including any mobile or transitory living quarters. "Residence" shall be construed to refer to the places where a sex offender resides, sleeps, habitually lives, or is stationed with regularity, regardless of whether the offender declares or characterizes such place as the residence of the offender.

"Sex act" means the same as the term is defined in Iowa Code section 702.17.

"Sex offender" means a person who is required to be registered under Iowa Code chapter 692A.

"Sex offense" means an indictable offense for which a conviction has been entered that is enumerated in Iowa Code section 692A.102 and means any comparable offense for which a conviction has been entered under prior law, or any comparable offense for which a conviction has been entered in a federal, military, or foreign court, or another jurisdiction.

"Sex offense against a minor" means an offense for which a conviction has been entered for a sex offense classified as a tier I, tier II, or tier III offense under this chapter if such offense was committed against a minor or otherwise involves a minor.

"Sexually violent offense" means an offense for which a conviction has been entered for any of the following indictable offenses:

1. Sexual abuse as defined under Iowa Code section 709.1.

2. Assault with intent to commit sexual abuse in violation of Iowa Code section 709.11.

3. Sexual misconduct with offenders and juveniles in violation of Iowa Code section 709.16.

4. Any of the following offenses, if the offense involves sexual abuse or assault with intent to commit sexual abuse: murder, attempted murder, kidnapping, burglary, or manslaughter.

5. A criminal offense committed in another jurisdiction, including a conviction in a federal, military, or foreign court, which would constitute an indictable offense under paragraphs "1" through "4" if committed in this state.

"Sexually violent predator" means a sex offender who has been convicted of an offense which would qualify the offender as a sexually violent predator under the federal Violent Crime Control and Law Enforcement Act of 1994, 42 U.S.C. Sections 14071(a)(3)(B), (C), (D), and (E).

“*SORNA*” means the Sex Offender Registration and Notification Act, which is Title I of the federal Adam Walsh Child Protection and Safety Act of 2006.

“*Student*” means a sex offender who enrolls in or otherwise receives instruction at an educational institution, including a public or private elementary school, secondary school, trade or professional school, or institution of higher education. “Student” does not mean a sex offender who enrolls in or attends an educational institution as a correspondence student, distance-learning student, or any other form of learning that occurs without the person's physical presence on the real property of an educational institution.

“*Superintendent*” means the superintendent or superintendent's designee of a public school or the authorities in charge of a nonpublic school.

“*Tier I offender*” means a registrant who has been convicted of one or more of the offenses enumerated in Iowa Code section 692A.102(1)“a.”

“*Tier II offender*” means a registrant who has been convicted of one or more of the offenses identified in Iowa Code section 692A.102(1)“b” and is not a “tier I offender.”

“*Tier III offender*” means a registrant who has been convicted of one or more of the offenses enumerated in Iowa Code section 692A.102(1)“c” and is not a “tier I offender” or a “tier II offender.”

“*Vehicle*” means a vehicle owned or operated by an offender, including but not limited to a vehicle for personal or work-related use, and including a watercraft or aircraft, that is subject to registration requirements under Iowa Code chapter 321, 328, or 462A.

[ARC 7974B, IAB 7/29/09, effective 7/1/09; ARC 5715C, IAB 6/16/21, effective 7/21/21]

661—83.3(692A) Forms and procedures. The following forms and procedures are prescribed for use with the Iowa sex offender registry. Supplies of these forms may be obtained by contacting the Iowa sex offender registry at the division of criminal investigation.

83.3(1) Notification. Form DCI-144, Notification of Registration Requirement, which notifies offenders of their duty to register with the Iowa sex offender registry, shall be provided, in printed form or electronically, to persons identified as being required to register. Failure to provide offenders with Form DCI-144 does not relieve offenders of their duty to register with the Iowa sex offender registry.

83.3(2) Registration.

a. Form DCI-145 or Form DCI-144R, Sex Offender Registration, shall be completed, as required by Iowa Code section 692A.104, on behalf of each offender and submitted, in printed or electronic form, to the sheriff of each county in which the offender will be residing, employed, or attending classes and to the division of criminal investigation, in order to satisfy the registration requirements of the Iowa sex offender registry. This form shall also be completed on behalf of each offender and submitted to the sheriff of any county in which the offender will be a student, be employed, or be engaged in a vocation on a full-time or part-time basis, in order to satisfy the registration requirements.

b. Form DCI-145, or information stored by the division of criminal investigation, shall be used to report changes of residence, telephone number, name of registrant, or change in status as a student, employee, or practicing a vocation at an institution of higher education. A completed copy of Form DCI-145 shall be submitted by the registrant to the sheriff of any county of residence each time the registrant's relevant information changes. A completed copy of Form DCI-145 shall be submitted by the registrant to the sheriff of the county in which the registrant is a student, an employee, or practicing a vocation on a full-time or part-time basis at an institution of higher education within five days of the registrant's becoming a student, an employee, or engaged in a vocation at the institution of higher education. The original of each completed Form DCI-145 shall be forwarded to the division of criminal investigation by the registering agency within three days of receiving the completed form.

(1) If any place of residence of a registrant changes from one county to another, the registrant shall submit copies, in printed or electronic form, of completed Form DCI-145 reporting the change of residence to the sheriff of the prior county of residence and the sheriff of the new county of residence. The sheriff of the new county of residence shall be responsible for transmitting a copy of completed Form DCI-145 to the Iowa sex offender registry.

(2) When the department receives notification that a registrant has changed residence to a location outside of Iowa, the department shall notify the registering state agency in the registrant's new state of residence of the registrant's name, new address, and telephone number. Upon notification of the appropriate out-of-state agency, the department shall remove the registrant from the active registry, unless the registrant continues to maintain a residence or place of employment in Iowa or attends school in Iowa. The registrant shall not be required to submit periodic verifications of address while not on the active registry. The department shall maintain the registrant's file in the event the registrant establishes a residence in Iowa or becomes a student, an employee, or practices a vocation at an institution of higher education in Iowa in the future. The department may also maintain the file for any other purpose.

c. Upon any submission of Form DCI-145, the form shall be accompanied by current photographs and fingerprints of the offender.

d. A list of all registrants within a county may be provided by the division of criminal investigation to the county sheriff.

83.3(3) Periodic verification. A registrant shall appear personally in the office of the sheriff of the county or counties of principal residence periodically as required by Iowa Code section 692A.108 to verify relevant information. A tier I offender shall appear annually, or more frequently if required by the sheriff; a tier II offender shall appear every six months, or more frequently if required by the sheriff; and a tier III offender shall appear every three months, or more frequently if required by the sheriff. Form DCI-146R, Periodic Verification Notification Form, shall be mailed by the division of criminal investigation to each registrant at the last address known to the registry at least 30 days prior to each required appearance. The registrant shall appear between the first and last day of the verification month. Form DCI-146R shall clearly state that it is to be returned to the division of criminal investigation if the addressee no longer resides at the address indicated and that Iowa law prohibits its being forwarded.

a. Each registrant shall report to the sheriff of the county of principal residence of the registrant. The sheriff shall take a current photograph of the registrant and shall submit the photograph to the registry.

b. The sheriff of any county of residence of a registrant may, at any time, instruct the registrant to report to the sheriff's office for the purpose of the taking of a current photograph. Such instructions shall be mailed to the registrant at the registrant's current address of registration. The registrant shall report to the sheriff's office within ten days of receiving such instructions. The sheriff shall submit the current photograph of the registrant to the registry.

83.3(4) Updating relevant information not requiring personal appearance. Any change in any item of relevant information other than changes of address, places of attendance as a student, or places of employment shall be communicated to the sheriff of the county of the registrant's principal residence in person, by telephone, or electronically, within five days of the change occurring. Any such change shall not be deemed to be completed until the registrant has received acknowledgment from the office receiving the change in printed or electronic form.

83.3(5) Application for determination. Form DCI-148, Application for Determination, shall be completed by a person to initiate a request that the department review whether one or more offenses of which the person has been convicted require registration with the Iowa sex offender registry, whether the time period during which the person is required to register has expired, whether the person is exempt from the placement of information on the sex offender registry website, and the tier placement of the offender. A person who submits a completed copy of Form DCI-148 for review shall provide with it copies of any sentencing or adjudicatory orders related to each offense for which a determination of whether registration is required is being requested. The completed application (Form DCI-148) shall specify the exact grounds for the application and shall include a statement of any additional facts or law which the person intends to present to the department in support of the application. Failure to submit any of the required information shall constitute grounds for denial of the application. If the application sets forth an issue of fact which cannot be evaluated based upon the record of convictions, sentencing and adjudicatory orders, relevant statutory provisions, and other records provided, and is material to the determination, the commissioner may refer the matter to an administrative law judge or presiding officer for a contested case hearing.

NOTE: Filing an application for determination does not excuse a person from having to comply with any of the applicable provisions of Iowa Code chapter 692A during the period prior to the issuance of the decision of determination.

83.3(6) *Decision of determination.*

a. Form DCI-149, Decision of Determination, shall be used by the division of criminal investigation to notify a person who has submitted an application for determination (Form DCI-148) of the results of that review. A completed Form DCI-149 shall be mailed to any person who has filed a completed Form DCI-148 within 90 days of the receipt by the division of criminal investigation of the completed Form DCI-148 and all required supporting documents. A decision of determination shall be signed by the commissioner and shall constitute final agency action for the purposes of Iowa Code chapter 17A.

b. If an administrative law judge or presiding officer has been assigned to hold a hearing regarding an application for determination, the administrative law judge or presiding officer shall prepare a proposed decision of determination. The proposed decision of determination shall be reviewed by the commissioner who may uphold or modify the proposed decision of determination and shall then sign a final decision of determination. The final decision of determination shall constitute final agency action for the purposes of Iowa Code chapter 17A.

83.3(7) *Request for information.* Requests for information about whether a specific individual is registered shall be made to a county sheriff or local police department and may be made in person, by telephone, or in writing.

83.3(8) *Confidential records.* Completed forms filled out pursuant to rules 661—83.1(692A) through 661—83.5(692A) are confidential records that shall not be released to the public.

83.3(9) *Fees.* Each registrant shall pay a fee of \$25 to the sheriff of the county in which the registrant maintains a principal residence upon establishment of the principal residence and annually thereafter. If the registrant maintains more than one principal residence simultaneously, the fee shall be paid only to the sheriff of the county in which the registrant first registered on or after July 1, 2009, and continues to register.

[ARC 7974B, IAB 7/29/09, effective 7/1/09; ARC 5715C, IAB 6/16/21, effective 7/21/21]

661—83.4(692A) Availability of records.

83.4(1) *Release of information to criminal or juvenile justice agencies.* The department may, without restriction, release information regarding any registrant to any criminal or juvenile justice agency, an agency of the state of Iowa, any sex offender registry of another state, or the federal government.

83.4(2) *Sex offender registry website.* The department shall place information regarding each registrant on the registry website (www.iowasexoffender.gov), except that information regarding any registrant for whom the sole basis of registration is a conviction or convictions for a violation or violations of Iowa Code section 709.4(1)“b”(3)(d), and whose offense was committed when the offender was under 20 years of age, shall not be placed on the website. Information regarding a registrant placed on the sex offender registry website may include any relevant information allowed under Iowa Code section 692A.121.

83.4(3) *Release of information by a criminal or juvenile justice agency.* A criminal or juvenile justice agency may provide relevant information from the sex offender registry to the following:

a. A criminal or juvenile justice agency, an agency of the state, any sex offender registry of another state, or the federal government.

b. The general public, including public and private agencies, organizations, public places, child care facilities, religious and youth organizations, neighbors, neighborhood associations, community meetings, and employers. Registry information may be distributed to the public through printed materials, visual or audio press releases, radio communications, or a criminal or juvenile justice agency’s website.

c. The administrative office of a school district in which the person required to register resides and any private school near the person’s residence.

83.4(4) *List of registrants in county.* Any county sheriff shall provide access to the list of all registrants within the county in which the sheriff has jurisdiction to any person who requests such a list; however, records of persons protected under 18 U.S.C. Section 3521 shall not be disclosed.

83.4(5) *Release of information in response to individual request.* A sheriff or police department that receives a request for information about whether a specific individual is registered or not shall inquire of the division of criminal investigation via the Iowa on-line warrants and articles (IOWA) system or the sex offender registry application (SORA) as to whether the person about whom information was requested is registered with the Iowa sex offender registry. If the division of criminal investigation notifies the sheriff or police department that the person about whom inquiry is made is not on the registry, the sheriff or police department shall so notify the person who submitted the request. If the division of criminal investigation notifies the sheriff or police department that the person about whom inquiry was made is a registrant with the Iowa sex offender registry, the sheriff or police department shall notify the person making the inquiry that the person about whom the inquiry was made is a registrant and may provide the requester with the relevant information allowed under Iowa Code section 692A.121 regarding the registrant.

83.4(6) *Submission of information to the National Sex Offender Registry.* The division shall submit sex offender registry data as required to the National Sex Offender Registry of the Federal Bureau of Investigation.

83.4(7) *Single contact repository.* The division shall perform a search of the sex offender registry for information about an individual, based on a request submitted through the single contact repository established pursuant to Iowa Code section 135C.33. The information provided from the registry shall be limited to whether the identified person is registered.

83.4(8) *No identification of victims.* Any release of information regarding any registrant, other than to criminal or juvenile justice agencies, shall not identify any victim of the registrant.

[ARC 5715C, IAB 6/16/21, effective 7/21/21]

661—83.5(692A) Expungement of records.

83.5(1) *Expungement upon reversal of conviction.* Upon receipt of a certified copy of a court order reversing a conviction which forms the basis for a registrant's being required to register, the division of criminal investigation shall expunge the registration, provided that the registrant has been convicted of no other offense requiring registration.

83.5(2) *Expungement upon expiration of registration period.* The division of criminal investigation shall expunge a registrant's registration upon expiration of the period during which the registrant is required to register, provided that the registrant has not subsequently been convicted of an offense that would require registration.

These rules are intended to implement Iowa Code chapter 692A.

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CHAPTER 159
STATEWIDE SOBRIETY AND DRUG MONITORING PROGRAM

661—159.1(901D) Program created. The statewide sobriety and drug monitoring program, also referred to as the “24/7 program,” is established in the department of public safety for use by participating jurisdictions. The program shall be available at least twice per day during hours designated by the law enforcement agency, seven days per week in the participating jurisdictions. Participation in or use of the 24/7 program is a voluntary decision of a participating jurisdiction. A participating jurisdiction cannot be required to participate in or to continue to participate in the 24/7 program.
[ARC 4010C, IAB 9/26/18, effective 10/8/18]

661—159.2 to 159.9 Reserved.

661—159.10(901D) Definitions. The following definitions apply to this chapter:

“*Alcohol*” means an alcoholic beverage as defined in Iowa Code section 321J.1.

“*Commissioner*” means the commissioner of public safety as defined in Iowa Code section 80.1A.

“*Controlled substance*” means the same as defined in Iowa Code section 124.101.

“*Department*” means the department of public safety.

“*Eligible offense*” means a criminal offense in which the abuse of alcohol or a controlled substance was a contributing factor in the commission of the offense, as determined by the court or a governmental entity of the participating jurisdiction. For purposes of operating while intoxicated offenses committed in violation of Iowa Code section 321J.2, “eligible offense” includes only the following offenses:

1. A first offense in which the person’s alcohol concentration exceeded .15.
2. A first offense in which an accident resulting in personal injury or property damage occurred.
3. A first offense in which the person refused to submit to a chemical test requested pursuant to Iowa Code section 321J.6.
4. A second or subsequent offense.

“*Failed test*” means any of the following:

1. A test or combination of tests that shows the presence of alcohol, a controlled substance, a combination of alcohol and one or more controlled substances, or a combination of two or more controlled substances, if any of the controlled substances are not prescribed by a health care provider or are not used in accordance with the health care provider’s written instructions.
2. A failure or refusal to submit to testing, including but not limited to the nonpayment of the required fee.
3. Incomplete testing or results that indicate efforts to tamper with or interfere with the test or with valid test results, whether or not those efforts are successful.
4. Failure to appear to submit to testing.

“*Immediate sanction*” means a sanction that is applied within minutes of a failed test result.

“*Law enforcement agency*” means a sheriff’s office or city police department that has been approved to administer, implement and enforce the statewide sobriety and drug monitoring program established in Iowa Code chapter 901D for the participating jurisdiction.

“*Participating jurisdiction*” means a county or a city that chooses to participate in the statewide sobriety and drug monitoring program and that has been approved for participation by the department.

“*Sobriety and drug monitoring program*” or “*24/7 program*” means the statewide sobriety and drug monitoring program established in Iowa Code chapter 901D.

“*Test*” or “*testing*” means a procedure or set of procedures performed using equipment, devices and methods approved by the commissioner to determine the presence of alcohol or a controlled substance in a person’s breath or bodily fluid, including blood, urine, saliva, and perspiration, and includes any combination of breath testing, drug patch testing, urine analysis testing, saliva testing, and continuous or transdermal alcohol monitoring.

“*Timely sanction*” means a sanction that is applied within hours or days after a failed test result. A timely sanction shall be applied as soon as possible, but the period between the failed test result and the application of the timely sanction shall not exceed five days.

[ARC 4010C, IAB 9/26/18, effective 10/8/18]

661—159.11(901D) Participating jurisdiction requirements.

159.11(1) Program requirements. As a participating jurisdiction of the 24/7 program, the participating jurisdiction shall:

a. Designate the law enforcement agency or third-party provider that will administer, implement and enforce the 24/7 program. More than one law enforcement agency or third-party provider may be designated.

b. Provide one or more locations for testing persons who are participating in the 24/7 program for the presence of alcohol or a controlled substance.

c. Ensure that each designated location is available at least twice per day, seven days per week for persons to be tested, during hours designated by the law enforcement agency.

d. Ensure that personnel who administer tests and collect bodily specimens for testing at the location have all required training and certifications to use or operate the testing equipment or devices.

e. Provide testing equipment and devices.

f. Designate the law enforcement agency that will be responsible to collect program fees from persons subject to testing and use program fees to pay for the participating jurisdiction’s costs to administer the program and purchase or maintain testing equipment and devices.

g. Provide for and apply immediate sanctions for failed tests.

h. Provide for and apply timely sanctions for failed tests.

i. Provide test results to the court, prosecutor, and person’s attorney and also provide test results and other required program information to the program data management system.

j. Provide for one or more alternative testing methods, if such methods have been approved by the commissioner, in cases of persons for whom testing at least twice per day creates a documented hardship or is geographically impractical.

k. Designate the law enforcement agency to establish and maintain a 24/7 program account, place all program fees collected into the account and use the funds in the account only for the purposes of administering and operating the 24/7 program, including but not limited to paying for the services of a third-party provider. The funds in the account shall be considered public funds and shall be subject to the rules and policies of the state auditor’s office.

l. Establish a program that is administered by the law enforcement agency to accept public or private grant funds, gifts, or donations and use the funds received to support program activities, including but not limited to the payment of fees for indigent persons. The funds collected under this program shall be deposited and held in the 24/7 program account.

m. Provide reports to the department as required.

n. Ensure that an audit of the 24/7 program account is conducted at least annually and make the audit report available to the department upon request.

o. Maintain sufficient security protocols to protect the personal information of persons subject to testing from unauthorized use.

p. Be approved by the department as a participating jurisdiction.

159.11(2) Third-party provider. A participating jurisdiction may designate a third-party provider to provide testing services as described in subrule 159.11(1), except, that the third-party provider shall not provide any of the requirements in paragraphs 159.11(1) “*f*,” “*g*,” “*h*,” “*k*,” and “*l*.” The department shall review any third-party provider designated by the participating jurisdiction as a part of the application process. A third-party provider must be approved by the department before providing any service of the 24/7 program.

159.11(3) Application. A county or city that desires to become a participating jurisdiction shall submit an application to the department. The application shall be made on a form provided by the department, which is available at www.dps.state.ia.us/commis/gtsb/index.shtml. The department shall

notify the participating jurisdiction whether it has been approved to participate in the 24/7 program. Approval shall be in the sole discretion of the department.

[ARC 4010C, IAB 9/26/18, effective 10/8/18]

661—159.12(901D) Participant requirements.

159.12(1) Requirements. A person subject to testing in the 24/7 program is required to do all of the following:

a. Abstain from all alcohol and controlled substances while enrolled in the program. If a person has been issued a prescription for a controlled substance, the person may participate in the 24/7 program and continue to take the prescribed controlled substance only with the health care provider's approval and in accordance with the health care provider's written instructions.

b. Submit to testing as required to determine whether alcohol or a controlled substance is present in the person's body.

c. Participate in the 24/7 program when ordered as a condition of bond, pretrial release, sentence, probation, or parole.

d. Sign all forms, waivers and releases and provide all required information that is necessary for participation in the program to enable the testing to occur and the test results to be reported, disseminated and used as required by the 24/7 program, including but not limited to providing testing information to the county attorney, person's attorney, court or parole or probation officer as appropriate.

e. Obtain a temporary restricted license when eligible, if the person's driver's license is suspended or revoked.

f. Unless otherwise ordered by the court, install an approved ignition interlock device on all motor vehicles owned or operated by the person if the person's driver's license is suspended or revoked or as is otherwise required by Iowa Code section 321J.17, and in any circumstance in which Iowa Code chapter 321J requires the installation of an ignition interlock device.

g. Pay all program fees, including but not limited to the enrollment fee; the costs of tests, test equipment or test devices; and the costs of installing, activating, monitoring, and deactivating any testing equipment or devices.

h. Agree to be subject to immediate sanctions or timely sanctions, as applicable, for noncompliance with the 24/7 program requirements.

159.12(2) Reserved.

[ARC 4010C, IAB 9/26/18, effective 10/8/18; ARC 5716C, IAB 6/16/21, effective 7/21/21]

661—159.13 to 159.19 Reserved.

661—159.20(901D) Testing.

159.20(1) Methods. The following methods and procedures shall be used to collect samples or perform testing to determine the presence of alcohol or a controlled substance in the person's breath or bodily fluid.

a. Evidentiary breath testing devices and methods as described in rule 661—157.2(321J).

b. Preliminary breath screening test devices and methods as described in rule 661—157.5(321J).

c. Urine collection methods and equipment as described in rule 661—157.3(321J).

d. The SCRAM® continuous alcohol monitoring or remote breath device.

159.20(2) Other devices and methods. Scientifically established tests or methods appropriate to a particular device shall be used in determining whether an alternative device or method meets an acceptable standard for operation, including accuracy. The department may, in its discretion, accept test results from another laboratory. The commissioner may consider all other factors in addition to scientific testing and accuracy, including but not limited to cost, availability, and training in determining whether or not to approve a method or device. Approval of other devices or methods is in the sole discretion of the commissioner.

[ARC 4010C, IAB 9/26/18, effective 10/8/18]

661—159.21 to 159.29 Reserved.

661—159.30(901D) Program fees.

159.30(1) Enrollment fee. A person subject to testing shall pay an enrollment fee of \$30 for each enrollment in the program. A person may be ordered or required to enroll in the program more than once, and the enrollment fee is required for each enrollment.

159.30(2) Fees for tests.

a. A person subject to testing shall pay all fees associated with the testing. The following fees are established:

- (1) For breath test, \$2 per test.
- (2) For a urine test, \$6 per test.
- (3) For a SCRAM® continuous alcohol monitoring or remote breath device, an installation fee of \$30 and a fee of \$7 per day.

b. The law enforcement agency shall inform a person subject to testing of each applicable test fee.

159.30(3) Payment of fees. A person subject to testing shall pay the fee for each test before taking the test. The law enforcement agency may, but shall not be required to, administer the test if the person subject to testing does not pay the fee for the test. For the device(s) approved for use in cases where twice-a-day testing creates a documented hardship or is geographically impracticable, the fee for two weeks' use of the device shall be paid prior to the installation of the device on the person. The person shall appear at the law enforcement agency a minimum of once per week according to the agency's instructions for the use of the device and shall pay each week's fee in advance. Failure to pay the required test fee may subject the person to immediate sanctions or timely sanctions. Community service or other in-kind payment is not authorized as a substitute for payment of the required fees. For a person who has been determined to be indigent or who is only able to pay a portion of the fee, the fees shall be paid from the 24/7 program account to the extent that funds are available.

[ARC 4010C, IAB 9/26/18, effective 10/8/18]

661—159.31 to 159.39 Reserved.

661—159.40(901D) Fees—indigent participants. A person subject to testing is required to pay the full fee for each test. The fees are established at the minimum level needed to purchase supplies and equipment and to cover the costs of administering the program.

159.40(1) Determination of indigency. A person subject to testing who requests a determination of indigency for purposes of the 24/7 program shall provide all requested financial information. An application for court-appointed counsel may be considered and used in determining whether a person is indigent. A finding of indigency by the court for purposes of determining whether a person should receive court-appointed counsel does not constitute a final determination of indigency for purposes of the 24/7 program. In determining indigency, all relevant information may be considered, including but not limited to income, assets, other sources of support, barter or in-kind payments, and expenditures including but not limited to expenditures for nonessential or luxury items.

159.40(2) Payment of indigent fees.

a. If a person subject to testing is determined to be indigent and is reasonably able to pay a portion of the required fee for testing but is not able to pay the full fee amount, the person shall pay only the portion of the fee which the person is reasonably able to pay. The law enforcement agency shall authorize payment of the remaining fee out of the 24/7 program funds, including but not limited to funds received from public or private grants, gifts or donations, if such funds have been received and there are funds remaining after paying the costs for testing supplies and devices and the costs to administer the program.

b. If a person subject to testing is determined to be indigent and is not reasonably able to pay any part of the required fee for testing, the law enforcement agency shall authorize the payment of the fee out of the 24/7 program funds, including but not limited to funds received from public or private grants, gifts or donations, if such funds have been received and there are funds remaining after paying the costs for testing supplies and devices and the costs to administer the program.

c. The participating jurisdiction, including the designated law enforcement agency or third-party provider, is not required to provide unpaid or free testing at the jurisdiction's, agency's or provider's

expense if there are not sufficient funds in the 24/7 program account. The participating jurisdiction or law enforcement agency shall first use the funds in the 24/7 program account to pay for the participating jurisdiction's costs to administer the program and purchase, rent, or maintain testing equipment and devices and then use any remaining funds to pay fees for indigent participants.

[ARC 4010C, IAB 9/26/18, effective 10/8/18]

661—159.41 to 159.49 Reserved.

661—159.50(901D) Stakeholder group. The department hereby establishes a stakeholder group for the 24/7 program. The designated stakeholder group for the 24/7 program shall be the Iowa impaired driving coalition. Representatives of other public or private groups may request to be added to the 24/7 program stakeholder group.

159.50(1) Duties. The 24/7 program stakeholder group shall act as an advisory group to the department and the governor's traffic safety bureau. The stakeholder group shall review the 24/7 program and recommend changes to the governor's traffic safety bureau.

159.50(2) Meetings. The 24/7 program stakeholder group shall meet as requested by the bureau chief of the governor's traffic safety bureau. Notice of the stakeholder meetings shall be provided as required by Iowa Code chapter 21. Records of the stakeholder group shall be subject to the provisions of Iowa Code chapter 22.

[ARC 4010C, IAB 9/26/18, effective 10/8/18]

661—159.51 to 159.59 Reserved.

661—159.60(901D) Grant program established. The department authorizes each participating jurisdiction to create a grant program account for the purpose of accepting public and private grant funds, gifts and donations to support the 24/7 program of the participating jurisdiction. The funds in the account shall be considered public funds and shall be subject to the rules and policies of the state auditor's office.

[ARC 4010C, IAB 9/26/18, effective 10/8/18]

These rules are intended to implement Iowa Code chapter 901D.

[Filed Emergency After Notice ARC 4010C (Notice ARC 3628C, IAB 2/14/18), IAB 9/26/18,
effective 10/8/18]

[Filed ARC 5716C (Notice ARC 5558C, IAB 4/21/21), IAB 6/16/21, effective 7/21/21]

CHAPTER 211
CARBON MONOXIDE ALARMS

661—211.1(86GA,SF2219) Scope. The provisions of this chapter apply to new and existing single-family residences, single-family rental units, and multiple-unit residential buildings. The provisions of this chapter do not apply to nonresidential occupancies including but not limited to Group I and Group E occupancies.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

661—211.2 to 211.9 Reserved.

661—211.10(86GA,SF2219) Definitions. The following definitions apply to this chapter.

“Building” means a combination of materials, whether portable or fixed, to form a structure affording facilities or shelter for persons, animals or property. The term “building” includes any part of a building or an addition to a building.

“Carbon monoxide alarm” means one or more devices, including but not limited to combination carbon monoxide alarm/smoke alarms, which detect carbon monoxide gas for the purpose of alerting occupants by a distinct audible signal, which incorporate a sensor, control components, and an alarm notification appliance in a single unit operated from a power source either in the unit or obtained at the point of installation, and which meet the standards established by the Underwriters Laboratories (UL). All carbon monoxide alarms shall meet the requirements of the National Fire Protection Association (NFPA) Standard 720, 2013 edition, and be UL listed in accordance with UL 2034.

“Carbon monoxide detection system” means a system or portion of a combination system which consists of a control unit, components, and circuits arranged to monitor and annunciate the status of carbon monoxide alarm initiating devices and to initiate the appropriate response to those signals, and which meets the standards established by the Underwriters Laboratories (UL). All carbon monoxide detection systems shall meet the requirements of the National Fire Protection Association (NFPA) Standard 720, 2013 edition, shall display a label or other identification issued by an approved testing agency, and shall be UL listed in accordance with UL 2075.

“Communicating opening” means a door, window, or any other opening which allows air to be exchanged between a fuel-burning appliance or garage and a sleeping unit or dwelling unit.

“Dwelling unit” means a room or suite of rooms used for human habitation which provide complete, independent living facilities for one or more persons, including permanent provisions for living, sleeping, eating, cooking and sanitation.

“Existing” means buildings, facilities or conditions that are already in existence, constructed or officially authorized prior to July 1, 2018.

“Fuel” means coal, kerosene, oil, fuel gases, or other petroleum products or hydrocarbon products such as wood that emit carbon monoxide as a byproduct of combustion.

“Fuel-burning” or *“fuel-fired”* means an appliance, heater, furnace, or fireplace which uses and combusts fuel as part of its designed use.

“Garage” or *“attached garage”* means a building or portion of a building in which motor vehicles are stored or kept.

“Listed” means equipment, materials, products or services included in a list published by an organization acceptable to the state fire marshal or local fire code official and concerned with evaluation of products or services that maintains periodic inspection of production of listed equipment or materials or periodic evaluation of services and whose listing states either that the equipment, material, product or service meets identified standards or has been tested and found suitable for a specified purpose. All carbon monoxide alarms, combination carbon monoxide alarm/smoke alarms, and carbon monoxide detection systems installed under these rules must be listed with the Underwriters Laboratories.

“Multiple-unit residential building” means a building that contains more than two dwelling units or sleeping units. “Multiple-unit residential building” includes but is not limited to condominiums;

townhouses; co-ops; apartment houses or portions of a building or an apartment house; hotels; motels; dormitories; or rooming houses.

“*Open-ended corridor*” means an interior corridor that is open on each end and connects to an exterior stairway or ramp at each end with no intervening doors or separation from the corridor.

“*Single-family rental unit*” means a building that contains not more than two dwelling units or sleeping units that are rented or leased for living purposes.

“*Single-family residence*” or “*single-family dwelling*” means a building that contains not more than two dwelling units that are used, or intended or designed to be used, for living purposes.

“*Sleeping unit*” means a room or space in a building in which people sleep, which can also include permanent provisions for living, eating, and either sanitation or kitchen facilities but not both. Such rooms and spaces that are also part of a dwelling unit are not sleeping units.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

661—211.11(86GA,SF2219) Carbon monoxide alarms—required. Carbon monoxide alarms are required in the following buildings if the building is served by a fuel-burning heater, fuel-burning furnace, fuel-burning appliance, fuel-burning fireplace, or has an attached garage.

211.11(1) *New construction.* Multiple-unit residential buildings and single-family residences for which construction is begun on or after July 1, 2018.

211.11(2) *Existing buildings.* Single-family rental units, single-family residences, and multiple-unit residential buildings.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

661—211.12(86GA,SF2219) Installation and placement of carbon monoxide alarms.

211.12(1) *Location.* When required by rule 661—211.11(86GA,SF2219), a carbon monoxide alarm shall be installed in the following locations:

- a. In the immediate vicinity of every room used for sleeping purposes in each dwelling unit.
- b. In each bedroom where a fuel-burning heater or furnace, fuel-burning appliance, or fireplace is located within the bedroom or its attached bathroom.
- c. In each sleeping unit, if the sleeping unit or its attached bathroom contains a fuel-burning appliance, fuel-burning heater or furnace, or fireplace.
- d. In the immediate vicinity of each sleeping unit where the sleeping unit or its attached bathroom does not contain a fuel-burning appliance, fuel-burning heater, or fireplace and is not served by a forced-air furnace.

211.12(2) *Carbon monoxide alarm location—exceptions.* A carbon monoxide alarm shall not be required in the locations specified by subrule 211.12(1) when:

- a. There are no communicating openings between the fuel-burning heater or furnace, fuel-burning appliance, fireplace, or attached garage and a dwelling unit or sleeping unit.
- b. There are no communicating openings between the fuel-burning heater or furnace, fuel-burning appliance or fireplace and a dwelling unit or sleeping unit and when a dwelling unit or sleeping unit is located more than one story above or below an attached garage.
- c. There are no communicating openings between the fuel-burning heater or furnace, fuel-burning appliance, or fireplace and a sleeping unit or dwelling unit and the attached garage connects to the building through an open-ended corridor.
- d. A carbon monoxide alarm is located on the ceiling of the room containing the fuel-burning heater, fuel-burning appliance or fireplace, or in the first room or area between the fuel-burning heater, fuel-burning appliance or fireplace and the dwelling unit or sleeping unit.

211.12(3) *Forced-air furnace—exception.* A carbon monoxide alarm shall not be required in a dwelling unit or sleeping unit which is served by a fuel-burning forced-air furnace when a carbon monoxide alarm is located on the ceiling of the room containing the forced-air furnace or in the first room or area served by each main duct leaving the forced-air furnace and the carbon monoxide alarm signals are automatically transmitted to the occupants of each dwelling unit or sleeping unit served by the forced-air furnace.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

661—211.13(86GA,SF2219) Carbon monoxide alarms—alternative systems.

211.13(1) Carbon monoxide detection systems. Commercially installed carbon monoxide detection systems which have the capability of notifying all occupants of dwelling units or sleeping units within a building shall be an acceptable alternative to the installation of carbon monoxide alarms and shall be deemed compliant with this chapter.

211.13(2) Combination alarms. The carbon monoxide alarm may be combined with smoke detecting devices provided that the combined unit complies with the respective provisions of 661—Chapter 210 regarding smoke detectors and this chapter regarding carbon monoxide alarms or other reference standards and applicable codes. A combined carbon monoxide alarm/smoke alarm shall emit different alarm signals for carbon monoxide and for smoke. Combination carbon monoxide alarm/smoke alarms shall be an acceptable alternative to carbon monoxide alarms.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

661—211.14(86GA,SF2219) Carbon monoxide alarms—power source.

211.14(1) New construction—power source. In buildings for which construction is begun on or after July 1, 2018, carbon monoxide alarms shall receive their primary power from the building wiring when such wiring is served from a commercial source. Wiring shall be permanent and without a disconnecting switch other than that required for overcurrent protection and shall be equipped with a battery backup.

211.14(2) Wiring installation. Any installation of wiring and equipment shall comply with 661—Chapter 504, Standards for Electrical Work, and requirements established by the manufacturer of the equipment serviced by the wiring.

211.14(3) Existing buildings—power source. New and replacement carbon monoxide alarms installed in existing buildings may be solely battery operated or may plug into an electrical socket and have a battery backup.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

661—211.15 to 211.19 Reserved.

661—211.20(86GA,SF2219) Responsibility for installation and maintenance of carbon monoxide alarms.

211.20(1) Owner, owner's agent, or manager. It is the responsibility of the owner, owner's agent, or manager of a multiple-unit residential building, single-family residence, or single-family rental unit to install carbon monoxide alarms as required by this chapter. However, if a dwelling unit in a multiple-unit residential building qualifies for a homestead credit pursuant to Iowa Code chapter 425, then only the owner-occupant of the dwelling unit shall have the responsibility to install and maintain carbon monoxide alarms as required by this chapter.

211.20(2) Maintenance of carbon monoxide alarms.

a. It is the responsibility of the owner of a multiple-unit residential building, single-family rental unit, or dwelling unit to supply and install all required carbon monoxide alarms and to ensure that the batteries are in operating condition at the time the lessee, tenant, guest or roomer takes possession of the dwelling unit or sleeping unit. The owner is responsible for providing written information regarding carbon monoxide alarm testing and maintenance to one lessee, tenant, guest or roomer per dwelling unit or sleeping unit.

b. An owner or manager may require a lessee, tenant, guest, or roomer who has a residency longer than 30 days to be responsible for general maintenance, including but not limited to replacement of any required batteries of the carbon monoxide alarms in the lessee's, tenant's, guest's, or roomer's dwelling unit or sleeping unit, and for testing the carbon monoxide alarms within the lessee's, tenant's, guest's, or roomer's dwelling unit or sleeping unit. The lessee, tenant, guest or roomer is responsible for notifying the owner or manager in writing of any deficiencies that the lessee, tenant, guest or roomer cannot correct. The lessee, tenant, guest or roomer shall provide the owner or manager with access to the dwelling unit or sleeping unit to correct any deficiencies in the carbon monoxide alarm that have been reported in writing to the owner or manager.

211.20(3) Deaf or hard-of-hearing tenant. An owner of a multiple-unit residential building or a single-family rental unit that has a fuel-fired heater or appliance, a fireplace, or an attached garage, or the owner's agent, shall, upon request of a tenant who is deaf or hard of hearing, install light-emitting carbon monoxide alarms.

[ARC 3662C, IAB 2/28/18, effective 2/7/18; ARC 5714C, IAB 6/16/21, effective 7/21/21]

661—211.21(86GA,SF2219) Certification of installation required. A person who files for a homestead credit pursuant to Iowa Code chapter 425 shall certify that the dwelling unit that has a fuel-fired heater or furnace, a fuel-fired appliance, a fireplace, or an attached garage has carbon monoxide alarms installed in compliance with this chapter or that such alarms will be installed within 30 days of the date the filing for the credit is made.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

661—211.22(86GA,SF2219) Inspections, notifications and remedies.

211.22(1) Inspections authorized. Inspections may be conducted by the state fire marshal or by the fire marshal's subordinates, chiefs of local fire departments, state or local building inspectors, or other fire, building, or safety officials authorized by the state fire marshal. Any inspections authorized under this rule are limited to the placement, repair, and operability of carbon monoxide alarms and carbon monoxide detection systems.

211.22(2) Inoperable carbon monoxide alarms. If a carbon monoxide alarm is found to be inoperable, the owner or manager of the multiple-unit residential building or single-family rental unit shall promptly provide for repair or replacement of the carbon monoxide alarm.

211.22(3) Corrective action. Upon receiving written notification by a tenant, guest, or roomer or by the state fire marshal, fire marshal's subordinates, a chief of a local fire department, a building inspector, or other fire, building or safety official that a carbon monoxide alarm is inoperable, the owner or manager of the multiple-unit residential building or single-family rental unit shall repair or replace the carbon monoxide alarm within 30 days.

211.22(4) Remedies by tenant, guest, or roomer. If the owner or manager of a multiple-unit residential building or single-family rental unit fails to correct the situation within the 30 days after receipt of written notice, the tenant, guest, or roomer may cause the carbon monoxide alarm to be repaired or may purchase and install a carbon monoxide alarm required under this chapter and may deduct the repair cost or purchase price from the next rental payment or payments made by the tenant, guest, or roomer.

[ARC 3662C, IAB 2/28/18, effective 2/7/18]

These rules are intended to implement 2016 Iowa Acts, Senate File 2219.

[Filed Emergency After Notice ARC 3662C (Notice ARC 3545C, IAB 1/3/18), IAB 2/28/18, effective 2/7/18]

[Filed ARC 5714C (Notice ARC 5559C, IAB 4/21/21), IAB 6/16/21, effective 7/21/21]

CHAPTER 12
FILING RETURNS, PAYMENT OF TAX, PENALTY AND INTEREST
[Prior to 12/17/86, Revenue Department[730]]

701—12.1(422) Returns and payment of tax. Every retailer collecting more than \$50 in tax in any one month shall make a monthly deposit with the department. A retailer collecting between \$50 and \$500 a month shall deposit the actual amount of tax collected during the month or an amount equal to not less than 30 percent of the amount of tax collected and paid during the preceding quarter. A retailer collecting \$500 or more a month shall deposit the actual amount of tax collected. This deposit is due by the twentieth of the month following the month in which the tax is collected and applies only to the first two months in the quarter.

On the quarterly return, every retailer shall report the gross sales for the entire quarter, listing allowable deductions and figuring tax for the entire quarter. Space is provided on the return for a deduction of tax deposited the first and second months of the quarter. The quarterly return is due on or before the last day of the month following the end of the quarter.

Effective January 1, 1983, retailers collecting \$50 a month and not more than \$4000 in tax in a semimonthly period shall deposit the actual amount of tax collected during the month or an amount equal to one-third of the amount of tax collected and paid during the preceding quarter.

Every retailer collecting more than \$4000 in tax in a semimonthly period shall make a semimonthly deposit with the department. A retailer collecting more than \$4000 in a semimonthly period shall deposit (1) the actual amount of tax collected or an amount equal to not less than one-sixth of the amount of tax collected and paid during the preceding quarter or (2) the actual amount of tax collected or an amount equal to not less than one-sixth of the amount of tax collected and paid during the same quarter of the previous year. The method of reporting selected by the retailer, either option 1 or option 2, shall remain consistent for at least four quarters. The first semimonthly deposit is for the period from the first of the month through the fifteenth of the month and is due on or before the twenty-fifth of the month. The second semimonthly deposit is for the period from the sixteenth through the end of the month and is due on or before the tenth day of the month following the month of collection. A deposit is not required for the last semimonthly period of the calendar quarter.

Retailers required to make semimonthly or monthly deposits under any of the above methods of estimating tax based upon a period when the tax rate was 4 percent shall adjust deposits for periods beginning on or after July 1, 1992, to reflect the increase in the tax rate to 5 percent as provided in Iowa Code section 422.43.

On the quarterly return, every retailer shall report the gross sales for the entire quarter listing all allowable deductions and figuring tax for the entire quarter. Space is provided on the return for a deduction of tax deposited for the previous five semimonthly deposits. The quarterly return is due on or before the last day of the month following the end of the calendar quarter.

A seasonal business retailer with gross receipts in only one quarter during the year may request, and the director may grant, permission to file and remit sales tax for only that specific quarter in which the retailer conducted business.

Effective January 1, 1980, if it is expected that the total annual tax liability of a retailer will not exceed \$120 for a calendar year, the retailer may request, and the director may grant, permission to file and remit sales tax on a calendar year basis. The returns and tax will be due and payable no later than January 31 following each calendar year in which the retailer carried on business.

Following are nonexclusive examples the department could reasonably expect to be within the guidelines for annual reporting:

1. A person selling tangible personal property or taxable services where a major portion of the business is the selling of tangible personal property or taxable services exempt from the imposition of tax; such as a wholesaler whose sales are primarily for resale, or a contractor whose business is primarily new construction.

2. A person whose business is primarily seasonal, or a person engaged in part-time selling of tangible personal property or taxable services.

3. A person whose sales are of a nontaxable service and who may, on occasion, sell tangible personal property incidental to the service.

When the due date falls on Saturday, Sunday, or a legal holiday, the return or deposit will be due the first business day following such Saturday, Sunday, or legal holiday. If a return or deposit is placed in the mails, properly addressed and postage paid, and postmarked on or before the due date for filing, no penalty will attach should the return or deposit not be received until after that date. Mailed returns should be addressed to Sales/Use Tax Processing, P.O. Box 10412, Des Moines, Iowa 50306.

This rule is intended to implement Iowa Code sections 421.14, 422.43, 422.47, 422.51, 422.52, and 423.2.

701—12.2(422,423) Remittances.

12.2(1) The correct amount of tax collected and due shall accompany the forms prescribed by the department unless requirements for electronic transmission of remittances or deposits and related information specify otherwise. The name, address, and permit number of the sender and amount of tax for the quarterly remittance or a semimonthly or monthly deposit shall be stated unless requirements for electronic transmission of remittances or deposits and related information specify otherwise. Every return shall be signed and dated. Reporting forms and a self-addressed return envelope shall be furnished by the department to the taxpayer unless electronic transmission requirements apply; and, when feasible, the taxpayer shall use them when completing and mailing a return and remittance. All remittances shall be made payable to the Iowa Department of Revenue.

12.2(2) Semimonthly deposits and quarterly remittances of taxpayers required to make semimonthly deposits shall be made electronically in a format and by means specified by the department. Deposit forms are not required to be filed when electronic transmission of deposits is done in the prescribed format by specified means. Quarterly returns shall be filed separately from the electronic transfer of remittances for taxpayers required to make semimonthly deposits. Deposits and remittances transmitted electronically are considered to have been made on the date that the deposit or remittance is added to the bank account designated by the treasurer of the state of Iowa. The filing of a return within the period prescribed by law and payment of the tax required to be shown thereon are simultaneous acts and if either condition is not met, a penalty shall be assessed.

This rule is intended to implement Iowa Code sections 422.16, 422.51, 422.52, 423.6, 423.13 and 423.14.

[ARC 5712C, IAB 6/16/21, effective 7/21/21]

701—12.3(422) Permits and negotiated rate agreements. A person making retail sales in Iowa is required to obtain a sales tax permit from the department of revenue. Certain qualified purchasers, users, or consumers may obtain a direct pay permit which allows qualified purchasers, users, or consumers to remit tax directly to the department rather than to the retailer at the time of purchase or use. The following provisions govern the issuance of each type of permit.

12.3(1) Sales tax permits. Sales tax permits will be required of all resident and nonresident persons making retail sales at permanent locations within the state. A permit must be held for each location except that retailers conducting business at a permanent location who also make sales at a temporary location are not required to hold a separate permit for any temporary location. All tax collected from the temporary location shall be remitted with the tax collected at the permanent location. Persons who are registered retailers pursuant to rule 701—29.1(423) relating to use tax may remit sales taxes collected at a temporary location with their quarterly retailers use tax return. Retailers conducting a seasonal business shall also obtain a regular permit. However, returns will be filed on either a quarterly or annual basis depending upon the number of quarters in which sales are made. Sales tax permits will be required of all persons, except cities and counties, who have sales activity from gambling.

12.3(2) Direct pay permits. Effective January 1, 1998, qualified purchasers, users, and consumers of tangible personal property or enumerated services pursuant to Iowa Code chapters 422, 422B, and 423 may remit tax owed directly to the department of revenue instead of the tax being collected and remitted by the seller. A qualified purchaser, user, or consumer may not be granted or exercise this direct pay

option except upon proper application to the department and only after issuance of the direct pay permit by the director of the department of revenue.

a. Qualifications for a direct pay permit. To qualify for a direct pay permit, all of the following criteria must be met:

(1) The applicant must be a purchaser, user, or consumer of tangible personal property or enumerated services.

(2) The applicant must have an accrual of sales and use tax liability on consumed goods of more than \$4,000 in a semimonthly period. A purchaser, user, or consumer may have more than one business location and can combine the sales and use tax liabilities on consumed goods of all locations to meet the requirement of \$4,000 in sales and use tax liability in a semimonthly period to qualify, if the records are located in a centralized location. If a purchaser, user, or consumer is combining more than one location, only one direct pay tax return for all of the combined locations needs to be filed with the department. However, local option sales and service tax should not be included in the tax base for determining qualification for a direct pay permit. If a purchaser, user, or consumer has more than one location, but not all locations wish to remit under a direct pay permit, the purchaser, user, or consumer must indicate which locations will be utilizing the direct pay permit at the time of application.

(3) The applicant must make deposits and file returns pursuant to Iowa Code section 422.52. See subrule 12.3(2), paragraph “d,” for further details.

b. Nonqualifying purchases or uses. The granting of a direct pay permit is not allowed for any of the following:

(1) Taxes imposed on the sale, furnishing, or service of gas, electricity, water, heat, pay television service, or communication service.

(2) Taxes imposed under Iowa Code section 422C.3 (sales tax on the rental receipts of qualifying rental motor vehicles), Iowa Code section 423.7 (use tax on the sale or use of motor vehicles), or Iowa Code section 423.7A (use tax on the lease price of qualifying leased motor vehicles).

c. Application and permit information. To obtain a direct pay permit, a purchaser, user, or consumer must properly complete an application form prescribed by the director of revenue and provide certification that the purchaser, user, or consumer has paid sales and use tax to the department of revenue or vendors over the last two years prior to application, an average of \$4,000 in a semimonthly period.

Upon approval, the director will issue a direct pay permit to qualifying applicants. The permit will contain direct pay permit identifying information including a direct pay permit identification number. The direct pay permit should be retained by the permit holder. When purchasing from a vendor, a permit holder should give the vendor a certificate of exemption containing the information as set forth in rule 701—15.3(422,423).

d. Remittance and reporting. Sales, use, and local option tax that is to be reported and remitted to the department will be on a semimonthly basis. Remittance of tax due under a direct pay permit will begin with the first quarter after the direct pay permit is issued to the holder. The tax to be paid under a direct pay permit must be remitted directly to the department by electronic funds transfer (EFT) only. A permit holder need not have remitted by EFT prior to obtaining a direct pay permit to qualify for such a permit. However, a permit holder must remit taxes due by EFT for transactions entered into on or after the date the permit is issued. All local option sales and service tax due must be reported and remitted at the same time as the sales and use taxes due under the direct pay permit for the corresponding tax period. However, local option sales and service tax should not be included in the tax base for determining qualification for a direct pay permit or frequency of remittance. Reports should be filed with the department on a quarterly basis. The director may, when necessary and advisable in order to secure the collection of tax due, require an applicant for a direct pay permit or a permit holder to file with the director a qualified surety bond as set forth in Iowa Code section 422.52. A permit holder who fails to report or remit any tax when due is subject to the penalty and interest provisions set forth in Iowa Code section 422.52.

e. Permit revocation and nontransferability. A direct pay permit may be used indefinitely unless it is revoked by the director. A direct pay permit is not transferable and it may not be assigned to a third party. The director may revoke a direct pay permit at any time the permit holder fails to meet the requirements for a direct pay permit, misuses the direct pay permit, or fails to comply with the provisions

in Iowa Code section 422.53. If a direct pay permit is revoked, it is the responsibility of the prior holder of the permit to inform all vendors of the revocation so the vendors may begin to collect tax at the time of purchase. A prior permit holder is responsible for any tax, penalty, and interest due for failure to notify a vendor of revocation of a direct pay permit.

f. Record-keeping requirements. The parties involved in transactions involving a direct pay permit shall have the following record-keeping duties:

(1) Permit holder. The holder of a direct pay permit must retain possession of the direct pay permit. The permit holder must keep a record of all transactions made pursuant to the direct pay permit in compliance with rule 701—11.4(422,423).

(2) Vendor. A vendor must retain a valid exemption certificate under rule 701—15.3(422,423) which is received from the direct pay permit holder and retain records of all transactions engaged in with the permit holder in which tax was not collected, in compliance with rule 701—11.4(422,423). A vendor's liability for uncollected tax is governed by the liability provisions of a seller under an exemption certificate set forth in rule 701—15.3(422,423).

12.3(3) Negotiated rate agreements. Any person who has been issued or who has applied for a direct pay permit may request the department to enter into a negotiated rate agreement with the permit holder or applicant. These agreements are negotiated on a case-by-case basis and, if approved by the department, allow a direct pay permit holder to pay the state sales, local option sales, or use tax on a basis calculated by agreement between the direct pay permit holder and the department. Negotiated rate agreements are not applicable to sales and use taxes set out in subrule 12.3(2), paragraph "b," above, and no negotiated rate agreement is effective for any period during which a taxpayer who is a signatory to the agreement is not a direct pay permit holder.

All negotiated rate agreements shall contain the following information or an explanation for its omission:

1. The name of the taxpayer who has entered into the agreement with the department.
2. The name and title of each person signing the agreement and the name, telephone or fax number, and email or physical address of at least one person to be contacted if questions regarding the agreement arise.
3. The period during which the agreement is in effect and the renewal or extension rights (if any) of each party, and the effective date of the agreement.
4. The negotiated rate or rates, the classes of sales or uses to which each separate rate is applicable, any items which will be excluded from the agreement, and any circumstances which will result in a changed rate or rates or changed composition of classes to which rates are applicable.
5. Actions or circumstances which render the agreement void, or voidable at the option of either party, and the time frame in which the agreement will be voided.
6. Rights, if any, of the parties to resort to mediation or arbitration.
7. An explanation of the department's right to audit aspects of the agreement, including any right to audit remaining after the agreement's termination.
8. The conditions by which the agreement may be terminated and the effective date of the termination.
9. The methodology used to determine the negotiated rate and any schedules needed to verify percentages.
10. Any other matter deemed necessary to the parties' mutual understanding of the agreement.

This rule is intended to implement Iowa Code sections 422.45(20) and 422.53 as amended by 1997 Iowa Acts, House File 266.

701—12.4(422) Nonpermit holders. Persons not regularly engaged in selling at retail and who do not have a permanent place of business but are temporarily engaged in selling from trucks, portable roadside stands, concessionaires at state, county, district, or local fairs, carnivals and the like shall collect and remit tax on a nonpermit basis. In such cases, a nonpermit identification certificate will be issued by the department for record-keeping purposes and may be displayed in the same manner as a sales tax permit. If the department deems it necessary and advisable in order to secure the collection of tax, transient or

itinerant sellers shall be required to post a bond or certificate of deposit. A cash bond or a surety bond issued by a solvent surety company authorized to do business in Iowa shall be acceptable, provided the bonding company is approved by the insurance commissioner as to solvency and responsibility. The amount and type of bond shall be determined according to the rules promulgated by the director.

The department shall determine the due date of returns and payment of tax for temporary permit holders, giving due consideration to the type of business and frequency of sales. Persons holding nonpermit identification certificates may be required to remit tax upon demand or at the end of the event.

Persons regularly engaged in selling tangible personal property which is exempt from tax, making nontaxable transactions, or engaged in performing a service which is not enumerated in Iowa Code section 422.43 shall not be required to obtain a sales tax permit. However, if the retailer makes taxable sales or provides taxable services, the retailer will be required to hold a permit under the provisions of this rule.

This rule is intended to implement Iowa Code section 422.53.

701—12.5(422,423) Regular permit holders responsible for collection of tax. A regular permit holder may operate by selling merchandise by trucks, canvassers, or itinerant salespeople over fixed routes within the county in which the permanent place of business is located or other counties in this state. When this occurs, the regular permit holder is liable for reporting and paying tax on these sales. The person doing the selling for the regular permit holder shall be required to have a form, either in possession or in the vehicle, which authorizes that person to collect tax. This form is obtained from the department and shall contain the name, address, and permit number of the retailer according to the records of the department.

This rule is intended to implement Iowa Code sections 422.53 and 423.9.

701—12.6(422,423) Sale of business. A retailer selling the business shall file a return within the succeeding month thereafter and pay all tax due. Any unpaid tax shall be due prior to the transfer of title of any personal property to the purchaser and the tax becomes delinquent one month after the sale.

A retailer discontinuing business shall maintain the business's records for a period of five years from the date of discontinuing the business unless a release from this provision is given by the department. See 701—subrule 18.28(2) regarding possible sales and use tax consequences relating to the sale of a business.

This rule is intended to implement Iowa Code sections 422.51(2) and 422.52.

701—12.7(422) Bankruptcy, insolvency or assignment for benefit of creditors. In cases of bankruptcy, insolvency or assignment for the benefit of creditors by the taxpayer, the taxpayer shall immediately file a return with the tax being due.

This rule is intended to implement Iowa Code section 422.51(2).

701—12.8(422) Vending machines and other coin-operated devices. An operator who places machines on location shall file a return which includes gross receipts from all machines or devices operated by the retailer in Iowa during the period covered by the return. The mandatory beverage container deposit required under the provisions of Iowa Code chapter 455C shall not be considered part of the gross receipts.

This rule is intended to implement Iowa Code sections 422.42(16), 422.43, 422.51, and Iowa Code chapter 455C.

701—12.9(422) Claim for refund of tax. Refunds of tax shall be made only to those who have actually paid the tax. A person or persons may designate the retailer who collects the tax as an agent for purposes of receiving a refund of tax. A person or persons who claim a refund shall prepare the claim on the prescribed form furnished by the department.

A claim for refund shall be filed with the department, stating in detail the reasons and facts and, if necessary, supporting documents for which the claim for refund is based. See 1968 O.A.G. 879. If the

claim for refund is denied, and the person wishes to protest the denial, the department will consider a protest to be timely if filed no later than 60 days following the date of denial. See rule 701—7.8(17A).

When a person is in a position of believing that the tax, penalty, or interest paid or to be paid will be found not to be due at some later date, then in order to prevent the statute of limitations from running out, a claim for refund or credit must be filed with the department within the statutory period provided for in Iowa Code section 422.73(1). The claim must be filed requesting that it be held in abeyance pending the outcome of any action which will have a direct effect on the tax, penalty or interest involved. Nonexclusive examples of such action would be: court decisions, departmental orders and rulings, and commerce commission decisions.

EXAMPLE: X, an Iowa sales tax permit holder, is audited by the department for the period July 1, 1972, to June 30, 1977. A \$10,000 tax, penalty and interest liability is assessed on materials the department determines are not used in processing. X does not agree with the department's position, but still pays the full liability even though X is aware of pending litigation involving the materials taxed in the audit.

Y is audited for the same period involving identical materials used to those taxed in the audit of X. However, Y, rather than paying the assessment, takes the department through litigation and wins. The final litigation is not completed until September 30, 1983.

X, on October 1, 1983, upon finding out about the decision of Y's case, files a claim for refund relating to its audit completed in June 1977. The claim will be totally denied as beyond the five-year statute of limitations. However, if X had filed a claim along with payment of its audit in June 1977, and requested that the claim be held in abeyance pending Y's litigation, then X would have received a full refund of their audit liability if the decision in Y's case was also applicable to X.

EXAMPLE: X, a utility company, filed a request for a rate increase with the commerce commission on June 30, 1967. The rate increase became effective January 1, 1968. However, a final decision of whether X was allowed this rate increase is not made until September 30, 1974. The rate increase was disallowed. X then had to refund to its customers all disallowed, but collected, rate increases plus sales tax. X files a claim for refund of the involved sales tax on December 30, 1974. Only the tax for the years 1970 to 1974 will be refunded. The tax for the years 1968 and 1969 will be denied as being beyond the five-year statute set forth in Iowa Code section 422.73(1). However, if X had filed a claim covering the rate increase any time before January 31, 1973, requesting it be held in abeyance pending the outcome of the commerce commission ruling, then X would have been allowed a full refund of all the sales tax that is refunded from the effective date of the rate increase, January 1, 1968, through September 30, 1974.

EXAMPLE: X is audited by the department for the period July 1, 1973, to June 30, 1978, and assessed July 31, 1978. X pays the assessment on December 31, 1978. No protest was filed and no claim for refund or credit was filed requesting it be held in abeyance. On January 31, 1980, X files a claim for refund relating to the entire audit. The claim is based on a recent court decision which makes the tax liability paid by X now refundable. However, only the tax paid from January 1, 1975, through June 30, 1978, will be allowed as this is the only portion within the five-year statute of limitations set forth in section Iowa Code 422.73(1). If the claim had been filed on or before December 31, 1979, then the entire audit period July 1, 1973, to June 30, 1978, could have been considered for refund as the claim would have been filed within one year of payment.

This rule is intended to implement Iowa Code section 422.73.

[ARC 0251C, IAB 8/8/12, effective 9/12/12]

701—12.10(423) Audit limitation for certain services.

12.10(1) Definitions. For purposes of this rule, the following definitions shall govern:

“*Landscaping*” means the same as defined in rule 701—26.61(423).

“*Lawn care*” means the same as defined in rule 701—26.61(423).

“*Tree trimming and removal*” means the same as defined in rule 701—26.66(423).

12.10(2) Audit limitation for lawn care, landscaping, and tree trimming and removal services. Notwithstanding any other provision of the Iowa Code to the contrary, the department shall not attempt to collect delinquent sales tax or use tax on a transaction involving the furnishing of lawn care, landscaping, or tree trimming and removal services which occurred more than five years prior to

the date of an audit. The date an audit will begin is when the department presents notification that the person is being contacted for an audit.

This rule is intended to implement Iowa Code section 423.31 as amended by 2008 Iowa Acts, Senate File 2428, section 23.

701—12.11 Reserved.

701—12.12(422) Extension of time for filing. Upon a proper showing of the necessity for extending the due date, the director is authorized to grant an extension of time in which to file a return. The extension shall not be granted for a period longer than 30 days. The request for the extension must be received on or before the original due date of the return. It will be granted only if the person requesting the extension shall have paid by the twentieth day of the month following the close of such quarter, 90 percent of the estimated tax due.

This rule is intended to implement Iowa Code section 422.51.

701—12.13(422) Determination of filing status.

12.13(1) Prior to January 1, 2003. Iowa Code sections 422.51(4) and 422.52 provide, based on the amount of tax collected, how often retailers file deposits or returns with the department (see rule 701—12.1(422)).

The department will determine if the retailer's current filing status is correct by reviewing the most recent four quarters of the retailer's filing history.

The following criteria will be used by the department to determine if a change in filing status is warranted.

<u>Filing Status</u>	<u>Statutory Requirement</u>	<u>Test Criteria</u>
Semimonthly	\$4,000 in tax in a semimonthly period.	Tax remitted in 3 of most recent 4 quarters exceeds \$24,000.
Monthly	\$50 in tax in a month.	Tax remitted in 3 of most recent 4 quarters exceeds \$150.
Annual	\$120 or less in tax in prior year.	Retailer remits \$120 or less in tax for last 4 quarters and requests annual filing.
Seasonal		Retailer remits tax for only 1 quarter during the previous calendar year and requests filing for 1 quarter only.
Quarterly	All other filers.	

When it is determined that a retailer's filing status is to be changed, the retailer will be notified and will be given 30 days to provide the department with a written request to prevent the change.

Retailers may request that they be allowed to file less frequently than the filing status selected by the department but exceptions will only be granted in two instances:

a. Incorrect historical data is used in the conversion. A business may meet the criteria based on initial information available, but, upon investigation, the filing history may prove that the business does not meet the dollar criteria because of adjustments, amended returns, or requests for refunds.

b. Data available may have been distorted by the fact that it reflected an unusual pattern in tax collection. The factors causing such a distortion must be documented and approved by department.

Exceptions will not be granted in instances where the retailer's request is based on a decline in business activity, reduction in employees or other potentially temporary business action which will affect current and future reporting.

Retailers will be notified in writing of approval or denial of their request for reduced filing periods.

Retailers may request that they be allowed to file more frequently than the filing status selected by the department. Approval will be granted based upon justification contained in the retailer's request.

12.13(2) January 1, 2003, and after. Effective July 1, 2002, the department and the department of management have the authority to change the above-mentioned filing thresholds established by department rule. After review of these filing thresholds, the department has determined that new thresholds are necessary and are to be implemented January 1, 2003. Accordingly, this subrule sets forth the filing thresholds for each filer based on the amount of sales tax collected.

<u>Filing Status</u>	<u>Threshold</u>	<u>Test Criteria</u>
Semimonthly	Greater than \$60,000 in annual state sales tax (more than \$2,500 in a semimonthly period).	Tax remitted in 3 of most recent 4 quarters examined exceeds \$15,000 per quarter.
Monthly	Between \$6,000 and \$60,000 in annual state sales tax (more than \$500 in a monthly period).	Tax remitted in 3 of most recent 4 quarters examined exceeds \$1,500 per quarter.
Quarterly	Between \$120 and \$6,000 in annual state sales tax.	Tax remitted in 3 of most recent 4 quarters examined exceeds \$30 per quarter.
Annual	Less than \$120 in state sales tax for the prior year.	Tax remitted in prior year is less than \$120.
Seasonal	Retailer remits tax for only 1 quarter during the previous calendar year and requests filing for 1 quarter only.	

A retailer shall be notified in writing when it is determined that a retailer's filing status will be changed. A retailer has the option of requesting, within 30 days of the date of the department's notice of a change in filing frequency, that the retailer file more or less frequently than required by the department. A request to file on a less frequent basis than assigned by the department must be in writing and submitted to the department. Once such a written request is filed by the retailer, the department will review the request and issue a written determination to the retailer.

A change in assigned filing status to file on a less frequent basis will be granted in only two instances:

a. Incorrect historical data is used in the conversion. A business may meet the criteria based on the original filing data, but, upon investigation, the filing history may prove that the business does not meet the dollar criteria because of adjustments, amended returns, or requests for refunds.

b. Data available may have been distorted by the fact that the data reflected an unusual pattern in tax collection. The factors causing such a distortion must be documented and approved by the department.

A retailer may also request to file more frequently than assigned by the department; the request may be made orally, in person, or by telephone. With the exception of those retailers who previously filed on a quarterly basis and have been changed to an annual filing frequency, any retailer seeking to file on a more frequent basis than assigned shall be required to deposit revenues by electronic funds transfer if the department allows the retailer to file more frequently.

The department and the department of management may perform review of filing thresholds every five years or as needed based on department discretion. Factors the departments will consider in determining if the filing thresholds need to be changed include, but are not limited to: tax rate changes, inflation, the need to maintain consistency with required multistate compacts, changes in law, and migration between filing brackets.

This rule is intended to implement Iowa Code sections 421.14, 422.51, and 422.52, and sections 422.54 as amended by 2002 Iowa Acts, House File 2622, section 11, and 423.13 as amended by 2002 Iowa Acts, House File 2622, section 14.

701—12.14(422,423) Immediate successor liability for unpaid tax. A retailer ceasing to do business is obligated to prepare a final return and pay all tax due within the time required by law. If a retailer ceasing to do business fails to do this, any immediate successor to the retailer who purchases the business or stock of goods is obligated to withhold from the purchase price enough of the purchase price to pay the tax, interest, or penalty which the retailer owes. Any immediate successor who intentionally fails to withhold sufficient of the purchase price to pay the delinquent tax, interest, and penalty is personally liable for the payment of the tax. However, if the immediate successor's purchase of the business or stock of goods was made in good faith that the retailer owed no tax, interest, or penalty, then the department may waive the immediate successor's liability.

12.14(1) Immediate successors having a duty to withhold. Only an immediate successor who, pursuant to a contract of sale, pays a purchase price to a retailer in return for the transfer of a going business or a stock of goods is obligated to inquire if tax, penalty, or interest is due and to withhold a portion of the purchase price if necessary. Persons who fail some aspect of this test, e.g., because they take by operation of law rather than by contract or provide no consideration, are not obligated to investigate or withhold. Nonexclusive examples of persons not so obligated are the following:

- a. A person foreclosing on a valid security interest.
- b. A person retaking possession of premises under a valid lease.
- c. A spouse electing to take under a will.
- d. A person taking by gift.
- e. Any other person taking for what would legally be considered "for value" but without the payment of a recognizable "purchase price."

Included within the meaning of the phrase "immediate successor" is a corporation resulting from the action of a sole proprietor who incorporates a business in which the sole proprietor is the only or the controlling shareholder; or a sole proprietorship established from a corporation of which the sole proprietor was the exclusive, majority, or controlling stockholder.

12.14(2) More than one immediate successor. If a retailer sells a business or stock of goods to two or more persons the following rules apply:

- a. *Sale of stock of goods to two or more persons.* If a retailer sells a substantial portion of the retail business's stock of goods to another person who will in turn offer those goods for sale in a retail business, that person is an "immediate successor" and personally liable for payment of tax to the extent of tax, interest, or penalty owed or the amount of the individual purchase price, whichever is the lesser.

EXAMPLE: A sells the stock of goods from a furniture business, in unequal portions, to B, C, and D. B pays a \$5,000 purchase price for a portion of the stock of goods, C pays \$20,000 for a portion of the stock of goods, and D pays a \$30,000 purchase price for the remainder of A's stock of goods. A, at the time of the transfers, owes the department of revenue \$10,000 in sales tax, interest, and penalty. Neither B, C, nor D withholds any amount for payment of tax from the purchase price. B, C, and D individually and together are liable for payment of the tax. Each is personally liable up to the amount of the purchase price which each has paid or the amount of tax, interest, and penalty owing, whichever is the lesser. In this example, B is liable for \$5,000, the lesser amount of B's purchase price (\$5,000) and the amount of tax which A owes (\$10,000); C is liable for \$10,000, since purchase price and tax owed are equal; and D is liable for \$10,000, the lesser amount of tax owed (\$10,000) and D's purchase price (\$30,000). The department can proceed against any one, two, or all three of the immediate successors up to the amount of tax which each owes, as it chooses.

- b. *Purchase of differing places of business.* If one person owns two or more places of business, each having a separate sales tax permit, each location having its own permit is a separate business and has a separate stock of goods for the purpose of determining successor liability. A person purchasing the business at one location or the stock of goods from one location would be personally liable only for the tax owed under the permit assigned to that location.

12.14(3) "Sale of a retailer's business" characterized. Usually, the sale of only the machinery or equipment used in a business without the sale or leasing of the realty of the business is not a sale of the business itself. *People v. Gabriel*, 135 P.2d 378 (Cal. App. 1943). The transfer of a retailer's machinery or equipment and business realty to a person who continues to use the machinery, equipment, and realty

for the sale of any type of tangible personal property constitutes the selling of the retailer's business, and the person to whom the business is sold is an "immediate successor" and liable for tax.

EXAMPLE: A is a furniture dealer. The furniture business falls on hard times. A sells the stock of goods (the furniture offered for sale) to B. A then sells the furniture store (business realty) to C. A also sells C the office equipment and all other tangible personal property used in the operation of the furniture store except for the stock of goods (furniture). C then uses the purchased store and the office equipment in the operation of a sporting goods store. B takes the furniture purchased from A to B's furniture store where it is sold. A owed the department \$7,000 in sales tax. Both B and C are immediate successors to A and personally liable for the sales tax.

12.14(4) *"Good faith" characterized.* An immediate successor to a retailer has purchased the retailer's business or stock of goods "in good faith" if the immediate successor demonstrates, by suitable evidence, that one of the following situations exists. The list of situations is exclusive:

a. The department has provided the immediate successor with a certified statement that no delinquent tax, interest, or penalty is unpaid; or

b. The immediate successor has taken "in good faith" a certified statement from the licensee, retailer, or seller that no delinquent tax, interest, or penalty is unpaid as of the date of purchase. Immediate successors should not rely upon oral statements from department personnel that no tax, interest, or penalty is unpaid. An immediate successor should request a written statement to this effect. For information regarding delinquent tax, interest, or penalty and tax liens write to: Collections Section Supervisor, Iowa Department of Revenue, P.O. Box 10471, Hoover State Office Building, Des Moines, Iowa 50306. A "certified statement" from a retailer is a statement the truth of which is attested to before a notary public or other officer authorized to take oaths. A certified statement has been taken from a retailer "in good faith" if the immediate successor, in the exercise of due diligence, had no reason to believe a retailer's statement was false or no reason to question the truth of the retailer's statement.

This rule is intended to implement Iowa Code section 421.28.

701—12.15(422,423) Officers and partners—personal liability for unpaid tax. If a retailer or purchaser fails to pay sales tax when due, any officer of a corporation or association, or any partner of a partnership, who has control of, supervision of, or the authority for remitting the sales tax payments and has a substantial legal or equitable interest in the ownership of the corporation or partnership is personally liable for payment of the tax, interest, and penalty if the failure to pay the tax is intentional. This personal liability is not applicable to sales tax due and unpaid on accounts receivable. The dissolution of a corporation, association, or partnership does not discharge a responsible person's liability for failure to pay tax.

12.15(1) *Personal liability—how determined.* There are various criteria which can be used to determine which officers of a corporation have control of, supervision of, or the authority for remitting tax payments. Some criteria are:

- a.* The duties of officers as outlined in the corporate bylaws,
- b.* The duties which various officers have assumed in practice,
- c.* Which officers are empowered to sign checks for the corporation,
- d.* Which officers hire and fire employees, and

e. Which officers control the financial affairs of the corporation. An officer in control of the financial affairs of a corporation may be characterized as one who has final control as to which of the corporation's bills should or should not be paid and when bills which had been selected for payment will be paid. "Final control" means a significant control over which bills should or should not be paid rather than exclusive control. The observations in this paragraph are applicable to partnerships as well as corporations.

12.15(2) *"Accounts receivable" described.* Officers and partners are not responsible for sales tax due and owing on accounts receivable. An "account receivable" is a contractual obligation owing upon an open account. An open account is one which is neither finally settled or finally closed, but is still running and "open" to future payments or the assumption of future additional liabilities. The ordinary consumer installment contract is not an "account receivable." The amount due has been finally settled

and is not open to future adjustment. The usual consumer installment contract is a “note receivable” rather than an account receivable. An account receivable purchased by a factor or paid by a credit card company is, as of the date of purchase or payment, not an account receivable. An officer or partner will be liable for the value of the account receivable purchased or paid. Officers and partners have the burden of proving that tax is not due because it is a tax on an account receivable.

12.15(3) *Beginning date of personal liability.* Officers and partners are not personally liable for state sales tax due and unpaid prior to March 13, 1986. They are liable for state sales taxes which are both due and unpaid on and after that date. See department rule 701—107.12(422B) for an explanation of officer and partner liability for unpaid local option sales tax.

701—12.16(422) Show sponsor liability. Persons sponsoring flea markets or craft, antique, coin, stamp shows, or similar events are, under certain circumstances, liable for payment of sales tax, interest, and penalty due and owing from any retailer selling property or services at the event. Included within the meaning of the term “similar event” is any show at which guns or collectibles, e.g., depression glassware or comic books, are sold or traded. To avoid liability, sponsors of these events must obtain from retailers appearing at the events proof that a retailer possesses a valid Iowa sales tax permit or a statement from the retailer, taken in good faith, that the property or service which the retailer offers for sale is not subject to sales tax. “Good faith” may demand that the sponsor inquire into the nature of the property or service sold or why the retailer believes the property or services for sale to be exempt from tax. A sponsor who fails to take these measures assumes all of the liabilities of a retailer. This includes not only the obligation to pay tax, penalty, and interest, but also to keep the records required of a retailer and to file returns.

Excluded from the requirements of this rule and from sponsor liability are organizations which sponsor events fewer than three times a year and state, county, or district agricultural fairs.

This rule is intended to implement the requirements of Iowa Code section 422.52.

701—12.17(423) Purchaser liability for unpaid sales tax. For sales occurring on and after March 13, 1986, if a purchaser fails to pay sales tax to a retailer required to collect the tax, the tax is payable by the purchaser directly to the department. The general rule is that the department may proceed against either the retailer or the purchaser for the entire amount of tax which the purchaser is, initially, obligated to pay the retailer. However, see 701—subrule 15.3(2) for a situation in which the obligation to pay the tax is imposed upon the purchaser alone. On or after January 1, 2016, see 701—Chapter 242 for a situation in which the obligation to pay the tax is not imposed on an out-of-state business operating within Iowa solely for the purpose of performing disaster or emergency-related work during a disaster response period as those terms are defined in Iowa Code section 29C.24.

This rule is intended to implement Iowa Code section 423.33.

[ARC 3085C, IAB 5/24/17, effective 6/28/17]

701—12.18(423) Biodiesel production refund. Information on the sales and use tax refund for biodiesel production is available at rule 701—250.1(423).

[ARC 9821B, IAB 11/2/11, effective 12/7/11; ARC 1665C, IAB 10/15/14, effective 11/19/14; ARC 3043C, IAB 4/26/17, effective 5/31/17]

701—12.19(15) Sales and use tax refund for eligible businesses. For eligible businesses approved under the high quality jobs program, enterprise zone program, housing enterprise zone program, or workforce housing tax incentives program by the economic development authority, a refund of sales and use tax is available.

12.19(1) *Sales and use tax eligible for refund.* The sales and use tax for which the eligible business can receive a refund consists of the following:

a. Sales and use tax paid for gas, electricity, water, or sewer utility services, goods, wares, or merchandise, or on services rendered, furnished, or performed to or for a contractor or subcontractor and used in the fulfillment of a written contract relating to the construction or equipping of a facility of the eligible business.

b. If the eligible business is involved in a warehouse or a distribution center, sales and use tax attributable to racks, shelving and conveyor equipment.

12.19(2) Sales and use tax ineligible for refund. The sales and use tax for which the eligible business cannot receive a refund consists of the following:

a. Any local option sales tax paid is not eligible for the refund. The refund is limited to the state sales and use tax paid.

b. Any sales and use tax attributable to intangible property, furniture, or furnishings is not eligible for the refund. “Furnishings” means any furniture, appliances, equipment, and accessories that are movable and with which a room or building is furnished for comfort, convenience, or aesthetic value. Examples include rugs, décor, and window coverings. “Furnishings” does not include installed flooring such as hardwood, carpet, ceramic, stone, laminate, or vinyl.

12.19(3) Claiming the refund. To receive the refund, the eligible business must file a claim for refund within one year of project completion. For a manufacturing facility, project completion is the first date upon which the average annualized production of finished project for the preceding 90-day period at the manufacturing facility is at least 50 percent of the initial design capacity of the facility. For purposes of the workforce housing tax incentives program, “project completion” means the same as defined in Iowa Code section 15.355(2). For all other facilities, project completion is the date of completion of all improvements necessary for the start-up, location, expansion or modernization of the business.

a. To request a refund of the sales and use tax paid for gas, electric, water or sewer utility services used during construction, the eligible business must file Form IA 843, Claim for Refund, with the department of revenue. The claim shall include the agreement number given by the Iowa economic development authority, along with copies of invoices or a schedule to support the refund amount.

b. To request a refund of the sales and use tax paid on goods, wares, or merchandise, or on services rendered to, furnished to, or performed for a contractor or subcontractor relating to the construction or equipping of a facility, the eligible business must file the Construction Contract Claim for Refund form, along with the Iowa Contractor’s Statement, with the department of revenue. It is not necessary to attach invoices to the Construction Contract Claim for Refund form, but the department reserves the right to request invoices when reviewing the refund claim.

c. To request a refund of the sales and use tax attributable to racks, shelving and conveyor equipment, the eligible business must file Form IA 843, Claim for Refund, with the department of revenue. The claim shall include the agreement number given by the Iowa economic development authority, along with copies of invoices or a schedule to support the refund amount. The combined amount of refunds attributable to sales and use tax paid on racks, shelving and conveyor equipment, along with tax credit certificates issued for sales and use tax paid on racks, shelving and conveyor equipment provided in 701—subrule 52.10(5), shall not exceed \$500,000 during a fiscal year. The requests for refunds or tax credit certificates will be processed in the order the requests are received on a first-come, first-served basis until the amount of refunds or credits authorized for issuance has been exhausted. If applications for refunds or tax credit certificates exceed the \$500,000 limitation for any fiscal year, the applications shall be considered in succeeding fiscal years.

[ARC 0414C, IAB 10/31/12, effective 12/5/12; ARC 1744C, IAB 11/26/14, effective 12/31/14; ARC 3837C, IAB 6/6/18, effective 7/11/18]

701—12.20(423) Collection, permit, and tax return exemption for certain out-of-state businesses. On or after January 1, 2016, see 701—Chapter 242 for the requirement of an out-of-state business to obtain a sales or use tax permit, collect and remit sales and use tax, or make and file applicable sales or use tax returns when operating in Iowa solely for the purpose of performing disaster or emergency-related work during a disaster response period as those terms are defined in Iowa Code section 29C.24.

This rule is intended to implement Iowa Code section 423.58.

[ARC 3085C, IAB 5/24/17, effective 6/28/17]

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[◇] Two or more ARCs

TITLE IX
PROPERTY
CHAPTER 70
REPLACEMENT TAX AND STATEWIDE PROPERTY TAX

DIVISION I
REPLACEMENT TAX

701—70.1(437A) Who must file return. Each taxpayer, as defined in Iowa Code Supplement section 437A.3(30), shall file a true and accurate return with the director. The return shall include all of the information prescribed in Iowa Code sections 437A.8(1)“a” through “f” and any other information or schedules requested by the director. The return shall be signed by an officer or other person duly authorized by the taxpayer and must be certified as correct. If the taxpayer was inactive or ceased the conduct of any activity subject to the replacement tax during the tax year, the return must contain a statement to that effect.

701—70.2(437A) Time and place for filing return. The return must be filed with the director on or before March 31 following the tax year. There is no authority for the director to grant an extension of time to file a return. Therefore, any return which is not filed on or before March 31 following the tax year is untimely.

A taxpayer whose replacement tax liability before credits is \$300 or less is not required to file a return. A taxpayer should not file a replacement tax return under such circumstances.

When the due date falls on a Saturday or Sunday, the return will be due the first business day following the Saturday or Sunday. If a return is placed in the mails, properly addressed and postage paid in ample time to reach the director or the department on or before the due date for filing, no penalty will attach should the return not be received until after that date. The functional meaning of this requirement is that if the return is placed in the mails, properly addressed and postage paid, on or before the due date for filing, no penalty will attach. Mailed returns should be addressed to Department of Revenue, Attention: Property Tax Division, Hoover State Office Building, Des Moines, Iowa 50319.

701—70.3(437A) Form for filing. Returns must be made by taxpayers on forms supplied by the department. Taxpayers not supplied with the proper forms shall make application for same to the department in ample time to have their returns made, verified and filed on or before the due date. Each taxpayer shall carefully prepare the taxpayer’s return so as to fully and clearly set forth the data required. All information shall be supplied and each direction complied with in the same manner as if the forms were embodied in these rules.

Failure to receive the proper forms does not relieve the taxpayer from the obligation of making the replacement tax return.

Returns received which are not completed, but merely state “see schedule attached,” “no tax due,” or some other conclusionary statement are not considered to be a properly filed return and may be returned to the taxpayer for proper completion. This may result in the imposition of penalties and interest due to the return’s being filed after the due date.

701—70.4(437A) Payment of tax. Payment of tax shall not accompany the filing of the replacement tax return with the director. Payment of tax shall never be made to the director or the state of Iowa. Payment of the proper amount of tax due shall be made to the appropriate county treasurer upon notification by the county treasurer to the taxpayer of the taxpayer’s replacement tax obligation.

701—70.5(437A) Statute of limitations.

70.5(1) The director has three years after a return is filed to determine the tax due if the return is found to be incorrect and to give notice to the taxpayer of the determination. This three-year statute of limitations does not apply in the instances specified in 70.5(2).

70.5(2) If a taxpayer files a false or fraudulent return with the intent to evade any tax, the correct amount of tax due may be determined by the director at any time after the return has been filed.

70.5(3) If a taxpayer fails to file a return, the three-year period of limitations does not begin to run until the return is filed with the director.

70.5(4) Waiver of statute of limitations. The department and the taxpayer may extend the three-year period of limitations provided in 70.5(1) above by signing a waiver agreement form provided by the department. The agreement shall designate the period of extension and the tax year for which the extension applies. The agreement shall provide that the taxpayer may file a claim for refund of replacement tax at any time prior to the expiration of the agreement.

701—70.6(437A) Billings.

70.6(1) *Notice of adjustments.*

a. An agent, auditor, clerk, or employee of the department, designated by the director to examine returns and make audits, who discovers discrepancies in returns or learns that items subject to tax may not have been listed or included as taxable, in whole or in part, or that no return was filed when one was due, is authorized to notify the person of this discovery by ordinary mail. This notice is not an assessment. It informs the person what amount would be due if the information discovered is correct. A copy of such notice shall also be sent to the appropriate county treasurer.

b. Right of person upon receipt of notice of adjustment. A person who has received notice of an adjustment in connection with a return may pay the additional amount stated to be due to the appropriate county treasurer. If payment is made, and the person wishes to contest the matter, the person should file a timely claim for refund. However, payment will not be required until an assessment has been made (although interest will continue to accrue if timely payment is not made). If no payment has been made, the person may discuss with the agent, auditor, clerk, or employee who notified the person of the discrepancy, either in person or through correspondence, all matters of fact and law which may be relevant to the situation. This person may also ask for a conference with the Department of Revenue, Property Tax Division, Hoover State Office Building, Des Moines, Iowa. Documents and records supporting the person's position may be required.

c. Power of agent, auditor, or employee to compromise tax claim. No employee of the department has the power to compromise any tax claims. The power of the agent, auditor, clerk, or employee who notified the person of the discrepancy is limited to the determination of the correct amount of tax.

70.6(2) *Notice of assessment.* If, after following the procedure outlined in 70.6(1) "b," no agreement is reached and the person does not pay the amount determined to be correct to the appropriate county treasurer, a notice of the amount of tax due shall be sent to the taxpayer. This notice of assessment shall bear the signature of the director and will be sent by ordinary mail to the taxpayer with a copy sent to the appropriate county treasurer.

A taxpayer has 60 days from the date of the notice of assessment to file a protest according to the provisions of rule 701—7.8(17A) or, if the taxpayer fails to timely appeal a notice of assessment, the taxpayer may make payment pursuant to rule 701—7.8(17A) to the appropriate county treasurer and file a refund claim with the director within the applicable period provided in Iowa Code section 437A.14(1) "b" for filing such claims.

70.6(3) *Supplemental assessments and refund adjustments.* The director may, at any time within the period prescribed for assessment or refund adjustment, make a supplemental assessment or refund adjustment whenever it is ascertained that any assessment or refund adjustment is imperfect or incomplete in any respect.

If an assessment or refund adjustment is appealed (protested under rule 701—7.8(17A)) and is resolved whether by informal proceedings or by adjudication, the director shall notify the appropriate county treasurer. Such resolution shall preclude the director and the taxpayer from making a supplemental assessment or refund adjustment concerning the same issue involved in the appeal for the same tax year unless there is a showing of mathematical or clerical error or showing of fraud or misrepresentation.

[ARC 0251C, IAB 8/8/12, effective 9/12/12]

701—70.7(437A) Refunds.

70.7(1) A claim for refund of replacement tax may be made on a form obtainable from the department. All claims for refund should be filed with the director, and not with the county treasurer. In the case of a refund claim filed by an agent or representative of the taxpayer, a power of attorney must accompany the claim. All claims for refund must be in writing.

70.7(2) A taxpayer shall not offset a refund or overpayment of tax for one tax year as a prior payment of tax of a subsequent tax year on the tax return of a subsequent year unless the provisions of Iowa Code section 437A.8(7) are applicable.

70.7(3) Refunds—statute of limitations. The statute of limitations with respect to which refunds or credits may be claimed are:

a. The later of three years after the due date of the tax payment upon which the refund or credit is claimed; or one year after which such payment was actually made.

b. Ninety days after the due date of the tax payment upon which refund or credit is claimed if the tax is alleged to be unconstitutional.

70.7(4) No credit or refund of taxes alleged to be unconstitutional shall be allowed if such taxes were not paid to the appropriate county treasurer under written protest which specifies the particulars of the alleged unconstitutionality.

70.7(5) The taxpayer responsible for paying the tax, or the taxpayer's successors, are the only persons eligible to file claims for refund or credit of the tax with the director and are the only persons eligible to receive such refunds or credits.

70.7(6) The director will promptly notify the appropriate county treasurer of the acceptance or denial of any refund claim or credit. The county treasurer shall pay the refund claim or portion thereof accepted by the director.

70.7(7) A taxpayer has 60 days from the date of the notice of denial of a refund or credit, in whole or in part, to file a protest according to the provisions of rule 701—7.8(17A).

[ARC 0251C, IAB 8/8/12, effective 9/12/12]

701—70.8(437A) Abatement of tax. The provisions of rule 701—7.31(421) are applicable to replacement tax. In the event that the taxpayer files a request for abatement with the director, the appropriate county treasurer shall be notified. The director's decision on the abatement request shall be sent to the taxpayer and the appropriate county treasurer.

[ARC 0251C, IAB 8/8/12, effective 9/12/12]

701—70.9(437A) Taxpayers required to keep records.

70.9(1) Records required. The records required in this rule must be made available for examination upon request by the director or the director's authorized representative. The records must include all of those which would support the entries required to be made on the tax return. These records include but are not limited to:

a. Records associated with the number of taxable kilowatt-hours of electricity delivered to consumers by the taxpayer within each electric competitive service area during the tax year. Such records shall also include those for calendar year 1998.

b. Records associated with the number of taxable kilowatt-hours of electricity consumed within each electric competitive service area during the tax year where the delivery of such electricity is not subject to the replacement delivery tax.

c. Records associated with the average centrally assessed property tax liability allocated to electric service of each taxpayer, other than a municipal utility, principally serving an electric competitive service area and of each generation and transmission electric cooperative for the assessment years 1993 through 1997. For municipal utilities, such records shall be for the 1997 assessment year and shall also include records associated with items in 1999 Iowa Acts, Senate File 473, section 30.

d. Records associated with the number of taxable kilowatt-hours of electricity generated within the state of Iowa during the tax year. Such records shall also include those for calendar year 1998.

e. Records associated with taxable pole miles of transmission lines owned or leased by the taxpayer for each of the line voltage tiers subject to tax imposed in Iowa Code section 437A.7. Such records shall also include those for calendar year 1998.

f. Records associated with the excess property tax liability of each generation and transmission electric cooperative assigned to the electric competitive service areas principally served on January 1, 1999, by its distribution electric cooperative members and by those municipal utilities which were purchasing members of a municipal electric cooperative association that is a member of the generation and transmission electric cooperative. Such records shall include those for calendar year 1998. "Excess property tax liability" means the amount by which the average centrally assessed property tax liability for the assessment years 1993 through 1997 of a generation and transmission electric cooperative exceeds the tentative generation and transmission taxes which would have been imposed on such generation and transmission electric cooperative under Iowa Code sections 437A.6 and 437A.7 for calendar year 1998.

g. Records associated with the number of taxable therms of natural gas delivered to consumers by the taxpayer within each natural gas competitive service area during the tax year. Such records shall also include those for calendar year 1998.

h. Records associated with the number of taxable therms of natural gas consumed within each natural gas competitive service area during the tax year where the delivery of such natural gas is not subject to the replacement delivery tax.

i. Records associated with the average centrally assessed property tax liability allocated to natural gas service of each taxpayer, other than a municipal utility, principally serving a natural gas competitive service area for the assessment years 1993 through 1997. For municipal utilities, such records shall be for the 1997 assessment year and shall also include records associated with items in 1999 Iowa Acts, Senate File 473, section 30.

j. Records associated with the taxpayer's calculation of the tentative replacement taxes due for the tax year and required to be shown on the tax return.

k. Records associated with increases or decreases in the tentative replacement tax required to be shown to be due where the electric and natural gas delivery tax rates are subject to recalculation under the provisions of Iowa Code section 437A.8(7).

l. Records associated with the kilowatt-hours of electricity and the therms of natural gas entitled to be exempted from the taxes imposed by Iowa Code sections 437A.4 to 437A.7 by the enumerated exemptions therein.

m. Records associated with kilowatt-hours of electricity and therms of natural gas delivered in a manner set forth in Iowa Code sections 437A.4(7) and 437A.5(6).

n. All work papers associated with any of the records described in this rule.

o. Records pertaining to any additions or deletions of property described as exempt from local property tax in Iowa Code section 437A.16.

p. Records associated with allocation of property described in paragraph "o" above among local taxing districts.

70.9(2) The records required to be maintained by these rules shall be maintained by taxpayers for a period of ten years following the later of the original due date for the filing of a tax return in which the replacement taxes are reported, or the date on which such return is filed. Upon application to the director and for good cause shown, the director may shorten the period for which any records should be maintained by a taxpayer.

701—70.10(437A) Credentials. Employees of the department have official credentials, and the taxpayer should require proof of the identity of persons claiming to represent the department. No charges shall be made nor gratuities of any kind accepted by an employee of the department for assistance given in or out of the office of the department.

701—70.11(437A) Audit of records. The director or the director's authorized representative shall have the right to examine or cause to be examined the books, papers, records, memoranda or documents of a taxpayer for the purpose of verifying the correctness of a tax return filed, of information presented,

or for estimating the tax liability of a taxpayer. When a taxpayer fails or refuses to produce the records for examination upon request, the director shall have authority to require, by a subpoena, the attendance of the taxpayer and any other witness(es) whom the director deems necessary or expedient to examine and compel the taxpayer and witness(es) to produce books, papers, records, memoranda or documents relating in any manner to the replacement tax.

701—70.12(437A) Collections/reimbursements. Neither the director nor the department is empowered to receive any payment of replacement tax. Therefore, taxpayers should never pay any replacement tax to the director or the state of Iowa. All payments of replacement tax are to be made to the appropriate county treasurer.

70.12(1) A person in possession of a renewable energy tax credit certificate issued pursuant to Iowa Code chapter 476C or a wind energy tax credit issued pursuant to Iowa Code chapter 476B may apply to the director for a reimbursement of the amount of taxes imposed and paid by the person pursuant to Iowa Code chapter 437A in an amount not more than the person received in renewable energy tax credit certificates or wind energy tax credit certificates. To obtain the reimbursement, the person shall include with the return required under Iowa Code section 437A.8 the renewable energy tax credit certificates or the wind energy tax credit certificates and provide any other information the director may require. The director shall direct that a warrant be issued to the person for an amount equal to the tax imposed and paid by the person. Any credit in excess of the person's tax liability may be claimed as a refund for the following seven years. Pursuant to Iowa Code section 437A.14, a taxpayer may file a claim for refund with the director within three years after the replacement tax became due. If the renewable energy or wind energy tax credit claim exceeds the replacement tax due in a year, the taxpayer has seven years to carry over the excess credit. Pursuant to Iowa Code section 476C.4(6), a person may not receive both a renewable energy tax credit and a wind energy tax credit. For the wind energy tax credit, the reimbursement applies to a qualified facility placed in service on or after July 1, 2005, but before July 1, 2012. For the renewable energy tax credit, the reimbursement applies to a qualified facility placed in service on or after July 1, 2005, but before January 1, 2017. The utilities board shall notify the department of revenue of the amount of kilowatt hours of electricity purchased from a renewable energy facility or the amount of kilowatt hours generated and purchased from a qualified wind energy facility or generated and used on site by the qualified wind energy facility. The department of revenue shall calculate the amount of the tax credit and issue the tax credit certificate. Wind energy and renewable energy tax credit certificates may be transferred, and a replacement tax credit certificate may reflect a different type of tax than the type of tax noted on the original tax credit certificate.

70.12(2) A person in possession of a soy-based transformer fluid tax credit certificate issued pursuant to Iowa Code chapter 476D may apply to the director for a reimbursement of the amount of taxes imposed and paid by the person pursuant to Iowa Code chapter 437A in an amount not more than the person received in soy-based transformer fluid tax credit certificates. To obtain the reimbursement, the person shall attach to the return required under section 437A.8 the soy-based transformer fluid tax credit certificates issued to the person and provide any other information the director may require. The director shall direct a warrant to be issued to the person for an amount equal to the tax imposed and paid by the person pursuant to Iowa Code chapter 437A but for not more than the amount of the soy-based transformer fluid tax credit certificates attached to the return. This subrule is rescinded December 31, 2009.

This rule is intended to implement Iowa Code sections 437A.17B and 437A.17C and chapters 476B and 476D and chapter 476C as amended by 2014 Iowa Acts, Senate File 2343.

[ARC 1665C, IAB 10/15/14, effective 11/19/14]

701—70.13(437A) Information confidential. Iowa Code subsections 437A.14(2) and (3) apply generally to the director, deputies, auditors, and present or former officers and employees of the department. Disclosure of the kilowatt-hours of electricity or therms of natural gas delivered by a taxpayer in a competitive service area disclosed on a tax return, return information, or investigative or audit information is prohibited. Other persons having acquired this confidential information will be

bound by the same rules of secrecy under these Iowa Code provisions as any member of the department and will be subject to the same penalties for violations as provided by law.

DIVISION II
STATEWIDE PROPERTY TAX

701—70.14(437A) Who must file return. Each taxpayer shall file a true and accurate return with the director. The return shall include all of the information prescribed in Iowa Code section 437A.21 and any other information or schedules requested by the director. The return shall be signed by an officer or other person duly authorized by the taxpayer and must be certified as correct. If the taxpayer was inactive or ceased the conduct of any activity for which the taxpayer's property was subject to the statewide property tax during the tax year, the return must contain a statement to that effect.

701—70.15(437A) Time and place for filing return. The return must be filed with the director on or before March 31 following the tax year. There is no authority for the director to grant an extension of time to file a return. Therefore, any return which is not filed on or before March 31 following the tax year is untimely.

When the due date falls on a Saturday or Sunday, the return will be due the first business day following the Saturday or Sunday. If a return is placed in the mails, properly addressed and postage paid in ample time to reach the director or the department on or before the due date for filing, no penalty will attach should the return not be received until after that date. The functional meaning of this requirement is that if the return is placed in the mails, properly addressed and postage paid, on or before the due date for filing, no penalty will attach. Mailed returns should be addressed to Department of Revenue, Attention: Property Tax Division, Hoover State Office Building, Des Moines, Iowa 50319.

701—70.16(437A) Form for filing. Replacement tax rule 701—70.3(437A) is incorporated herein by reference.

701—70.17(437A) Payment of tax. Payment of the tax required to be shown due on the statewide property tax return shall accompany the filing of the return. All checks shall be made payable to the Iowa Department of Revenue. Failure to pay the tax required to be shown due on the tax return by the due date shall render the tax delinquent.

[ARC 5712C, IAB 6/16/21, effective 7/21/21]

701—70.18(437A) Statute of limitations. Replacement tax rule 701—70.5(437A) is incorporated herein by reference.

701—70.19(437A) Billings.

70.19(1) Notice of adjustments. Replacement tax subrule 70.6(1) is incorporated herein by reference.

70.19(2) Notice of assessment. If, after following the procedure outlined in 70.6(1) "b," no agreement is reached and the person does not pay the amount determined to be correct to the director, a notice of the amount of tax due shall be sent to the taxpayer. This notice of assessment shall bear the signature of the director and will be sent by ordinary mail to the taxpayer.

A taxpayer has 60 days from the date of the notice of assessment to file a protest according to the provisions of rule 701—7.8(17A) or, if the taxpayer fails to timely appeal a notice of assessment, the taxpayer may make payment pursuant to rule 701—7.8(17A) to the director and file a refund claim with the director within the applicable period provided in Iowa Code sections 437A.22 and 437A.14(1) "b" for filing such claims.

70.19(3) Supplemental assessments. Replacement tax subrule 70.6(3) is incorporated by reference.
[ARC 0251C, IAB 8/8/12, effective 9/12/12]

701—70.20(437A) Refunds. Replacement tax subrules 70.7(1) to 70.7(3), 70.7(5) and 70.7(7) are incorporated herein by reference.

No credit or refund of taxes alleged to be unconstitutional shall be allowed if such taxes were not paid under written protest which specifies the particulars of the alleged unconstitutionality.

701—70.21(437A) Abatement of tax. The provisions of rule 701—7.31(421) are applicable to the statewide property tax.

[ARC 0251C, IAB 8/8/12, effective 9/12/12]

701—70.22(437A) Taxpayers required to keep records.

70.22(1) Records required. The records required in this rule must be made available for examination upon request by the director or the director's authorized representative. The records must include all of those which would support the entries required to be made on the tax return. These records include but are not limited to:

- a. Records associated with the assessed value and base year assessed value of property subject to the statewide property tax.
- b. Records associated with the computation of the statewide property tax required to be shown due on the tax return.
- c. Records associated with the book value of the local amount of any major addition by local taxing district.
- d. Records associated with the book value of the statewide amount of any major addition.
- e. Records associated with the transfer or disposal of all operating property in the preceding calendar year, by local taxing district.
- f. Records associated with the book value of all other taxpayer property subject to the statewide property tax.
- g. Records associated with the book value of any major addition, by situs, eligible for the urban revitalization exemption provided for in Iowa Code chapter 404.
- h. All work papers associated with any of the records described in this rule.
- i. Records associated with allocation of property subject to statewide property tax among local taxing districts.

70.22(2) The records required to be maintained by these rules shall be maintained by taxpayers for a period of ten years following the later of the original due date for the filing of a tax return in which the statewide property tax is reported, or the date on which such return is filed. Upon application to the director and for good cause shown, the director may shorten the period for which any records should be maintained by a taxpayer.

701—70.23(437A) Credentials. Replacement tax rule 701—70.10(437A) is incorporated herein by reference.

701—70.24(437A) Audit of records. Replacement tax rule 701—70.11(437A) is incorporated herein by reference.

These rules are intended to implement Iowa Code chapter 437A as amended by 2007 Iowa Acts, Senate File 278.

[Filed 9/3/99, Notice 7/28/99—published 9/22/99, effective 10/27/99]

[Filed 9/10/04, Notice 8/4/04—published 9/29/04, effective 11/3/04]

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[Filed ARC 0251C (Notice ARC 0145C, IAB 5/30/12), IAB 8/8/12, effective 9/12/12]

[Filed ARC 1665C (Notice ARC 1590C, IAB 8/20/14), IAB 10/15/14, effective 11/19/14]

[Filed ARC 5712C (Notice ARC 5579C, IAB 4/21/21), IAB 6/16/21, effective 7/21/21]

CHAPTER 78
REPLACEMENT TAX AND STATEWIDE PROPERTY
TAX ON RATE-REGULATED WATER UTILITIES

REPLACEMENT TAX

701—78.1(437B) Who must file return. Beginning with property tax years and replacement tax years beginning on or after January 1, 2013, each taxpayer, as defined in Iowa Code section 437B.2, shall file a true and accurate return with the director. The return shall include all of the information prescribed in Iowa Code sections 437B.4(1) “a” and “b” and any other information or schedules requested by the director. The return shall be signed by an officer or other person duly authorized by the taxpayer and must be certified as correct. If the taxpayer was inactive or ceased the conduct of any activity subject to the replacement tax during the tax year, the return must contain a statement to that effect.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.2(437B) Time and place for filing return. The return must be filed with the director on or before March 31 following the tax year. There is no authority for the director to grant an extension of time to file a return. Therefore, any return which is not filed on or before March 31 following the tax year is untimely.

A taxpayer whose replacement tax liability before credits is \$300 or less is not required to file a return. A taxpayer should not file a replacement tax return under such circumstances.

When the due date falls on a Saturday or Sunday, the return will be due the first business day following the Saturday or Sunday. If a return is placed in the mails, properly addressed and postage paid in ample time to reach the director or the department on or before the due date for filing, no penalty will attach should the return not be received until after the due date for filing. The functional meaning of this requirement is that if the return is placed in the mails, properly addressed and postage paid, on or before the due date for filing, no penalty will attach. Mailed returns should be addressed to Department of Revenue, Attention: Property Tax Division, Hoover State Office Building, Des Moines, Iowa 50319. [ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.3(437B) Form for filing. Returns must be made by taxpayers on forms supplied by the department. Taxpayers not supplied with the proper forms shall make application for proper forms to the department in ample time to have the taxpayers’ returns made, verified and filed on or before the due date. Each taxpayer shall carefully prepare the taxpayer’s return so as to fully and clearly set forth the data required. All information shall be supplied and each direction complied with in the same manner as if the forms were embodied in these rules.

Failure to receive the proper forms does not relieve the taxpayer from the obligation of making the replacement tax return.

Returns received which are not completed, but merely state “see schedule attached,” “no tax due,” or some other conclusionary statement are not considered to be properly filed returns and may be returned to the taxpayer for proper completion. This may result in the imposition of penalties and interest due to the return’s being filed after the due date.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.4(437B) Payment of tax. Payment of tax shall not accompany the filing of the replacement tax return with the director. Payment of tax shall not be made to the director or the state of Iowa. Payment of the proper amount of tax due shall be made to the appropriate county treasurer upon notification by the county treasurer to the taxpayer of the taxpayer’s replacement tax obligation.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.5(437B) Statute of limitations.

78.5(1) The director has three years after a return is filed to determine the tax due if the return is found to be incorrect and to give notice to the taxpayer of the determination. This three-year statute of limitations does not apply in the instances specified in subrule 78.5(2).

78.5(2) If a taxpayer files a false or fraudulent return with the intent to evade any tax, the correct amount of tax due may be determined by the director at any time after the return has been filed.

78.5(3) If a taxpayer fails to file a return, the three-year statute of limitations does not begin until the return is filed with the director.

78.5(4) Waiver of statute of limitations. The department and the taxpayer may extend the three-year period of limitations provided in subrule 78.5(1) above by signing a waiver agreement form provided by the department. The agreement shall designate the period of extension and the tax year for which the extension applies. The agreement shall provide that the taxpayer may file a claim for refund of replacement tax at any time prior to the expiration of the agreement.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.6(437B) Billings.

78.6(1) Notice of adjustments.

a. Authorization to send notice of adjustments. An agent, auditor, clerk, or employee of the department, designated by the director to examine returns and make audits, who discovers discrepancies in returns or learns that items subject to tax may not have been listed or included as taxable, in whole or in part, or that no return was filed when one was due is authorized to notify the taxpayer of this discovery by ordinary mail. This notice is not an assessment. It informs the taxpayer what amount would be due if the information discovered is correct. A copy of such notice shall also be sent to the appropriate county treasurer.

b. Right of taxpayer upon receipt of notice of adjustment. A taxpayer who has received notice of an adjustment in connection with a return may pay the additional amount stated to be due to the appropriate county treasurer. If payment is made, and the taxpayer wishes to contest the matter, the taxpayer should file a timely claim for refund. However, payment will not be required until an assessment has been made, although interest will continue to accrue if timely payment is not made. If no payment has been made, the taxpayer may discuss with the agent, auditor, clerk, or employee who notified the taxpayer of the discrepancy, either in person or through correspondence, all matters of fact and law which may be relevant to the situation. The taxpayer may also ask for a conference with the Department of Revenue, Property Tax Division, Hoover State Office Building, Des Moines, Iowa. Documents and records supporting the taxpayer's position may be required.

c. Power of agent, auditor, or employee to compromise tax claim. No employee of the department has the power to compromise any tax claims. The power of the agent, auditor, clerk, or employee who notified the taxpayer of the discrepancy is limited to the determination of the correct amount of tax.

78.6(2) Notice of assessment. If, after following the procedure outlined in paragraph 78.6(1) "b," no agreement is reached and the taxpayer does not pay the amount determined to be correct to the appropriate county treasurer, a notice of the amount of tax due shall be sent to the taxpayer. This notice of assessment shall bear the signature of the director and will be sent by ordinary mail to the taxpayer with a copy sent to the appropriate county treasurer.

A taxpayer has 60 days from the date of the notice of assessment to file a protest according to the provisions of rule 701—7.8(17A), or if the taxpayer fails to timely appeal a notice of assessment, the taxpayer may make payment pursuant to rule 701—7.8(17A) to the appropriate county treasurer and file a refund claim with the director within the applicable period provided in Iowa Code section 437B.10(1) "b" for filing such claims.

78.6(3) Supplemental assessments and refund adjustments. The director may, at any time within the period prescribed for assessment or refund adjustment, make a supplemental assessment or refund adjustment whenever it is ascertained that any assessment or refund adjustment is imperfect or incomplete in any respect.

If an assessment or refund adjustment is appealed (protested under rule 701—7.8(17A)) and is resolved whether by informal proceedings or by adjudication, the director shall notify the appropriate county treasurer. Such resolution shall preclude the director and the taxpayer from making a supplemental assessment or refund adjustment concerning the same issue involved in the appeal for the same tax year unless there is a showing of mathematical or clerical error or showing of fraud or misrepresentation.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.7(437B) Refunds.

78.7(1) A claim for refund of replacement tax may be made on a form obtainable from the department. All claims for refund should be filed with the director and not with the county treasurer. In the case of a refund claim filed by an agent or representative of the taxpayer, a power of attorney must accompany the claim. All claims for refund must be in writing.

78.7(2) A taxpayer shall not offset a refund or overpayment of tax for one tax year as a prior payment of tax of a subsequent tax year on the tax return of a subsequent year unless the provisions of Iowa Code section 437B.4(5) are applicable.

78.7(3) Refunds—statute of limitations. The statute of limitations with respect to which refunds or credits may be claimed are:

a. The later of three years after the due date of the tax payment upon which the refund or credit is claimed or one year after which such payment was actually made.

b. Ninety days after the due date of the tax payment upon which refund or credit is claimed if the tax is alleged to be unconstitutional.

78.7(4) No credit or refund of taxes alleged to be unconstitutional shall be allowed if such taxes were not paid to the appropriate county treasurer under written protest which specifies the particulars of the alleged unconstitutionality.

78.7(5) The taxpayer responsible for paying the tax, or the taxpayer's successors, are the only persons eligible to file claims for refund or credit of the tax with the director and are the only persons eligible to receive such refunds or credits.

78.7(6) The director will promptly notify the appropriate county treasurer of the acceptance or denial of any refund claim or credit. The county treasurer shall pay the refund claim or portion thereof accepted by the director.

78.7(7) A taxpayer has 60 days from the date of the notice of denial of a refund or credit, in whole or in part, to file a protest according to the provisions of rule 701—7.8(17A).

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.8(437B) Abatement of tax. The provisions of rule 701—7.31(421) are applicable to replacement tax. In the event that the taxpayer files a request for abatement with the director, the appropriate county treasurer shall be notified. The director's decision on the abatement request shall be sent to the taxpayer and the appropriate county treasurer.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.9(437B) Taxpayers required to keep records.

78.9(1) Records required by taxpayers taxed under Iowa Code chapter 437B. The records required in this rule must be made available for examination upon request by the director or the director's authorized representative. The records must include all of those which would support the entries required to be made on the tax return. These records include but are not limited to:

a. Records associated with the total number of gallons of water carried through the taxpayer's distribution system during the tax year and during each of the immediately preceding five calendar years. For calendar years prior to tax year 2013, the total number of gallons of water carried through the taxpayer's distribution system is calculated as though Iowa Code chapter 437B was in effect for such calendar year.

b. Records associated with the total amount of nonrevenue water, as that term is defined in Iowa Code section 437B.2(9), carried through the taxpayer's distribution system during the tax year and during each of the immediately preceding five calendar years. For calendar years prior to tax year 2013, the total number of gallons of nonrevenue water carried through the taxpayer's distribution system is calculated as though Iowa Code chapter 437B was in effect for such calendar year.

c. Records associated with the total taxable gallons of water delivered by the taxpayer to consumers, as that term is defined in Iowa Code section 437B.2(2), within the service area during the tax year and during each of the immediately preceding five calendar years. For calendar years prior to tax year 2013, the total taxable gallons delivered by the taxpayer to consumers by the water utility is the difference between the gallons of water calculated in paragraphs 78.9(1) "a" and "b."

d. For tax years 2013, 2014, and 2015, records associated with property tax amounts due and payable as the result of assessment years 2010 and 2011.

e. Records associated with the taxpayer's calculation of the tentative replacement taxes due for the tax year and required to be shown on the tax return.

f. Records associated with increases or decreases in the tentative replacement tax required to be shown to be due where the replacement delivery tax rates are subject to recalculation under the provisions of Iowa Code section 437B.4(5).

g. All work papers associated with any of the records described in this subrule.

h. Records pertaining to any additions or deletions of property described as exempt from local property tax in Iowa Code section 437B.12.

i. Records associated with allocation of property described in paragraph 78.9(1) "h" above among local taxing districts.

78.9(2) The records required to be maintained by this rule shall be maintained by taxpayers for a period of ten years following the later of the original due date for the filing of a tax return in which the replacement taxes are reported or the date on which such return is filed. Upon application to the director and for good cause shown, the director may shorten the period for which any records should be maintained by a taxpayer.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.10(437B) Credentials. Employees of the department have official credentials, and the taxpayer should require proof of the identity of persons claiming to represent the department. No charges shall be made nor gratuities of any kind accepted by an employee of the department for assistance given in or out of the office of the department.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.11(437B) Audit of records. The director or the director's authorized representative shall have the right to examine or cause to be examined the books, papers, records, memoranda or documents of a taxpayer for the purpose of verifying the correctness of a tax return filed or of information presented or for estimating the tax liability of a taxpayer. When a taxpayer fails or refuses to produce the records for examination upon request, the director shall have authority to require, by a subpoena, the attendance of the taxpayer and any other witness(es) whom the director deems necessary or expedient to examine and compel the taxpayer and witness(es) to produce books, papers, records, memoranda or documents relating in any manner to the replacement tax.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.12(437B) Information confidential. Iowa Code sections 437B.10(2) and 437B.10(3) apply generally to the director, deputies, auditors, and present or former officers and employees of the department. Disclosure of the gallons of water delivered by a taxpayer taxed under Iowa Code chapter 437B in a service area disclosed on a tax return, return information, or investigative or audit information is prohibited. Other persons having acquired this confidential information will be bound by the same

rules of secrecy under these Iowa Code provisions as any member of the department and will be subject to the same penalties for violations as provided by law.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

STATEWIDE PROPERTY TAX

701—78.13(437B) Who must file return. Each taxpayer shall file a true and accurate return with the director. The return shall include all of the information prescribed in Iowa Code section 437B.17 and any other information or schedules requested by the director. The return shall be signed by an officer or other person duly authorized by the taxpayer and must be certified as correct. If the taxpayer was inactive or ceased the conduct of any activity for which the taxpayer's property was subject to the statewide property tax during the tax year, the return must contain a statement to that effect.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.14(437B) Time and place for filing return. The return must be filed with the director on or before March 31 following the tax year. There is no authority for the director to grant an extension of time to file a return. Therefore, any return which is not filed on or before March 31 following the tax year is untimely.

When the due date falls on a Saturday or Sunday, the return will be due the first business day following the Saturday or Sunday. If a return is placed in the mails, properly addressed and postage paid in ample time to reach the director or the department on or before the due date for filing, no penalty will attach should the return not be received until after that date. The functional meaning of this requirement is that if the return is placed in the mails, properly addressed and postage paid, on or before the due date for filing, no penalty will attach. Mailed returns should be addressed to Department of Revenue, Attention: Property Tax Division, Hoover State Office Building, Des Moines, Iowa 50319.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.15(437B) Form for filing. Rule 701—78.3(437B) is incorporated herein by reference.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.16(437B) Payment of tax. Payment of the tax required to be shown due on the statewide property tax return shall accompany the filing of the return. All checks shall be made payable to the Iowa Department of Revenue. Failure to pay the tax required to be shown due on the tax return by the due date shall render the tax delinquent.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16; ARC 5712C, IAB 6/16/21, effective 7/21/21]

701—78.17(437B) Statute of limitations. Rule 701—78.5(437B) is incorporated herein by reference.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.18(437B) Billings.

78.18(1) Notice of adjustments. Subrule 78.6(1) is incorporated herein by reference.

78.18(2) Notice of assessment. If, after following the procedure outlined in paragraph 78.6(1) "b," no agreement is reached and the person does not pay the amount determined to be correct to the director, a notice of the amount of tax due shall be sent to the taxpayer. This notice of assessment shall bear the signature of the director and will be sent by ordinary mail to the taxpayer.

A taxpayer has 60 days from the date of the notice of assessment to file a protest according to the provisions of rule 701—7.8(17A), or if the taxpayer fails to timely appeal a notice of assessment, the taxpayer may make payment pursuant to rule 701—7.8(17A) to the director and file a refund claim with the director within the applicable period provided in Iowa Code sections 437B.10 and 437B.18 for filing such claims.

78.18(3) Supplemental assessments. Subrule 78.6(3) is incorporated herein by reference.
[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.19(437B) Refunds. Subrules 78.7(1) to 78.7(3), 78.7(5) and 78.7(7) are incorporated herein by reference.

No credit or refund of taxes alleged to be unconstitutional shall be allowed if such taxes were not paid under written protest which specifies the particulars of the alleged unconstitutionality.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.20(437B) Abatement of tax. The provisions of rule 701—7.31(421) are applicable to the statewide property tax.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.21(437B) Taxpayers required to keep records.

78.21(1) Records required. The records required in this rule must be made available for examination upon request by the director or the director's authorized representative. The records must include all of those which would support the entries required to be made on the tax return. These records include but are not limited to:

a. Records associated with the assessed value and base year assessed value of property subject to the statewide property tax.

b. Records associated with the computation of the statewide property tax required to be shown due on the tax return.

c. Records associated with the book value of the local amount of any major addition by the local taxing district.

d. Records associated with the book value of the statewide amount of any major addition.

e. Records associated with the transfer or disposal of all operating property, as that term is defined in Iowa Code section 437B.2(10), in the preceding calendar year, by local taxing district.

f. Records associated with the book value of all other taxpayer property subject to the statewide property tax.

g. Records associated with the book value of any major addition, by situs, eligible for the urban revitalization exemption provided for in Iowa Code chapter 404.

h. All work papers associated with any of the records described in this rule.

i. Records associated with allocation of property subject to statewide property tax among local taxing districts.

78.21(2) The records required to be maintained by these rules shall be maintained by taxpayers for a period of ten years following the later of the original due date for the filing of a tax return in which the statewide property tax is reported or the date on which such return is filed. Upon application to the director and for good cause shown, the director may shorten the period for which any records should be maintained by a taxpayer.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.22(437B) Credentials. Rule 701—78.10(437B) is incorporated herein by reference.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

701—78.23(437B) Audit of records. Rule 701—78.11(437B) is incorporated herein by reference.

[ARC 0965C, IAB 8/21/13, effective 8/2/13; ARC 1105C, IAB 10/16/13, effective 11/20/13; ARC 2696C, IAB 8/31/16, effective 10/5/16]

These rules are intended to implement Iowa Code chapter 437B.

[Filed Emergency ARC 0965C, IAB 8/21/13, effective 8/2/13]

[Filed ARC 1105C (Notice ARC 0966C, IAB 8/21/13), IAB 10/16/13, effective 11/20/13]

[Filed ARC 2696C (Notice ARC 2574C, IAB 6/8/16), IAB 8/31/16, effective 10/5/16]

[Filed ARC 5712C (Notice ARC 5579C, IAB 4/21/21), IAB 6/16/21, effective 7/21/21]

CHAPTER 82
CIGARETTE TAX AND REGULATION OF DELIVERY SALES OF ALTERNATIVE NICOTINE
PRODUCTS OR VAPOR PRODUCTS

[Prior to 12/17/86, Revenue Department[730]]

701—82.1(453A) Permits required. Every person selling or distributing cigarettes or using or consuming untaxed cigarettes within the state of Iowa must first obtain the appropriate permit.

82.1(1) Distributor's permit. Every person acting as a distributor as defined in Iowa Code section 453A.1 must obtain a permit from the department. A distributor is any person who obtains unstamped cigarettes within or without this state by manufacture, production, import or by any means for the purpose of making the first intrastate sale or distribution or the first use or consumption in Iowa. Every distributor holding a distributor's permit will cause to be affixed, within or without Iowa, all cigarette tax stamps or meter impressions as set forth in rule 701—82.8(453A) and Iowa Code section 453A.10. The distributor permit expires annually on June 30, and costs \$100. A distributor must obtain a duplicate permit for each place of business owned or operated by the distributor from which distributor activities are carried on. Duplicate distributor permits may be obtained from the department at an annual cost of \$5 for each duplicate permit. A distributor may act as a wholesaler without obtaining a wholesaler's permit, but a wholesaler's permit may be obtained upon meeting all of the requirements for the issuance of a wholesaler's permit. If a distributor performs any other function which requires a permit, a separate permit must be obtained. If a person is not performing the functions of a distributor, a permit will not be issued.

82.1(2) Wholesaler's permit. Every person acting as a wholesaler as defined in Iowa Code section 453A.1 must obtain a wholesaler's permit. A wholesaler is any person, other than a distributor or a distributing agent, who sells or distributes cigarettes within Iowa for resale. A "sale or distribution" of cigarettes connotes a transfer of cigarettes from one person or entity to another person or entity. *Union Oil Co. of California v. State*, 2 Wash. 2d 436, 98 P, 2d 660 (1940); *State v. Nash Johnson and Sons' Farms Inc.*, 263 N.C. 66, 138 S.E. 2d 773 (1964). Therefore, an intraentity transfer is not a transaction which qualifies as a function of a wholesaler. The wholesaler permit expires annually on June 30, and costs \$100 annually. A wholesaler must obtain a duplicate permit for each place of business owned or operated by the wholesaler from which wholesale activities are carried on. Duplicate wholesaler permits may be obtained from the department at an annual cost of \$5 for each duplicate permit. If a person is not performing the functions of a wholesaler, a permit will not be issued.

The following example will illustrate the application of this subrule:

The XYZ Grocery Chain has a warehouse in Des Moines where stamped cigarettes are stored. The stamped cigarettes are purchased from a permitted distributor. XYZ transfers the cigarettes to its retail outlets across the state for the purpose of making retail sales, and makes no other sales. The storage of stamped cigarettes and the retail sale of cigarettes are not functions of a wholesaler, and XYZ would not be eligible for a wholesaler's permit.

82.1(3) Cigarette vendor's permit. Every person acting as a cigarette vendor as defined in Iowa Code section 453A.1 must obtain a permit from the department. A cigarette vendor is any person who takes responsibility for furnishing, installing, servicing, operating or maintaining one or more vending machines for the purpose of selling cigarettes at retail, and does so by reason of ownership, agreement or contract.

A retailer who holds a retail permit is not required to get a cigarette vendor's permit if the retail permittee is, in fact, the owner of the cigarette vending machine(s) which is operated in the location described in the retail permit. The cigarette vendor's permit expires annually on June 30, and costs \$100 annually. A cigarette vendor must have a duplicate permit for each place of business from which cigarette vending machines are furnished, installed or serviced. A duplicate permit can be obtained from the department for an annual cost of \$5. The duplicate permit applies to additional places of business from which the cigarette vendor conducts operations and not to those places of business where the cigarette vending machines are installed for retail sales.

EXAMPLE: A cigarette vendor owns three warehouses from which the vendor supplies cigarettes to 100 vending machines located at various retail establishments. The total permit cost for the vendor would be \$110 (\$100 for a regular permit plus \$10 for two duplicate permits at \$5 each).

82.1(4) *Railway retail permit.* A retail permit may be issued to a railway dining car company, railway sleeping car company, railroad or a railway company. A retailer's permit for railway cars is issued by the department for an annual cost of \$25 and expires on June 30 of each year. A duplicate permit is required for each car in which cigarettes are stored for sale or sold and each duplicate permit is issued by the department at an annual cost of \$2.

82.1(5) *Manufacturer's permit.* Any manufacturer, as defined in Iowa Code section 453A.1, may obtain a manufacturer's permit from the department. A manufacturer is any person who ships cigarettes into this state from outside the state. The permit is issued without cost and is valid until revoked or canceled. The permit allows the manufacturer to purchase tax stamps from the department and to affix such stamps to cigarettes outside of this state prior to their shipment into the state. A manufacturer is required to affix stamps to cigarettes prior to their shipment into this state unless the cigarettes are shipped to an Iowa permitted distributor or an Iowa permitted distributor's agent.

82.1(6) *Distributing agent's permit.* Every person acting as a distributing agent as defined in Iowa Code section 453A.1 must obtain a permit from the department. A distributing agent is any person in this state who acts as an agent of any manufacturer outside of the state by storing cigarettes received in interstate commerce from such manufacturer subject to distribution or delivery to distributors upon orders received from the manufacturer in interstate commerce and transmitted to such distributing agent for fulfillment from such storage place. The distributing agent's permit is issued by the department at an annual cost of \$100 and expires on June 30 of each year. A separate permit at the \$100 cost must be obtained for each place of business owned or operated within the state by the distributing agent. The permit authorizes the distributing agent to store unstamped cigarettes which are received in interstate commerce for distribution or delivery to distributors upon orders received from outside this state or to be sold outside this state. Stocks of cigarettes held for interstate and intrastate commerce must be kept separate.

82.1(7) *Retailer's permit.*

a. In general. Every person acting as a retailer, as defined in Iowa Code section 453A.1, must obtain a permit. A retailer is any person who:

- (1) Directly sells, distributes or offers for sale cigarettes for consumption, or
- (2) Possesses cigarettes for direct sale for consumption.

Retail permits are issued by the following authorities at the following prices:

1. Within unincorporated areas of a county, by the county board of supervisors at an annual cost of \$50.
2. Within the city limits of a city of less than 15,000 population, by the city council, at an annual cost of \$75.
3. Within the city limits of a city equal to or greater than 15,000 population, by the city council, at an annual cost of \$100.

The retail permit expires on June 30 of each year. A renewal sticker furnished by the department containing the appropriate year and number may be issued in lieu of a new permit where the place of business of the retail permit holder has remained the same. The retail permit is valid only for the location described in the permit, and a retailer must obtain a separate permit for each place of business owned or operated by the retailer. (See subrule 82.2(3))

The power to grant the retail permit is discretionary with the city council or board of supervisors, and uniform, nondiscriminatory limits may be placed on its issuance. *Bernstein v. City of Marshalltown*, 215 Iowa 1168, 248 N.W. 26 (1933); *Ford Hopkins Co. v. City of Iowa City*, 216 Iowa 1286, 248 N.W. 668 (1933); 1938 O.A.G. 708. The city or county must submit a copy of any retail permit issued and the application for the permit to the department of public health within 30 days of issuance.

b. Mobile retailer. If a cigarette retailer sells cigarettes from a mobile concession vehicle, the vehicle itself shall be considered a place of business. A city has the discretionary power to grant a retail cigarette permit to a place of business located within the corporate limits of that city. A county

has the discretionary power to grant a retail cigarette permit to a place of business located within the unincorporated areas of the county. If a retailer is selling cigarettes from a mobile concession vehicle within the area of several permit-issuing authorities, the retailer must obtain a permit from each authority. The retailer is operating a single place of business within the jurisdiction of the several authorities and is, therefore, subject to regulation by each.

The location described on the permit shall include identification of the vehicle and the address of the permanent place of business from which the vehicle is dispatched. If the vehicle is traded in for a new vehicle, the exchange provisions of subrule 82.2(3) shall apply.

This rule is intended to implement Iowa Code section 453A.13 as amended by 2000 Iowa Acts, Senate File 2366, and sections 453A.16, 453A.17, and 453A.23.

701—82.2(453A) Partial year permits—payment—refund—exchange. For purposes of this rule, “year” means the cigarette tax year running from July 1 of year A to June 30 of year B and “quarter” means a yearly quarter with the first quarter commencing on July 1.

82.2(1) Partial payment. If any permit is granted other than in the first quarter, the following partial payments are required:

1. During the second quarter - 75 percent of the permit fee.
2. During the third quarter - 50 percent of the permit fee.
3. During the fourth quarter - 25 percent of the permit fee.

82.2(2) Partial refund. If any unrevoked permit for which the entire annual fee has been paid is voluntarily surrendered, the following permit fees will be refunded:

1. During the first quarter - 75 percent of the permit fee.
2. During the second quarter - 50 percent of the permit fee.
3. During the third quarter - 25 percent of the permit fee.

If any unrevoked permit for which 75 percent of the annual fee has been paid is voluntarily surrendered, the following permit fees will be refunded by the entity which issued the permit:

1. During the second quarter - 50 percent of the permit fee.
2. During the third quarter - 25 percent of the permit fee.

If any unrevoked permit for which 50 percent of the annual fee has been paid is voluntarily surrendered, the following permit fees will be refunded:

During the third quarter - 25 percent of the annual fee.

82.2(3) Exchange of permits. If a permittee changes the location of an operation requiring a permit but remains within the jurisdiction of the same entity which granted the original permit, the permittee may exchange the invalid permit (valid only for the location described in the permit) for a valid permit free of charge, without the partial payment-partial refund process. (1934 O.A.G. 106)

The following nonexclusive examples will illustrate the application of this rule:

EXAMPLE 1: City Bar and Grill sells cigarettes at retail and has obtained a retail cigarette permit from the city of Des Moines. The establishment is moved across the street but remains within the city limits of Des Moines. The retail permit is valid only for the location described in the permit, and therefore, the original permit is no longer valid. However, since the establishment has remained within the jurisdiction of the entity which granted the original permit, Des Moines, the original, presently invalid permit may be exchanged for a valid permit with a new location description at no cost.

EXAMPLE 2: Same as Example 1, except the new location of City Bar and Grill is outside the corporate limits of Des Moines and within the unincorporated area of Polk County. City Bar and Grill would have to surrender the old permit to the city of Des Moines and obtain a new permit from Polk County with the schedules set forth in this rule applying.

This rule is intended to implement Iowa Code section 453A.13, subsections 3 and 4.

701—82.3(453A) Bond requirements. The amount of the bond required for each permit shall be as follows:

1. Distributor permit - \$2,500
2. Wholesaler permit - \$2,500

3. Vendor permit - \$1,000
4. Railway car retail permit - \$500
5. Manufacturer permit - \$5,000
6. Distributing agent permit - \$2,500
7. Retail permit - \$0-
8. Nonpermittee storing interstate cigarettes - \$5,000

If a person is required to obtain more than one type of permit, the bond requirements shall be cumulative and additional bonds or a single bond equal to the total aggregate requirements must be obtained. (See rule 701—81.7(453A) for the required form of the bond.)

This rule is intended to implement Iowa Code sections 453A.14, 453A.17 and 453A.23.

701—82.4(453A) Cigarette tax—attachment—exemption—exclusivity of tax.

82.4(1) Tax. See Iowa Code section 453A.6 for the rate of tax imposed on cigarettes.

82.4(2) Attachment. The tax is imposed when the cigarettes are received by any person in Iowa for the purpose of making a “first sale” of the cigarettes (as defined in Iowa Code section 453A.1). If the tax is not paid by the person making the first sale, it must be paid by any person into whose possession such cigarettes come until the tax has been paid, the tax to be paid only once. The fact that the tax is eventually paid will not relieve the person’s standing prior in the chain of distribution of the sanctions for distributing untaxed cigarettes if the tax should have been paid sooner by said person.

The tax must be added to the selling price of every package of cigarettes so that the ultimate consumer bears the burden of the tax.

82.4(3) Exemption. If all of the following conditions are met, the Iowa cigarette tax need not be paid:

- a. The cigarettes are imported on or about the person claiming the exemption,
- b. The total quantity of cigarettes so imported is equal to or less than 40,
- c. The seal of the individual cigarette package has been broken, and
- d. The cigarettes are actually used by the person so importing and are not sold or offered for sale.

82.4(4) Exclusivity of tax. No other occupation or excise tax may be imposed by any political subdivision of the state. However, this provision does not apply to occupation or excise taxes imposed by the state.

82.4(5) Sales exempt from tax. Sales of cigarettes which the state is prohibited from taxing under the Constitution or the laws of the United States or under the Constitution of this state are exempt from the tax. If the sale is exempt from the tax, stamps must not be attached. No refund will be issued for stamps which are attached to cigarette packages which are later sold exempt.

a. *Sales to the federal government.* Military post exchanges or instrumentalities of the federal government are not required to comply with the provisions of Iowa Code chapter 453A nor pay the tax imposed thereunder. However, individuals who have purchased or obtained cigarettes from a federal instrumentality and come within the jurisdiction of the state, are subject to the provisions of Iowa Code sections 453A.6(2), 453A.36(1) and 453A.37. *U.S. v. Tax Commission of Mississippi*, 421 U.S. 599, 44 L.Ed. 2d 404, 95 S.Ct. 1872 (1975).

b. *Sales by or to Indians.* Sales by Indians to other Indians of their own tribe on federally recognized Indian reservations or settlements of which they are tribal members are exempt from the tax. The Indian sellers are subject to the record-keeping requirements of Iowa Code chapter 453A. The cigarettes must be purchased by the Indian seller with the tax included in the purchase price. The tax exemption is allowed to the Indian purchaser by the purchaser’s filing a claim for refund of the tax paid or to the tribe of which the Indian purchaser is a member by the tribe’s filing a claim for refund of the tax paid by the tribe on cigarettes sold to the Indian purchaser.

This rule is intended to implement Iowa Code section 453A.6 as amended by 1999 Iowa Acts, chapter 151.

701—82.5(453A) Cigarette tax stamps.

82.5(1) In general. To evidence the payment of the cigarette tax, cigarette stamps must be securely affixed to the individual cigarette containers. The stamps shall be provided by the director, and either

sold directly to a distributor or a manufacturer holding a valid distributor's or manufacturer's permit or through authorized banks, as defined in Iowa Code section 524.103 to these same permittees. The possession of unstamped cigarettes by persons not authorized to possess unstamped cigarettes shall be prima facie evidence of the nonpayment of the tax. The penalty for possession of unstamped cigarettes is set forth in Iowa Code section 453A.31(1) as amended by 1999 Iowa Acts, chapter 151, section 81. Any person in possession of unstamped cigarettes must pay the tax directly to the department. If sales of cigarettes exceed the purchase of cigarette stamps by persons authorized and responsible to affix stamps, there is established a rebuttable presumption that the excess cigarettes were sold without the tax stamps affixed thereto.

82.5(2) *Purchase of stamps from the department.* Stamps may be purchased from the department and from authorized banks in unbroken rolls of 30,000 stamps, or other quantities authorized by the director. The stamps may be purchased only by persons holding an unrevoked distributor's permit or an unrevoked manufacturer's permit.

When cigarette stamps are purchased from the department, orders shall be sent directly to the department on a form prescribed by and available upon request from the department. The order must be accompanied by a remittance payable to the Iowa Department of Revenue in the amount of the face value of the stamps less any discount as provided in rule 701—82.7(453A). The stamps shall be sent to the purchaser through the United States Postal Service by registered mail or similar delivery service at the department's expense. The purchaser may request alternate methods of transmission, but such methods shall be at the expense of the purchaser. Regardless of the method used to send the stamps, title transfers to the purchaser at the time the department delivers the stamps to the carrier.

82.5(3) *Purchase of stamps from authorized bank.* The purchase of stamps from an authorized bank must be made by the distributor or manufacturer or the distributor's or manufacturer's representative. The permittee shall furnish the bank with a requisition form prescribed by the department along with payment for the full price of the stamps less any discount as provided in rule 701—82.7(453A). The director may require such payments to be by cashier's check or certified check as to any individual distributor or manufacturer. The authorized bank shall be notified in writing by the department of any such requirement. Distributors or manufacturers who elect to purchase stamps from authorized banks shall advise the department in writing of the authorized bank so elected. The distributor or manufacturer may not purchase from any other bank other than the one so selected, but may still purchase stamps directly from the department. See rule 701—82.6(453A) for restrictions on authorized banks as to the sale of stamps. Also see rule 701—82.11(453A) relating to refunds.

This rule is intended to implement Iowa Code sections 453A.6, 453A.8, and 453A.28 as amended by 1999 Iowa Acts, chapter 151, and Iowa Code sections 453A.7, 453A.10, 453A.12, and 453A.35.
[ARC 5712C, IAB 6/16/21, effective 7/21/21]

701—82.6(453A) Banks authorized to sell stamps—requirements—restrictions.

82.6(1) *Authorization.* The director has the discretion to allow the sale or distribution of stamps through authorized banks as defined in Iowa Code section 524.103. The authorization of a bank to sell stamps is not a mandatory direction, but may be utilized by the director to enhance the efficiency of the tax stamp distribution system. Some of the factors the director will consider in determining whether or not to authorize a bank to sell stamps are:

- a. Geographical location in relation to distributors or manufacturers requesting alternative purchase locations,
- b. The anticipated volume of stamps to be purchased by the requesting distributors or manufacturers,
- c. Access to transportation systems, and
- d. Prior experience with the bank.

82.6(2) *Sale of stamps.* An authorized bank may sell cigarette stamps only to distributors or manufacturers holding valid permits who have "elected" (as per subrule 82.5(3)) to purchase stamps from that bank. The department shall furnish each bank with a list of all such distributors or manufacturers who have so elected, and the bank shall not sell stamps to persons not on the list. The

bank must receive payment in full, less the discount, before selling stamps. See rule 82.7(453A). A bank is not authorized to accept credit memorandums from distributors or manufacturers.

82.6(3) *Stamp inventory.* Each bank shall keep an adequate inventory of stamps on hand to supply distributors or manufacturers assigned to said bank for at least six weeks. Stamps will be shipped freight prepaid to the bank from the department or from the supplier of the stamps. The supplier of the stamps shall advise the department at once by mail of a shipment to a bank and the bank shall advise the department at once by mail of the receipt of the stamps. Each bank shall store stamps in a secure vault.

82.6(4) *Reports and remittances.* Each bank authorized to sell stamps shall forward to the department the invoices, requisitions, and remittances for stamps sold on a daily basis. Each bank shall forward to the department, on the first working day of each month, an inventory report which shall minimally include as to the prior month: the quantity of stamps on hand at the beginning of the month, the quantity of stamps received during the month, the quantity of stamps sold as to each distributor or manufacturer, the quantity of stamps on hand at the end of the month and the signature of the person responsible for the stamps.

82.6(5) *Audit.* For the purpose of auditing for the end of the fiscal year, no bank shall sell cigarette stamps on the days from June 25 to June 30. With or without notice, the department or a representative designated by the department may take an inventory of stamps and audit stamp sales.

Each bank must retain all records of inventory, stamp receipts, and stamp sales for a period of three years.

82.6(6) *Termination of authorization.* The director may terminate the authorization of a bank to sell stamps if the bank has failed to comply with the provisions of this rule or Iowa Code chapter 453A, or if the director deems it desirable for the efficient distribution of stamps. Notice of termination shall be sent to the bank by certified mail. The bank may appeal the termination determination by filing a protest pursuant to 701—Chapter 7 within 30 days of notice of termination. A bank may voluntarily terminate the sale of stamps by giving the department 90 days' written notice. Upon termination, the bank must immediately return all stamps and present a final accounting, along with any remittances, to the department.

This rule is intended to implement Iowa Code sections 453A.8, 453A.12, and 453A.25.

701—82.7(453A) *Purchase of cigarette tax stamps—discount.* Upon the purchase of cigarette tax stamps, the distributor or manufacturer shall be entitled to a discount of 2 percent from the face value of the stamps.

This rule is intended to implement Iowa Code section 453A.8.

701—82.8(453A) *Affixing stamps.* Every package of cigarettes received in this state by a permitted distributor or for distribution within or without the state of Iowa must be stamped within 48 hours of its receipt, unless the distributor is also permitted as and is acting as a distributing agent. The cigarettes held by a person acting as a distributor and those held by the same person who is also acting as a distributing agent must be kept separate, and if not, the entire inventory will be subject to the 48-hour limitation. The 48-hour period shall be exclusive of Sundays and legal holidays. (See 1958 O.A.G. 25.)

This rule is intended to implement Iowa Code sections 453A.10 and 453A.17.

701—82.9(453A) *Reports.* Every person permitted as a cigarette distributor or manufacturer, or any other person as deemed necessary by the director, must file a monthly report on or before the tenth day of the month following the month for which the report is made. The report must be complete and certified by the person responsible for filling out the report. The failure to file a report or the filing of a false or incomplete report shall subject the person to a penalty as set forth in Iowa Code section 453A.31. (See rule 701—10.76(453A).) The report must be so certified or the report shall be considered incomplete. Whenever “cigarette” is used in this rule, it shall also include taxable “little cigars.”

82.9(1) *In-state distributors not exporting cigarettes.* Every distributor with a place of business in Iowa where cigarettes are stamped and who is not engaged in exporting cigarettes from this state shall

file Forms 70-017 (Monthly Cigarette Tax Report) and 70-020 (Self Audit Report). The two forms are considered a multipart report and both forms must be completed before the report will be considered “filed.”

- a. The Monthly Cigarette Tax Report shall include, but not be limited to:
 1. The distributor’s name, permit number and address;
 2. The amount of Iowa revenue purchased during the month;
 3. The quantity of cigarettes on hand at the end of the month;
 4. The amount of revenue on hand at the end of the month;
 5. Purchases of cigarettes during the month and as to each purchase, the seller’s name, the date of purchase, the invoice number, and the quantity purchased;
 6. An inventory report as to out-of-state revenue;
 7. The quantity of cigarettes returned to the factory along with supporting documents; and
 8. The certification of the person responsible for making the report.
- b. The Self Audit Report shall include, but not be limited to:
 1. The distributor’s name, permit number and address;
 2. An inventory accounting for cigarettes; and
 3. An inventory accounting for revenue.

The quantity of cigarettes distributed or stamped should be equal to the tax equivalent of the revenue used. Any discrepancy must be adequately explained.

82.9(2) *In-state distributors exporting cigarettes.* Every distributor with a place of business in Iowa where cigarettes are stamped who also engages in exporting cigarettes from this state shall file Form 70-017 (Monthly Cigarette Tax Report). This form must be completed before the report will be considered “filed.”

82.9(3) *Out-of-state distributors.* Every distributor stamping cigarettes only without the state shall file Form 70-018 (Monthly Cigarette Tax Report). The Monthly Cigarette Tax Report (Form 70-018) shall include, but not be limited to:

1. The distributor’s name, address and permit number;
2. An itemized statement of Iowa revenue purchased;
3. An inventory accounting of Iowa revenue;
4. A detailed schedule of cigarette distribution in Iowa and as to each distribution, the date, the name of purchaser or receiver, the purchaser’s address and the quantity of cigarettes distributed; and
5. The certification of the person responsible for making the report.

82.9(4) *Manufacturers and other persons.* The monthly reports for manufacturers and other persons shall contain such information as the director deems necessary.

This rule is intended to implement Iowa Code section 453A.15 as amended by 1999 Iowa Acts, chapter 151.

701—82.10(453A) Manufacturer’s samples.

82.10(1) Iowa Code section 453A.39 provides a method for manufacturers to distribute free sample packages of cigarettes or little cigars. This method is to be followed to the exclusion of all others. (See 1982 O.A.G. #710.)

The cigarettes or little cigars must:

- a. Rescinded IAB 1/22/92, effective 2/26/92.
- b. Be sent to a permitted distributor.
- c. Rescinded IAB 1/22/92, effective 2/26/92.
- d. Have tax paid thereon by a distributor.
- e. Be clearly marked “sample.”
- f. Contain acknowledgment of tax being paid on each carton containing free samples.

The manufacturer must notify the department by affidavit of shipment and the distributor must notify the department by affidavit of receipt and separately remit the tax. The tax must be computed on a per cigarette basis rather than a per package basis.

82.10(2) Remittance of tax and acknowledgment of payment. Iowa Code section 453A.39 provides that the tax will be paid by a permitted distributor. The payment of tax should accompany the distributor's affidavit (Form 70-033).

The department will stamp the distributor's affidavit containing the remittance and return a copy of the affidavit to the distributor as the acknowledgment that taxes have been paid on the samples. After receiving the acknowledgment, and before the sample cigarettes are distributed, each distributor is requested to stamp the cartons of free samples with a stamp containing the following information:

IOWA STATE TAX PAID

Distributor's name

Permit number

The department will make every effort to return a copy of the distributor's remittance report on the same day it is received. In the event the distributor needs acknowledgment sooner, the distributor may request that the department acknowledge by telephone and follow up with the affidavit acknowledgment at a later date.

In the event sample cigarettes must be returned to the manufacturer for some reason, a refund of the taxes previously paid will be made to the distributor who actually remitted the tax to the department. The refund will be made in the same manner as for regular cigarettes by the distributor filing the appropriate forms with the department.

82.10(3) Promotions using cigarettes, noncigarettes or coupons. Promotional situations are specifically covered by Iowa Code section 421B.4. A promotional situation as described in section 421B.4 is valid provided it is a promotion scheme complying with the procedural requirements that it be a sale. A sale is defined to "mean and include any transfer for a consideration, exchange, barter, gift, offer for sale and distribution in any manner or by any means whatsoever."

Once a sale has occurred, the gift may be any kind whatsoever.

a. Promotion using cigarettes. If a manufacturer wants to run a promotion where two packs of cigarettes are sold for the price of one, the manufacturer could give the complimentary cigarettes to a distributor to be stamped who would then give them to a retailer who gives the cigarettes away with the purchase of another pack. Provided the distributor is reimbursed for the cost of the tax stamps, there is no violation of Iowa Code chapter 421B, by anyone. The following example illustrates what a manufacturer can do.

EXAMPLE. A manufacturer ships packs of 20, free of charge, to a permitted distributor with instructions to stamp them and send them to retail outlets or deliver them to one of the manufacturer's employees. The manufacturer reimburses the distributor for the cost of stamping the cigarettes. The manufacturer sends or furnishes the retailers instructions and display materials for the retail distribution of the cigarettes. This method of distribution would be proper.

The cost provisions of 421B.4 would not prevent the distribution of cigarettes in this example, since 421B.4 is silent with respect to below cost combination sales by manufacturers. The cost of cigarettes which are sold is controlled by section 421B.2. The cigarettes sold under the "buy one" portion of the promotion will have a cost of the lower of the true invoice or the lowest replacement cost. The cigarettes sold under the "get one free" portion of the promotion and which were obtained free of charge will have no invoice cost to the retailer.

b. Promotions using noncigarette items. A manufacturer wants to give away promotional items with the purchase of cigarettes at the regular price. Since Iowa Code section 421B.4 is silent with respect to below cost combination sales by manufacturers, the practice of the manufacturer providing a gift item such as cigarette lighters through wholesale channels to retailers which will be delivered to the customer at the time of the sale of the cigarettes does not violate chapter 421B. (See 1958 O.A.G. #22.)

c. Coupons. A manufacturer distributes coupons to the general public to allow the purchase of cigarettes at a reduced price. Provided it is the manufacturer who absorbs the entire cost of the reduction in price, there would be no violation of Iowa Code chapter 421B. Coupons which are sent to the final consumer to be redeemed by a retailer who is reimbursed by a manufacturer do not violate chapter 421B. (See 1968 O.A.G. #68.) This would be true even though the coupon represented the full price of the cigarettes.

d. Replacement packages. A manufacturer wants to respond to a customer complaint by replacing a package of 20 cigarettes purchased by the customer with another package of 20 cigarettes. The replacement package must be clearly marked with the following information:

COMPLIMENTARY. NOT FOR SALE. ALL APPLICABLE STATE TAXES PAID.

The manufacturer may pay the tax directly to the department by submitting an affidavit to the department containing the number of replacement packages sent into the state during the previous month, along with the remittance. The number of replacement packages and remittance may be submitted as part of the manufacturer's affidavit required under Iowa Code section 453A.39 (manufacturer's samples).

This rule is intended to implement Iowa Code sections 453A.1, 453A.13, 453A.16, 453A.22, 453A.31, 453A.39 and chapter 421B.

701—82.11(453A) Refund of tax—unused and destroyed stamps.

82.11(1) *Refunds of unused stamps and destroyed stamps.* Refunds shall be issued for unused stamps which are returned to the department for any reason by a person entitled to receive a refund. This includes unused stamps unaffixed at the close of the business day next preceding the effective date of a decrease in the tax rate which are in excess of the unstamped cigarette inventory on hand as of that date. Banks which are authorized to sell stamps or meter settings are not authorized to issue a refund; the stamps must be returned to and a refund will be issued only by the department. This subrule would also cover stamps which are recalled by the director for purposes of effectuating a change of design of the stamps. A refund will also be issued for stamps which have been lost through destruction, since destroyed stamps have not been used. A refund will not be issued for stamps which are lost (misplaced) or stolen, it being the distributor's or manufacturer's responsibility to maintain proper control over cigarette tax stamps. The claim for refund must be supported by proof of the fact of the loss and proof of the quantity of the loss. The claim must be filed within 30 days of the loss.

82.11(2) *Return of used stamps.* Refunds shall be issued for stamps which have been affixed to cigarettes which have become unfit for use or consumption or unsaleable. This refund is available to any permitted distributor or manufacturer upon proof that the cigarettes were returned to the person who manufactured the cigarettes. The proof required shall be an affidavit from the distributor setting forth to whom the cigarettes were returned and verifying that cigarette stamps had been affixed thereto. There must also be included therewith an affidavit from the manufacturer to whom the cigarettes were returned verifying the information.

82.11(3) *Cigarettes which have been destroyed.* The tax shall be returned on cigarettes which have been destroyed after the tax stamps have been affixed, to the person stamping the cigarettes. The person claiming the loss must be able to prove the fact of the loss and quantity of the loss. The claim, accompanied by proof of the loss and proof of the quantity of the loss, must be filed with the department no later than 30 days following the date the loss occurred. The amount of the refund shall be the face value of the stamps less the applicable discount allowed purchasers of tax stamps. This provision does not apply to cigarettes which are lost (misplaced) or stolen.

82.11(4) *Credit in lieu of a refund.* There are no statutory provisions to allow a credit in lieu of a refund of taxes paid for returned or destroyed cigarette stamps.

This rule is intended to implement Iowa Code section 453A.8.

701—82.12(453A) Delivery sales of alternative nicotine products or vapor products. Pursuant to Iowa Code section 453A.47C, Iowa sales and use taxes are imposed on all delivery sales of alternative nicotine products or vapor products within Iowa in accordance with Iowa Code chapter 423.

82.12(1) *Delivery sale permit.* Every person located within or outside of Iowa making a delivery sale of alternative nicotine products or vapor products within Iowa must obtain a delivery sale permit from the department. Iowa Code section 453A.47A shall govern the permit application and fee process.

a. Out-of-state retailers. An out-of-state retailer who has applied and otherwise qualifies for a delivery sale permit shall be issued the permit for the retailer's principal place of business.

b. Permitted sales. The delivery sale permit allows a retailer with such a permit to make delivery sales of alternative nicotine products or vapor products via the Internet, telephone, or mail order into Iowa.

82.12(2) Sales and use tax permit. A retailer holding a delivery sale permit must also have an Iowa sales or use tax permit. A retailer holding a delivery sale permit must collect and remit all Iowa sales and use tax due, including any applicable local option sales tax, on all sales in Iowa.

82.12(3) Bond required. A bond of \$1,000 is required to obtain a delivery sale permit.

82.12(4) Prohibited delivery sales. All delivery sales of cigarettes and tobacco products to consumers in Iowa are prohibited.

82.12(5) Penalties. Permit suspension and revocation and other penalties imposed in Iowa Code sections 453A.22 and 453A.50 shall apply to retailers holding a delivery sale permit.

This rule is intended to implement Iowa Code sections 453A.47A, 453A.47B, and 453A.47C.
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