

CHAPTER 38  
GENERAL PROVISIONS FOR RADIATION MACHINES  
AND RADIOACTIVE MATERIALS

**641—38.1(136C) Purpose and scope.**

**38.1(1)** Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, by-product material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

**38.1(2)** All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of September 15, 2010.

**38.1(3)** The provisions of Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 39 to 45.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

**641—38.2(136C) Definitions.** As used in these rules, these terms have the definitions set forth below and are adopted by reference and included herein for 641—Chapters 39 to 45.

*“Absorbed dose”* means the energy imparted by ionizing radiation per unit mass of irradiated material. It is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The units of absorbed dose are the gray (Gy) and the rad.

*“Absorbed dose rate”* means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

*“Accelerator”* means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, “particle accelerator” is an equivalent term.

*“Accelerator-produced material”* means any material made radioactive by a particle accelerator.

*“Act”* means 1984 Iowa Acts, chapter 1286, relating to regulation of radiation machines and radioactive materials. (Iowa Code chapter 136C)

*“Activity”* means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

*“Adult”* means an individual 18 years of age or older.

*“Agency”* means the Iowa department of public health.

*“Agreement state”* means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954 as amended (73 Stat. 689).

*“Airborne radioactive material”* means any radioactive material dispersed in the air in the form of dusts, fumes, particles, mists, vapors, or gases.

*“Airborne radioactivity area”* means a room, enclosure, or area in which airborne radioactive material (composed wholly or partly of licensed material) exists in concentrations (1) in excess of the derived air concentrations (DACs) specified in Appendix A of 641—Chapter 40; or (2) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

*“Air kerma (K)”* means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing

particles liberated by uncharged ionizing particles in air of mass  $dM$ . The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

*“Air-purifying respirator”* means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

*“Annually”* means at least once every 365 days.

*“As low as is reasonably achievable”* (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

*“Assembler”* means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

*“Assigned protection factor (APF)”* means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

*“Atmosphere-supplying respirator”* means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

*“Background radiation”* means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. “Background radiation” does not include sources of radiation from radioactive materials regulated by the agency.

*“Barrier”* (see “Protective barrier”).

*“Beam axis”* means a line from the source through the centers of the X-ray fields.

*“Beam-limiting device”* means a field defining collimator, integral to the system, which provides a means to restrict the dimensions of the X-ray field or useful beam.

*“Beam monitoring system”* means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

*“Becquerel”* (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

*“Bioassay”* means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, “radiobioassay” is an equivalent term.

*“Bone densitometry unit”* means a medical device which uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

*“Brachytherapy”* means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

*“Brachytherapy source”* means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

*“By-product material”* means:

1. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “by-product material” within this definition;

3. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity or any material that:

- Has been made radioactive by use of a particle accelerator; and
- Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

- The Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat to the public health and safety or the common defense and security similar to the threat posed by a discrete source of radium-226; and

- Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

“*Cabinet radiography*” means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

“*Calendar quarter*” means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method of determining calendar quarters for purposes of these rules except at the beginning of a year.

“*Calibration*” means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

“*Carrier*” means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

“*CFR*” means Code of Federal Regulations.

“*Changeable filters*” means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

“*Collective dose*” means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

“*Committed dose equivalent*” ( $H_{T,50}$ ) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

“*Committed effective dose equivalent*” ( $H_{E,50}$ ) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ( $H_{E,50} = \sum w_T H_{T,50}$ ).

“*Consignment*” means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

“*Consortium*” means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a federal facility or a medical facility.

“*Constraint*” or “*dose constraint*” means a value above which specified licensee actions are required.

“*Controlled area*” means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

“*Critical group*” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

“*Curie*” means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7E+10$  transformations per second (tps).

“*Decay-in-storage*” means the holding of radioactive material having half-lives of less than 65 days, except Cobalt-57, until it decays to background levels. Before disposal in ordinary trash, the material must have been held for a minimum of ten half-lives and its radioactivity is indistinguishable from background as indicated by a survey meter set on its most sensitive scale with no interposing shielding.

“*Decommission*” means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license; or
2. Release of the property under restricted conditions and termination of the license.

“*Deep dose equivalent*” ( $H_d$ ), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ( $1000 \text{ mg/cm}^2$ ).

“*Demand respirator*” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

“*Depleted uranium*” means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

“*Detector*” (see “Radiation detector”).

“*Diagnostic clinical procedures manual*” means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

“*Diagnostic imaging system*” means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.

“*Diagnostic X-ray imaging system*” means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image which are designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

“*Direct supervision*” means guidance and instruction by a qualified individual who is physically present and watching the performance of the radiological operation or procedure and in such proximity that contact can be maintained and immediate assistance can be given as required.

“*Discrete source*” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

“*Disposable respirator*” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

“*Distinguishable from background*” means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

“*Dose*” is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, “radiation dose” is an equivalent term.

“*Dose equivalent ( $H_T$ )*” means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

“*Dose limits*” means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, “limits” is an equivalent term.

“*Effective dose equivalent ( $H_E$ )*” means the sum of the products of the dose equivalent to each organ or tissue ( $H_T$ ) and the weighting factor ( $w_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum w_T H_T$ ).

“*Embryo/fetus*” means the developing human organism from conception until the time of birth.

“*Entrance or access point*” means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

“*Exposure*” means being exposed to ionizing radiation or to radioactive material.

“*Exposure*” means the quotient of dQ by dm where “dQ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “dm” are completely stopped in air. (The special unit of exposure is the roentgen (R) (see 38.2(136C) for SI equivalent coulomb per kilogram). When not underlined as above or when indicated as ‘exposure’ or (X), the term “exposure” has a more general meaning in these rules.

“*Exposure rate*” means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

“*External dose*” means that portion of the dose equivalent received from any source of radiation outside the body.

“*Extremity*” means hand, elbow, arm below the elbow, foot, knee, and leg below the knee. See 641—subrule 42.1(2) for definitions of “lower extremities” and “upper extremities” for purposes of certification standards.

“*Facility*” means the location, building, vehicle, or complex under one administrative control, at which radioactive material is stored or used or at which one or more radiation machines are installed, located or used.

“*Filtering facepiece (dust mask)*” means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, which is not equipped with elastomeric sealing surfaces and adjustable straps.

“*Fit factor*” means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

“*Fit test*” means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

“*Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities*” means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

“*Generally applicable environmental radiation standards*” means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

“*Gray (Gy)*” means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (1 Gy=100 rad).

“*Half-value layer (HVL)*” 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-half of the value measured without the material at the same point. The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

“*Hazardous waste*” means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

“*Healing arts*” means the occupational fields of diagnosing or treating disease, providing health care and improving health by the practice of medicine, osteopathy, chiropractic, podiatry, dentistry, nursing, veterinary medicine, and supporting professions, such as physician assistants, nurse practitioners, radiologic technologists, and dental hygienists.

“*Helmet*” means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

“*High dose-rate remote afterloader*” means a brachytherapy device that remotely delivers a dose rate in excess of 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

“*High-level radioactive waste*” or “*HLW*” means (1) irradiated reactor fuel; (2) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel; and (3) solids into which such liquid wastes have been converted.

“*High radiation area*” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual’s receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

“*Highway route controlled quantity*” means a quantity within a single package which exceeds:

1. 3,000 times the  $A_1$  value of the radionuclides as specified in 49 CFR 173.435 for special form Class 7 (radioactive) material;
2. 3,000 times the  $A_2$  value of the radionuclides as specified in 49 CFR 173.435 for normal form Class 7 (radioactive) material; or
3. 1,000 TBq (27,000 Ci), whichever is least.

“*Hood*” means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

“*Human use*” means the internal or external administration of radiation or radioactive material to human beings.

“*Individual*” means any human being.

“*Individual monitoring*” means the assessment of:

1. Dose equivalent by the use of devices designed to be worn by an individual or by the use of survey data; or
2. Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. See the definition of DAC-hours in 641—Chapter 40.

“*Individual monitoring devices*” means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, “personnel dosimeter” and “dosimeter” are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescent (OSL) devices, and personal air sampling devices.

“*Industrial radiography*” means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

“*Inspection*” means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

“*Instrument traceability*” means, for ionizing radiation measurements, the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be from a laboratory accredited by a program which required continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

“*Interlock*” means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

“*Internal dose*” means that portion of the dose equivalent received from radioactive material taken into the body.

*“Ionizing radiation.”* See “Radiation.”

*“Irradiation”* means the exposure of a living being or matter to ionizing radiation.

*“Kilovolt (kV)(kilo electron volt (keV))”* means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum.

*“Lead equivalent”* means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

*“Leakage radiation”* means radiation emanating from the diagnostic or therapeutic source assembly except for:

1. The useful beam, and
2. Radiation produced when the exposure switch or timer is not activated.

*“Lens dose equivalent (LDE)”* applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>).

*“License”* means a license issued by the agency in accordance with the rules adopted by the agency.

*“Licensed (or registered) material”* means radioactive material received, possessed, used, transferred or disposed of under a general or specific license (or registration) issued by the agency.

*“Licensed practitioner”* means a person licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, or dentistry in Iowa, or certified as a physician assistant as defined in Iowa Code section 148C.1, subsection 6, and is authorized to prescribe X-ray tests for the purpose of diagnosis or treatment.

*“Licensee”* means any person who is licensed by the agency in accordance with these rules and the Act.

*“Licensing state”* means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

*“Light field”* means that area of the intersection of the light beam from the beam-limiting device and 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 illumination is one-fourth of the maximum in the intersection.

*“Limits.”* See “Dose limits.”

*“Loose-fitting facepiece”* means a respiratory inlet covering that is designed to form a partial seal with the face.

*“Lost or missing licensed (or registered) source of radiation”* means licensed (or registered) source of radiation whose location is unknown. This definition includes licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

*“Lot tolerance percent defective”* means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

*“Low dose-rate remote afterloader”* means a brachytherapy device that remotely delivers a dose rate of less than or equal to 200 rads (2 gray) per hour at the point or surface where the dose is prescribed.

*“mA”* means milliamperere.

*“Major processor”* means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this rule.

*“Mammography”* means the radiography of the breast except as defined in 641—subrule 41.6(1).

*“Mammography unit”* 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.

*“Manual brachytherapy”* means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

“*Medical use*” means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

“*Medium dose-rate remote afterloader*” means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

“*Member of the public*” means any individual except when that individual is receiving an occupational dose.

“*Minor*” means an individual less than 18 years of age.

“*Misadministration*” means the administration of:

Radiation doses received from linear accelerator therapy, deep X-ray machine therapy or superficial therapy; involving;

Administration of external beam radiation that results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

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.

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 patient or human research subject.

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.

“*Monitoring (radiation monitoring, radiation protection monitoring)*” means the measurement of radiation levels, radioactive material concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

“*NARM*” means any naturally occurring or accelerator-produced radioactive material. It does not include by-product, source, or special nuclear material.

“*Natural radioactivity*” means radioactivity of naturally occurring nuclides. For the purpose of meeting the definition of a licensing state by the Conference of Radiation Control Program Directors, Inc., (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for licensing state designation purposes.

“*Negative pressure respirator (tight fitting)*” means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

“*Nuclear Regulatory Commission (NRC)*” means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

“*Occupational dose*” means the dose received by an individual in the course of employment in which the individual’s assigned duties involve exposure to radiation or to radioactive material from licensed or unlicensed and registered or unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

“*Package*” means the packaging together with its radioactive contents as presented for transport.

“*Particle accelerator*.” See “Accelerator.”

“*Patient*” means an individual or animal subjected to healing arts examination, diagnosis or treatment.

*“Peak tube potential”* means the maximum value of the potential difference across the X-ray tube during an exposure.

*“Person”* means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.

*“Personnel monitoring equipment.”* See “Individual monitoring devices.”

*“Phantom”* means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

*“Pharmacist”* means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

*“Physician”* means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy.

*“Positive pressure respirator”* means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

*“Positron emission tomography (PET) radionuclide production facility”* means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

*“Powered air-purifying respirator (PAPR)”* means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

*“Preceptor”* means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

*“Prescribed dosage”* means the specified activity or range of activity of unsealed radioactive material as documented:

1. In a written directive; or
2. In accordance with the directions of the authorized user for procedures performed in 641—subrules 41.2(31) and 41.2(33).

*“Prescribed dose”* means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, particle accelerators and X-ray therapy systems, the total dose and dose per fraction as documented in the written directive;
3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

*“Pressure demand respirator”* means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

*“Primary dose monitoring system”* means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been delivered.

*“Primary protective barrier”* (see “Protective barrier”).

*“Principal activities,”* as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

*“Protective barrier”* means a barrier used to reduce radiation exposure. The types of protective barriers are as follows:

1. *“Primary protective barrier”* means the material, excluding filters, placed in the useful beam.
2. *“Secondary protective barrier”* means a barrier sufficient to attenuate the stray radiation to the required degree.

“*Public dose*” means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released under 641—subrule 41.2(27) or from voluntary participation in medical research programs.

“*Pyrophoric material*” means any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.4° C) or solid, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

“*Qualified expert*” means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. For example, individuals certified in the appropriate field by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

“*Qualitative fit test (QLFT)*” means a pass-fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

“*Quality factor*” (Q) means the modifying factor, listed in Tables I and II of 38.4(4), that is used to derive dose equivalent from absorbed dose.

“*Quantitative fit test (QNFT)*” means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

“*Rad*” means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

“*Radiation*” means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

“*Radiation area*” means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

“*Radiation detector*” means a device which, in the presence of radiation, by either direct or indirect means, provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

“*Radiation dose.*” See “Dose.”

“*Radiation machine*” means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

“*Radiation safety officer*” means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

“*Radioactive material*” means any solid, liquid, or gas which emits radiation spontaneously.

“*Radioactivity*” means the transformation of unstable atomic nuclei by the emission of radiation.

“*Radiobioassay.*” See “Bioassay.”

“*Radiographic imaging system*” means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

“*Radionuclide*” means a radioactive element or a radioactive isotope.

“*Registrant*” means any person who is registered with the agency or is legally obligated to register with the agency pursuant to these rules and the Act.

“*Registration*” means registration with the agency in accordance with the rules adopted by the agency.

“*Regulations of the U.S. Department of Transportation*” means the regulations in 49 CFR Parts 100-189.

“*Rem*” means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

“*Reportable medical event*” means the medical event, except for an event that results from patient intervention, in which the administration of by-product material or radiation from by-product material results in:

a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

1. The total dose delivered differs from the prescribed dose by 20 percent or more;
2. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

b. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

1. An administration of the wrong radioactive drug containing by-product material;
2. An administration of a radioactive drug containing by-product material by the wrong route of administration;
3. An administration of a dose or dosage to the wrong individual or human research subject;
4. An administration of a dose or dosage delivered by the wrong mode of treatment; or
5. A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

d. An event resulting from intervention of a patient or human research subject in which administration of by-product material or radiation from by-product material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

“*Research and development*” means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

“*Residual radioactivity*” means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee’s control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 641—Chapter 40 or any previous state or federal licenses, rules or regulations.

“*Restricted area*” means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

“*Roentgen*” means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulombs/kilogram of air (see “Exposure” and 38.4(4)).

“*Scattered radiation*” means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

“*Sealed source*” means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

“*Secondary dose monitoring system*” means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

“*Secondary protective barrier*” (see “Protective barrier”).

“*Self-contained breathing apparatus (SCBA)*” means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

“*Shallow dose equivalent*” ( $H_s$ ), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter ( $7 \text{ mg/cm}^2$ ).

“*Shutter*” means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

“*SI*” means the abbreviation for the International System of Units.

“*Sievert*” means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor ( $1 \text{ Sv} = 100 \text{ rem}$ ).

“*Simulator (radiation therapy simulation system)*” means any X-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

“*Site area emergency*” means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off site.

“*Site boundary*” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

“*Source*” means the focal spot of the X-ray tube.

“*Source material*” means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or
2. Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

“*Source material milling*” means any activity that results in the production of by-product material as defined by definition (2) of by-product material.

“*Source of radiation*” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

“*Source traceability*” means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology or by a laboratory which participates in continuing measurement quality assurance programs with the National Institute of Standards and Technology or other equivalent national or international program.

“*Special form radioactive material*” means radioactive material which satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
3. It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

“*Special nuclear material*” means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the agency declares by order to be special nuclear material after the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
2. Any material artificially enriched by any of the foregoing but does not include source material.

“*Special nuclear material in quantities not sufficient to form a critical mass*” means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

“*SSD*” means the distance between the source and the skin entrance plane of the patient (see “Target-to-skin distance (TSD)”).

“*Stray radiation*” means the sum of leakage and scattered radiation.

“*Supplied-air respirator (SAR)*” or “*airline respirator*” means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

“*Survey*” means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.

“*Target-to-skin distance (TSD)*” means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron virtual source scattering foil to the surface of the irradiated object or patient.

“*Teletherapy*” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“*Termination of irradiation*” means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“*Test*” means the process of verifying compliance with an applicable regulation.

“*These rules*” means 641—Chapters 38 to 45.

“*Tight-fitting facepiece*” means a respirator inlet covering that forms a complete seal with the face.

“*Total effective dose equivalent*” (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

“*Total organ dose equivalent*” (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 641—40.86(1) “f.”

“*Traceable to a national standard.*” See “Instrument traceability” or “Source traceability.”

“*Treatment site*” means the anatomical description of the tissue intended to receive a radiation dose, as described in the written directive.

“*Tube*” means an X-ray tube unless otherwise specified. See “X-ray tube.”

“*Tube housing assembly*” means the tube housing with tube installed. It includes high-voltage or filament transformers, or both, and other appropriate elements when such are contained within the tube housing.

“*Type A quantity*” means a quantity of radioactive material, the aggregate radioactivity of which does not exceed  $A_1$  for special form radioactive material, or  $A_2$ , for normal form radioactive material as defined in 10 CFR 71.4.

“*Type B quantity*” means a quantity of radioactive material greater than a Type A quantity as defined in 10 CFR 71.4.

“*Unrefined and unprocessed ore*” means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

“*Unrestricted area*” means an area to which access is neither limited nor controlled by the licensee or registrant. For purposes of these rules, “uncontrolled area” is an equivalent term.

“*U.S. Department of Energy*” means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

“*User seal check (fit check)*” means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

“*Very high radiation area*” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual’s receiving an absorbed dose in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.

“*Waste*” means those low-level radioactive wastes containing source, special nuclear, or by-product material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or by-product material as defined in paragraphs “2,” “3” and “4” of the definition of “by-product material” set forth in this chapter.

“*Waste handling licensees*” means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

“*Wedge filter*” means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

“*Week*” means seven consecutive days starting on Sunday.

“*Whole body*” means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

“*Worker*” means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

“*Working level*” (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of  $1.3E+5$  MeV of potential alpha particle energy. The short-lived radon daughters are—for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

“*Working level month*” (WLM) means an exposure to 1 working level for 170 hours—2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

“*Written directive*” means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or by an individual qualified by training and experience to conduct particle accelerator therapy or radiation for X-ray therapy, as specified in 641—subrule 41.2(87).

“*X-radiation*” means penetrating electromagnetic radiation with energy greater than 0.1 kV produced by bombarding a metallic target with fast electrons in a high vacuum.

“*X-ray tube*” means any electron tube which is designed to be used primarily for the production of X-rays.

“*Year*” means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to

determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

#### **641—38.3(136C) Exemptions from the regulatory requirements.**

**38.3(1) General provision.** The agency may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in 641—Chapters 38 to 46 as it determines are authorized by law and will not result in undue hazard to public health and safety or property. Application for exemptions or exceptions should be made in accordance with 641—Chapter 178.

**38.3(2) Persons using by-product material under certain Department of Energy and Nuclear Regulatory Commission contracts.**

*a.* Except to the extent that NRC facilities or activities of the types subject to licensing pursuant to the Energy Reorganization Act of 1974 are involved, any prime contractor of the NRC is exempt from the license requirements of these rules and from the regulations of these rules to the extent that such contractor, under the contractor's prime contract with the NRC, manufactures, produces, transfers, receives, acquires, owns, possesses, or uses by-product material for:

(1) The performance of work for a department at the United States government-owned or government-controlled site, including the transportation of by-product material to or from such site and the performance of contract services during temporary interruptions of such transportation;

(2) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(3) The use or operation of nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel.

*b.* In addition to the foregoing exemptions and subject to the requirement for licensing of NRC facilities and activities pursuant to the requirements of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the NRC is exempt from the requirements for a license set forth in the Act and from the regulations in these rules to the extent that such prime contractor or subcontractor manufactures, produces, transfers, receives, acquires, owns, possesses, or uses by-product material under the contractor's or subcontractor's prime contract or subcontract when the NRC determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work can be accomplished without undue risk to the public health and safety.

*c.* Carriers. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from these rules to the extent that they transport or store radioactive material in the regular course of carriage for another or of storage incident thereto.

#### **641—38.4(136C) General regulatory requirements.**

##### **38.4(1) Records.**

*a.* Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

*b.* Electronic records.

(1) A record or signature shall not be denied legal effect or enforceability solely because it is in electronic form.

(2) A contract shall not be denied legal effect or enforceability solely because an electronic record was used in its formation.

(3) If a rule requires a record to be in writing, an electronic record shall satisfy the rule.

(4) If a rule requires a signature, an electronic signature shall satisfy the rule.

##### **38.4(2) Inspections.**

*a.* Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

*b.* Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

**38.4(3) Tests.** Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

- a.* Sources of radiation;
- b.* Facilities wherein sources of radiation are used or stored;
- c.* Radiation detection and monitoring instruments; and
- d.* Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

**38.4(4) Units of exposure and dose.**

*a.* As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I  
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent (see footnote "1")
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

1. Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

*b.* If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 38.4(4) "a," 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II  
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor <sup>a</sup> (Q)	Fluence per Unit Dose Equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> rem <sup>-1</sup> )	Fluence per Unit Dose Equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> Sv <sup>-1</sup> )
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8

Neutron Energy (MeV)	Quality Factor <sup>a</sup> (Q)	Fluence per Unit Dose Equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> rem <sup>-1</sup> )	Fluence per Unit Dose Equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> Sv <sup>-1</sup> )
1E-1	7.5	170E+6	170E+8
5E-1	11	39E+6	39E+8
1	11	27E+6	27E+8
2.5	9	29E+6	29E+8
5	8	23E+6	23E+8
7	7	24E+6	24E+8
10	6.5	24E+6	24E+8
14	7.5	17E+6	17E+8
20	8	16E+6	16E+8
40	7	14E+6	14E+8
60	5.5	16E+6	16E+8
1E+2	4	20E+6	20E+8
2E+2	3.5	19E+6	19E+8
3E+2	3.5	16E+6	16E+8
4E+2	3.5	14E+6	14E+8

<sup>a</sup>Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

<sup>b</sup>Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

**38.4(5) Units of activity.** Rescinded IAB 4/8/98, effective 7/1/98.

**38.4(6) Additional requirements.** The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

**641—38.5(136C) Administrative actions.** Rescinded IAB 4/3/02, effective 5/8/02.

**641—38.6(136C) Prohibited uses.** A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health. A shoe-fitting fluoroscopic device shall not be used. Radiation from radiation-emitting machines or radioactive materials shall not be used on humans for nonmedical purposes.

**641—38.7(136C) Communications.**

**38.7(1)** All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, Des Moines, Iowa 50319.

**38.7(2)** Drafts of proposed regulations released to the department from the federal government which constitute essential information needed by the department to ensure compliance with federal regulations are not available for public examination. Therefore, pursuant to Iowa Code section 22.9, the department waives the provision of Iowa Code section 22.2 as it applies to these proposed draft regulations.

**641—38.8(136C) Fees.**

**38.8(1) Radiation machines.**

*a.* Each registrant shall, at the time of registration and the anniversary date thereafter, as long as the registrant owns the radiation machine, remit to the agency a nonrefundable fee sufficient to defray the cost of registering the equipment with the department. All fees shall be paid annually in the form of a check or money order made payable to the Iowa Department of Public Health. The fees to be paid shall be in the amount computed by the following schedule:

## ANNUAL FEE SCHEDULE

Type of X-ray machine	Fee per tube	Maximum fee
1. Medical	\$51	\$1500
2. Osteopathy	\$51	\$1500
3. Chiropractic	\$51	\$1500
4. Dentistry	\$39	\$1000
5. Podiatry	\$39	\$1000
6. Veterinary Medicine	\$25	—
7. (Industrial/Nonmedical Use)	\$50	—
8. Food Sterilization	\$1000	—
9. Accelerators and Electronic Brachytherapy Units	\$100	—
10. Electron Microscope	\$20	—
11. Bone Densitometry	\$25	—

Fees for radiation machines not listed in the above schedule shall not be less than \$50 per unit/tube.

*b.* Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

(1) Mammography unit inspections fees:

- \$900 for the first unit and, if the facility has additional units at the address of the first unit, a fee of \$325 for each additional unit; or
- \$900 per portable unit for each site where the unit is off-loaded and used and where the processing and patient films are stored; or
- Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria; or
- \$450 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances; or
- \$900 for each stereotactic breast biopsy unit.

(2) Mammography interpretation fees of \$100 per mammography examination provided to the department for the purpose of determining film diagnostic quality.

(3) Industrial and oncology accelerator registrants and electronic brachytherapy registrants shall pay for each inspection a fee of \$400 for the first unit and \$100 for each additional unit.

(4) Industrial radiography X-ray units/walk-in cabinet radiography X-ray unit registrants shall pay for each inspection a fee of \$250 for the first unit and \$75 for each additional unit.

*c.* Each person who is engaged in the business of installing or offering to furnish radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or service in the state shall apply for registration of such service with the agency prior to furnishing or offering to furnish any such service. Application shall be on a form provided by the department and include an annual nonrefundable fee of \$100.

*d.* Each person engaged in providing health physics services in mammography in Iowa, who meets the requirements of 641—paragraph 41.6(3) “c” and is deemed qualified by this agency, must submit a \$40 annual listing fee to this agency.

*e.* All mammography facilities providing services in Iowa must submit a \$50 annual authorization certification fee.

*f.* All Iowa-accredited facilities providing mammography services in Iowa must submit a \$200 accreditation fee for initial accreditation and each reaccreditation.

**38.8(2) Radioactive material fee schedule.** Fees associated with the possession and use of radioactive materials in Iowa shall not exceed those specified in 10 CFR 170.31 and 10 CFR 171.16. The following fee schedule shall apply.

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(3.L.)	01100	AAB	Academic Type A Broad	\$5,000	1	\$10,500
(8.A.)	03710	CD	Civil Defense	\$1,000	5	\$1,000
(3.E.)	03510	I1	Irradiators, Self-Shielding <10,000 Curies	\$2,000	5	\$650
(3.O.)	03320	IR1	Industrial Radiography – Temporary Job Sites	\$4,500	1	\$4,300
(3.P.)	03120	FG	Measuring Systems – Fixed Gauge	\$1,300	5	\$650
(3.P.)	03121	PG	Measuring Systems – Portable Gauge	\$1,300	5	\$650
(3.P.)	02410	IVL	<i>In-Vitro</i> Testing Laboratory	\$1,300	5	\$650
(7.C.)	02230	HDR	High Dose Rate Afterloader	\$2,300	1	\$3,400
(7.C.)	02120	M1	Medical – Diagnostic & Therapy	\$2,300	3	\$1,500
(7.C.)	02121	M2	Medical – Diagnostic Only	\$2,300	4	\$1,200
(7.C.)	02240	MET	Medical – Diagnostic, Therapeutic, Emerging Technologies	\$2,300	2	\$2,000
(3.S.)	03210	PET	Accelerator-Produced RAM	\$3,000	1	\$4,300
(3.C.)	02500	NP	Nuclear Pharmacy	\$3,000	1	\$3,500
(7.C.)	02231	NV1	Nuclear Medical Van	\$2,300	2	\$1,800
(7.C.)	22160	PMM	Pacemaker – By-Product and/or SNM	\$2,300	T	Note 5
(3.M.)	03620	RD2	Research & Development – Other	\$2,500	3	\$1,350
(2.C.)	11300	SM1	Source Material, Other, >150 Kilograms	\$6,000	3	\$2,250
(1.D.)	22120	SNM2	SNM Plutonium – Neutron Source	\$1,500	5	\$500
(3.P.)	03221	CAL	Calibration and W/L Tests	\$1,300	5	\$650
(3.P.)	03122	XRF	X-Ray Fluorescent Analyzer	\$1,300	7	\$650
(3.P.)	02400	VMT	Veterinary Medicine – Therapy	\$1,300	3	\$650
(3.B.)	03214	MD	Manufacturing/Distribution	\$3,500	3	\$1,800

## Notes:

1. Reciprocity fee is \$1,800 annually (180 days).
2. Inspection priorities are based on NRC inspection manual chapter 2800. Priority “T” is a telephonic contact and is not considered an inspection.
3. License amendment fee for all categories is \$400.
4. Annual fees are due no later than September 1 of each year. A 10% late charge will be assessed per month for late payments. Licensees with more than two authorized locations of use will be charged an additional 10% of the annual fee per location.
5. Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses with the agency.
6. General license registration fee is \$250 annually on registration anniversary.

**38.8(3) Industrial radiography testing and certification.**

a. A nonrefundable fee of \$175 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

b. A fee of \$25 shall be submitted in order to replace lost identification cards issued to industrial radiographers by the agency pursuant to 641—subrule 45.1(10).

c. A nonrefundable fee of \$75 shall be submitted with each application, not associated with an agency-administered industrial radiography examination, for a trainee or trainer card issued to a radiographer's assistant or an industrial radiographer.

**38.8(4) Owner-assessed expenses.** In cases in which the agency determines that the cost of regulating or inspecting registered radiation machine facilities or radioactive materials licensees significantly exceeds the fees charged to the facility, it may assess an additional fee to the owner or user of the source(s) of radiation to cover the actual expenses incurred by the agency.

**38.8(5) Environmental surveillance fee.** A fee may be levied against any licensee, registrant, corporation, company, business, or individual for environmental surveillance activities which are necessary to assess the radiological impact of activities conducted by the licensee, registrant, corporation, company, business, or individual. This fee shall be sufficient to defray actual costs incurred by the agency, including, but not limited to, salaries of agency employees, per diem, travel, and costs of laboratory analysis of samples, when required.

**38.8(6) Certification fees.** Diagnostic radiographers, radiologist assistants, radiation therapists, and nuclear medicine technologists (as defined in 641—Chapter 42), other than licensed practitioners of the healing arts, are required to pay fees sufficient to defray the cost of administering 641—Chapter 42. For podiatry assistant fees, see 641—42.7(136C). Fees are as follows:

a. *Annual fee.* Each individual must submit a \$60 initial fee for the first year and \$50 annually. These fees are nonrefundable.

b. *Examination fee.* Each individual making application to take an examination given by the agency as a limited or general nuclear medicine technologist, limited or general radiation therapist, or limited or general diagnostic radiographer as defined in 641—Chapter 42 must pay a nonrefundable fee of \$110 each time the individual takes the examination required by 641—Chapter 42.

c. *Recertification fees.* Once certification has been terminated for failure to complete continuing education requirements, any individual who requests permission to reestablish certification within six months of the initial continuing education due date must meet the training and testing requirements of 641—Chapter 42, submit proof of continuing education hours and shall submit a late fee of \$30 in addition to the annual fee in order to obtain reinstatement of certification.

d. *Continuing education late fee.* Any individual who will not complete the required continuing education before the continuing education due date and wishes to submit a plan of correction as set forth in 641—subparagraph 42.2(3) “g”(2) shall submit a nonrefundable fee of \$25 along with the written plan of correction.

**38.8(7) Returned check and late fees.** Persons who fail to pay required fees to the agency are subject to the following penalties:

a. \$25 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the agency.

b. \$25 for each month for failure to pay any fee administered by this agency starting 30 days after the due date of the original notice. This fee is added to the unpaid fee.

**38.8(8) Reciprocity.** Fees paid for reciprocal recognition of out-of-state persons wishing to utilize radiation machines or radioactive materials in Iowa shall allow the out-of-state person to operate for a total of 180 days during the 365-day reciprocity period starting the date the fee is received by the agency.

a. *Radiation machines.* Any out-of-state person who wishes to bring an X-ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of \$100 for each source of radiation.

b. *Radioactive materials.* Out-of-state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90)).

If a reciprocity fee is applicable, it shall be assessed at the rate for reciprocity specified in the radioactive materials fee schedule available through the agency for each 365-day reciprocity period. In addition, if the agency performs an inspection of the out-of-state person's activities while in Iowa, the appropriate inspection fee as specified in the radioactive materials fee schedule will be assessed.

c. Industrial radiographers wishing to operate in Iowa under an identification card from a jurisdiction recognized by Iowa that charges Iowa card holders a fee will be assessed and must pay a \$100 fee prior to conducting industrial radiography in Iowa.

**38.8(9)** *Radon certification.* Rescinded IAB 4/3/02, effective 5/8/02.

**38.8(10)** *Radon mitigation credentialing.* Rescinded IAB 4/3/02, effective 5/8/02.

**38.8(11)** *Radioactive material transport fee schedule.*

a. All shippers shall pay the following fee(s) unless the department obtains sufficient funding from another source, which may include but is not limited to a federal agency or a contract with a shipper.

(1) \$1800 per highway cask for each truck shipment of spent nuclear fuel, high-level radioactive waste, transuranic waste, or highway route controlled quantity of radioactive materials or any material shipped in accordance with 641—subrule 40.54(5) traversing the state or any portion thereof. Single cask truck shipments are subject to a surcharge of \$20 per mile for every mile over 250 miles traveled.

(2) \$1300 for the first cask and \$125 for each additional cask for each rail shipment of spent nuclear fuel, high-level radioactive waste, transuranic waste, or highway route controlled quantity of radioactive materials or any material shipped in accordance with 641—subrule 40.54(5) traversing the state or any portion thereof.

(3) \$175 for each shipment by truck or by rail paid by the shipper for low-level radioactive waste shipped in or across Iowa. The department may accept an annual shipment fee as negotiated with a shipper or accept payment per shipment. This fee applies to waste shipped to a site authorized by a government agency to receive low-level radioactive waste or shipped to a storage site to be held for future disposal.

b. All fees must be paid by the shipper prior to shipment. Shippers must request an application for a permit to ship radioactive material from the Iowa Department of Transportation, Office of Motor Carrier Services. Assistance may be obtained by calling the Bureau of Radiological Health at (515)281-3478. Other methods of fee payment may be considered by the department on a case-by-case basis upon request of the shipper. A request for an alternative method of payment must be made to the department prior to shipment.

c. All fees received pursuant to this subrule shall be used for purposes related to transporting radioactive material, including enforcement and planning, developing, and maintaining a capability for emergency response.

**38.8(12)** *Fee waiver.* Any fee may be waived in exchange for services (low-level waste disposal, radiation detection instrument calibration, instrument repair, sample analysis, etc.) provided to the agency. The waiver may only occur as a result of a 28E agreement between the parties.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

#### **641—38.9(136C) Administrative enforcement actions.**

##### **38.9(1)** *Scope.*

a. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, registration, or certificate or to take other action as may be proper against any person subject to the jurisdiction of the agency. The term “regulated entity” as used in this rule refers to any facility, person, partnership, corporation or other organization which is regulated by the agency by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation. “Authorization” means license, registration, certificate, permit, or any other document issued or received by the agency that authorizes specific activities related to the possession and use of radioactive materials or radiation-producing machines in Iowa.

b. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4, to impose serious misdemeanor penalties pursuant to Iowa Code section 136B.5 or to impose simple misdemeanor penalties pursuant to Iowa Code section 136D.8.

**38.9(2) Notice of violation.**

a. In response to an alleged violation of any provision of the Iowa Code, these rules, the conditions of an authorization issued by the agency or any order issued by the agency, the agency may serve on the regulated entity a written notice of violation; a separate notice may be omitted if an order pursuant to 38.9(3) or demand for information pursuant to 38.9(5) is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation(s) and will require that the regulated entity submit, within 30 days of the date of the notice or other specified time, a written explanation or statement in reply including:

- (1) Corrective steps which have been taken by the regulated entity and the results achieved;
- (2) Corrective action which will be taken to prevent recurrence; and
- (3) The date when full compliance will be achieved.

b. The notice may require the regulated entity subject to the jurisdiction of the agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the agency may issue an order or a demand for information as to why the authorization should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

c. Violations are categorized according to five levels of severity, which are:

(1) Severity Levels I and II: Violations are of very significant regulatory concern involving actual or high potential impact on the public health and safety.

(2) Severity Level III: Violations are cause for significant concern.

(3) Severity Level IV: Violations are less serious but are of more than minor concern and that, if left uncorrected, could lead to a more serious health and safety concern.

(4) Severity Level V: Violations are of minor safety or environmental concern.

d. A group of violations may be evaluated in the aggregate and assigned a single higher severity level if the violations have the same underlying cause or if the violations contributed to or were unavoidable consequences of the underlying problem.

e. The severity level of a violation may be increased if the violation can be considered a repetitive violation. The term “repetitive violation” or “similar violation” means a violation that reasonably could have been prevented by a regulated entity’s corrective action for a previous violation normally occurring within the past two years of the inspection at issue or the period within the last two inspections, whichever is longer.

f. The severity level of a violation may be increased if the violation involves casual disregard of requirements, deception, or other indications of willfulness. The term “willfulness” is that characteristic of violations ranging from deliberate intent to violate or falsify to intentional disregard for regulatory requirements.

**38.9(3) Orders.**

a. The agency may institute a proceeding to modify, suspend, or revoke an authorization or to take other action as may be proper by serving on the regulated entity an order which will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient grounds for the proposed action;

(2) Provide that the regulated entity may file a written answer to the order under oath or affirmation within 20 days of its date, or such other time as may be specified in the order;

(3) Inform the regulated entity of its right, within 20 days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the regulated entity has consented in writing to the order;

(4) Specify the issues for hearing; and

(5) State the effective date of the order; if the agency finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

b. A regulated entity who receives an order may respond to an order under this subrule by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order and may set forth the matters of fact and law on which the regulated entity relies, and, if the order is not consented to, the reasons as to why the order should not have been issued. Except as provided in paragraph “d” of this subrule, the answer may demand a hearing.

c. If the answer demands a hearing, the agency will issue an order designating the time and place of hearing.

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the regulated entity to whom the order has been issued shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum 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 agency, and shall be effective as provided in the order.

**38.9(4) Settlement and compromise.** At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty.

**38.9(5) Demand for information.**

a. The agency may issue to a regulated entity a demand for information for the purpose of determining whether an order under 38.9(3) should be issued, or whether other action should be taken, which demand will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for issuing the demand; and

(2) Provide that the regulated entity must file a written answer to the demand for information under oath or affirmation within 20 days of its date, or such time as may be specified in the demand for information.

b. A regulated entity to whom the agency has issued a demand for information under this subrule must respond to the demand by filing a written answer under oath or affirmation. The regulated entity’s answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described above, or by setting forth its 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 filed pursuant to 38.9(5) “a”(2), or if no answer is filed, the agency may institute a proceeding pursuant to 38.9(3) to take such action as may be proper.

d. An answer may consent to the entry of an order pursuant to 38.9(3) in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in 38.9(3) “d.”

**38.9(6) Civil penalties.**

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to 38.9(2). 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, license, permit, 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 agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

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 violation fails to answer within the time specified in 38.9(6) "b," an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6) "a."

d. If the person charged with violation files an answer to the notice of violation, the agency, 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 violation requests a hearing, the agency will issue an order designating the time and place of hearing.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The agency may compromise any civil penalty, subject to the provisions of 38.9(4).

h. If the civil penalty is not compromised, or is not remitted by the presiding officer or the agency, and if payment is not made within ten days following either the service of the order described in 38.9(6) "c" or "f," or the expiration of the time for requesting a hearing described in 38.9(6) "d," the agency may refer the matter to the attorney general for collection.

i. 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 136C.4 shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

**38.9(7) Requests for action under this rule.**

a. Any person may file a request to institute a proceeding pursuant to 38.9(3) to modify, suspend, or revoke an authorization as may be proper. Such a request shall be addressed to the Chief, Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. The requests shall specify the action requested and set forth the facts that constitute the basis for the request. The bureau chief will discuss the matter with staff to determine appropriate action in accordance with 38.9(7) "b."

b. Within a reasonable time after a request pursuant to 38.9(7) "a" has been received, the bureau chief shall either institute the requested proceeding in accordance with this rule or shall advise the person who made the request in writing that no proceeding will be instituted, in whole or in part, with respect to the request, and the reasons for the decision.

c. (1) The bureau chief's decisions under this rule will be filed and within 25 days after the date of the bureau chief's decision under this rule that no proceeding will be instituted or other action taken in whole or in part, the agency may on its own motion review that decision, in whole or in part, to determine if the bureau chief has abused discretion. This review power does not limit in any way either the agency's supervisory power over delegated staff actions or the agency's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.

(2) No petition or other request for agency review of a bureau chief's decision under this rule will be entertained by the agency.

**38.9(8) Impounding.** The agency may impound or order the impounding of radioactive material in the possession of a person who fails to observe the provisions of Iowa Code chapter 136C, or any rules, license or registration conditions, or orders issued by this agency.

a. If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give to either the owner or the possessor of the source of radiation written notice of the intention to impound the source of radiation.

(1) Either the owner or the possessor shall have 20 days from the date of personal service of certified mailing to request a hearing, except in the case where the regulated entity has consented in writing to the impoundment.

(2) If a hearing is requested, the agency will issue an order designating the time and place of hearing.

*b.* At the agency's direction, the impounded sources of radiation may be disposed of by:

(1) Returning the source of radiation to a properly licensed or registered owner that did not cause the emergency;

(2) Returning the source of radiation to a licensee or registrant after the emergency is over and after settlement of any compliance action; or

(3) Selling, destroying, or disposing of the source of radiation in another manner within the agency's discretion.

#### **641—38.10(136C) Deliberate misconduct.**

**38.10(1)** Any licensee, registrant, applicant for a license or certificate of registration, employee of a licensee, registrant or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or registrant or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, registrant, contractor, or subcontractor any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities in this rule, may not:

*a.* Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the agency; or

*b.* Deliberately submit to the agency, a licensee, registrant, applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the agency.

**38.10(2)** A person who violates paragraph 38.10(1) "a" or "b" may be subject to enforcement action in accordance with the procedures in 641—38.9(136C).

**38.10(3)** For the purposes of paragraph 38.10(1) "a," deliberate misconduct by a person means an intentional act or omission that the person knows:

*a.* Would cause a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the agency; or

*b.* Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

These rules are intended to implement Iowa Code chapter 136C.

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<sup>0</sup> Two or more ARCs

<sup>1</sup> Effective date of 38.8(11) delayed 70 days from May 9, 2001, by the Administrative Rules Review Committee at its meeting held May 4, 2001.

At its meeting held July 10, 2001, the Committee delayed the effective date until adjournment of the 2002 Session of the General Assembly.