PUBLIC HEALTH DEPARTMENT[641]

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CHAPTER 1
REPORTABLE DISEASES, POISONINGS AND CONDITIONS, AND QUARANTINE AND ISOLATION

1.1(139A) Definitions
1.2(139A) Authority
1.3(139A,141A) Reportable communicable and infectious diseases, poisonings or conditions, and cancers
1.4(135,139A) Reporting requirements

INVESTIGATION

1.5(135,139A) Investigation of reportable diseases

ISOLATION AND QUARANTINE

1.6(135,193A) Isolation and quarantine
1.7(139A,22) Confidentiality

STATE HYGIENIC LABORATORY

1.8(135,139A) Specimens for which the fee charged by the state hygienic laboratory will be waived

CHAPTER 2
HEPATITIS PROGRAMS

VIRAL HEPATITIS PROGRAM—VACCINATIONS AND TESTING

2.1(135) Definitions
2.2(135) Exposure risks for hepatitis C virus
2.3(135) Information for public distribution
2.4(135) Hepatitis vaccination and testing program

CHAPTER 3
EARLY HEARING DETECTION AND INTERVENTION (EHDI) PROGRAM

3.1(135) Definitions
3.2(135) Program components
3.3(135) Screening the hearing of all newborns
3.4(135) Procedures required of birthing hospitals
3.5(135) Procedures required of birth centers
3.6(135) Procedures to ensure that children born in locations other than a birth center or birthing hospital receive a hearing screening
3.7(135) Reporting hearing screening results and information to the department and child's primary care provider
3.8(135) Conducting and reporting screening results and diagnostic audiologic assessments to the department and child's primary care provider
3.9(135) Congenital cytomegalovirus (cCMV) testing for newborns who do not pass the initial newborn hearing screening
3.10(135) Information sharing and confidentiality
3.11(135) Procedure to accommodate parental objection
3.12(135) Civil/criminal liability

CHAPTER 4
CONGENITAL AND INHERITED DISORDERS

4.1(136A) Definitions
4.2(136A) Iowa newborn screening program (INSP)
4.3(136A) Iowa maternal prenatal screening program (IMPSP)
4.4(136A) Regional genetic consultation service (RGCS)
4.5(136A) Neuromuscular and other related genetic disease program (NMP)
4.6(136A) Iowa registry for congenital and inherited disorders (IRCID)

CHAPTERS 5 and 6

Reserved

CHAPTER 7
IMMUNIZATION AND IMMUNIZATION EDUCATION: PERSONS ATTENDING ELEMENTARY OR SECONDARY SCHOOLS, LICENSED CHILD CARE CENTERS OR INSTITUTIONS OF HIGHER EDUCATION

7.1(139A) Definitions
7.2(139A) Persons included
7.3(139A) Persons excluded
7.4(139A) Required immunizations
7.5(139A) Required education
7.6(139A) Proof of immunization
7.7(139A) Provisional enrollment
7.8(139A) Records and reporting
7.9(139A) Compliance
7.10(22) Statewide registry
7.11(22) Release of immunization and health screening information

CHAPTERS 8 to 10
Reserved

CHAPTER 11
HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

11.1(139A,141A) Definitions
11.2(141A) HIV testing—obtaining consent—voluntary HIV-related tests for adults who are not pregnant
11.3(139A,141A) HIV testing—obtaining consent—voluntary HIV-related tests for minors who are not pregnant
11.4(141A) HIV testing—obtaining consent—voluntary HIV-related tests for pregnant women
11.5(141A) HIV test results—posttest counseling
11.6(141A) Reporting of diagnoses and HIV-related tests, events, and conditions to the department
11.7(141A) Confidentiality of information
11.8(135) HIV and AIDS training programs where occupational exposure to blood or other potentially infectious materials may occur
11.9(139A,141A) Partner notification program
11.10(141A) Direct notification of an identifiable third party by a physician, physician associate or the department
11.11(139A,141A) Care provider notification upon exposure to contagious or infectious diseases—exposures in nonclinical settings
11.12(139A,141A) Care provider notification upon exposure to contagious or infectious diseases—exposures in clinical settings
11.13(915) Testing, reporting, and counseling of convicted or alleged sexual assault assailants
11.14(141A) Ryan White program

CHAPTER 12
APPROVAL OF CONFIRMATORY LABORATORIES FOR PRIVATE SECTOR DRUG-FREE WORKPLACE TESTING

12.1(730) Definitions
12.2(730) Powers and duties
12.3(730) Application procedures and requirements
12.4(730) Requirements of laboratory personnel involved in confirmatory testing for alcohol or other drugs, or their metabolites
12.5(730) Quality assurance program and procedure manual requirements
12.6(730) Analytical quality control
12.7(730) Sample security and confidentiality of test results
12.8(730) Confirmatory testing
12.9(730) Documentation of the confirmatory testing process
12.10(730) Reporting of confirmed positive test results to the medical review officer
12.11(730) Reporting requirements to department
12.12(730) Approval, renewal, and inspection fees

12.13(730) Renewal
12.14(730) Reciprocity
12.15(730) Changes during approval periods
12.16(730) Enforcement
12.17(730) Denial, suspension, modification or revocation of approval
12.18(730) Restoration of approval
12.19(730) Appeals process
12.20(730) Complaints

CHAPTERS 13 to 23
Reserved

CHAPTER 24
PRIVATE WELL TESTING, RECONSTRUCTION, AND PLUGGING—IOWA PRIVATE WELL GRANTS

24.1(455E,135) Grant procedures

CHAPTERS 25 to 36
Reserved

CHAPTER 37
GENERAL PROVISIONS FOR RADIATION AND RADIATION PROTECTION STANDARDS

37.1(136C) General provisions
37.2(136C) Definitions
37.3(136C) General regulatory requirements
37.4(136C) Records
37.5(136C) Units of exposure and dose
37.6(136C) Prohibited uses
37.7(136C) Communications
37.8(136C) Requirements for registrations
37.9(136C) Fees
37.10(136C) Administrative enforcement actions
37.11(136C) Standards for protection against radiation
37.12(136C) Records
37.13(136C) Reports
37.14(136C) Notices, instructions, and reports to workers
37.15(136C) Inspections

CHAPTER 38
PERMITS TO OPERATE IONIZING RADIATION PRODUCING MACHINES OR ADMINISTER RADIOACTIVE MATERIALS FOR MEDICAL IMAGING

38.1(136C) Definitions
38.2(136C) Exemptions
38.3(136C) Permit application and renewal
38.4(136C) Permit to practice—general radiologic technologist, nuclear medicine technologist, radiation therapist
38.5(136C) Permit to practice as a general nuclear medicine technologist with computed tomography endorsement
38.6(136C) Permit to practice as a radiologist assistant
38.7(136C) Permit to practice as a limited radiologic technologist with categories of chest, spine, extremities, shoulder, pediatric
38.8(136C) Permit to practice as an X-ray equipment operator in podiatric radiography or bone densitometry (dual energy X-ray absorptiometry or DEXA)
38.9(136C) Closed classification or category permits
38.10(136C) Combining permits for an individual qualifying for permits in more than one classification
38.11(136C) Submission of proof of completion of continuing education by permit holder to meet continuing education requirements to renew or reinstate a permit
38.12(136C) Requirements for formal education
38.13(136C) Standards for formal education for limited radiologic technologists

38.14(136C) Standards for formal education for X-ray equipment operators in podiatric radiography
38.15(136C) Standards for formal education for X-ray equipment operators in bone densitometry
38.16(136C) Administrative items and grounds for disciplinary action
38.17(136C) Rules of conduct, self-reporting requirements, and enforcement actions for all permit holders or applicants
38.18(136C) Procedures for demand for information, notice of proposed action, and orders for penalties, suspensions, revocations, and civil penalties for all individuals under this chapter

CHAPTER 39
REGISTRATION AND SAFETY REQUIREMENTS FOR RADIOACTIVE MATERIALS
39.1(136C) General provisions
39.2(136C) Definitions
39.3(136C) General regulatory requirements for incorporating CFR by reference
39.4(136C) Notices, instructions and reports to workers: inspection and investigations
39.5(136C) Standards for protection against radiation
39.6(136C) Rules of general applicability to licensing of byproduct material
39.7(136C) General domestic licenses for byproduct material
39.8(136C) Specific domestic licenses to manufacture or transfer certain items containing byproduct material
39.9(136C) Specific domestic licenses of broad scope for byproduct material
39.10(136C) Licenses for industrial radiography and radiation safety requirements for industrial radiographic operations
39.11(136C) Medical use of byproduct material
39.12(136C) Licenses and radiation safety requirements for irradiators
39.13(136C) Physical protection of category 1 and category 2 quantities of radioactive material
39.14(136C) Licenses and radiation safety requirements for well logging
39.15(136C) Domestic licensing of source material
39.16(136C) Domestic licensing of special nuclear material
39.17(136C) Packaging and transportation of radioactive material
39.18(136C) Reciprocal recognition of licenses

CHAPTER 40
REGISTRATION AND SAFETY REQUIREMENTS FOR RADIATION EMITTING MACHINES IN THE HEALING ARTS—MEDICINE, PODIATRY, DENTAL, CHIROPRACTIC, AND VETERINARY MEDICINE
40.1(136C) General provisions
40.2(136C) Definitions
40.3(136C) General regulatory requirements
40.4(136C) Administrative controls
40.5(136C) General requirements for all diagnostic X-ray systems
40.6(136C) General requirements for all fluoroscopy and interventional X-ray systems
40.7(136C) General requirements for dental intraoral, panoramic, cephalometric, and volumetric dental imaging equipment
40.8(136C) Computed tomography X-ray systems
40.9(136C) Dual-energy X-ray absorptiometry (DXA)
40.10(136C) Veterinary medicine X-ray systems

CHAPTER 41
REGISTRATION AND SAFETY REQUIREMENTS FOR MAMMOGRAPHY AND STEREOTACTIC BREAST BIOPSY
41.1(136C) Registration and safety requirements for mammography and stereotactic breast biopsy
41.2(136C) Definitions
41.3(136C) General provisions for mammography
41.4(136C) Mammography registration, certification, and general requirements
41.5(136C) Mammography personnel
41.6(136C) Retention of personnel records for mammography
41.7(136C) Equipment and safety requirements for mammography
41.8(136C) Medical records and reports for mammography
41.9(136C) Contents and terminology for mammography

41.10(136C) Quality assurance for mammography
41.11(136C) Revocation, suspension, reinstatement and appeals for mammography
41.12(136C) Alternative requirements for quality standards for mammography
41.13(136C) General provisions for stereotactic breast biopsy
41.14(136C) Registration and application standards and requirements for stereotactic breast biopsy
41.15(136C) Requirements for physicians performing stereotactic breast biopsy
41.16(136C) Requirements for radiologic technologists performing stereotactic breast biopsy
41.17(136C) Requirements for medical physicists performing surveys of stereotactic breast biopsy systems
41.18(136C) Obtaining and preserving records for stereotactic breast biopsy
41.19(136C) Quality assurance program for stereotactic breast biopsy
41.20(136C) Equipment and safety standards for stereotactic breast biopsy
41.21(136C) Suspension, revocation, denial, and reinstatement of authorization for stereotactic breast biopsy

CHAPTER 42
REGISTRATION AND SAFETY REQUIREMENTS FOR THERAPEUTIC USE OF RADIATION MACHINES, PARTICLE ACCELERATORS FOR NONHUMAN USE, AND ANALYTICAL X-RAY EQUIPMENT

42.1(136C) General provisions
42.2(136C) Definitions
42.3(136C) Registration or license requirements
42.4(136C) General administrative requirements for facilities using therapeutic radiation machines
42.5(136C) Training for external beam radiation therapy authorized users
42.6(136C) Training for radiation therapy physicist
42.7(136C) Qualifications of operators
42.8(136C) Written safety procedures and rules
42.9(136C) Exposure to the useful beam
42.10(136C) Records of visiting authorized users
42.11(136C) Information and maintenance record and associated information
42.12(136C) Record retention
42.13(136C) Written directives
42.14(136C) General technical requirements for facilities using therapeutic radiation machines
42.15(136C) Therapeutic radiation machines of less than 500 kV
42.16(136C) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above)
42.17(136C) Shielding and safety design requirements
42.18(136C) Calibration of survey instruments
42.19(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use
42.20(136C) Radiation safety requirements for analytical X-ray equipment

CHAPTER 43
RADON TESTING AND ANALYSIS REQUIREMENTS

43.1(136B) General provisions
43.2(136B) Definitions
43.3(136B) General regulatory requirements
43.4(136B) Application for certification
43.5(136B) Radon measurement certification fees
43.6(136B) Enforcement actions
43.7(136B) Records and reporting requirements
43.8(136B) Continuing education
43.9(136B,280) School district employee measurement training
43.10(136B) Exemptions
43.11(136B) Penalties

CHAPTER 44
RADON MITIGATION REQUIREMENTS

44.1(136B) General provisions
44.2(136B) Definitions
44.3(136B) General regulatory requirements

44.4(136B) Application for credentialing
44.5(136B) Renewal application of annual credentialing
44.6(136B) Radon mitigation credentialing fees
44.7(136B) Enforcement actions
44.8(136B) Records and reporting requirements
44.9(136B) Continuing education
44.10(136B) Exemptions
44.11(136B) Penalties

CHAPTERS 45 to 50
Reserved

CHAPTER 51
DENTAL SCREENING

51.1(135) Definitions
51.2(135) Persons included
51.3(135) Persons excluded
51.4(135) Dental screening components
51.5(135) Dental screening providers
51.6(135) Timeline for valid dental screening
51.7(135) Proof of dental screening
51.8(135) Dental screening documentation
51.9(135) Ensuring dental screening services
51.10(135) Records
51.11(135) Reporting
51.12(135) Release of dental screening information
51.13(135) Referral requirements
51.14(135) Provider training

CHAPTER 52
VISION SCREENING

52.1(135) Definitions
52.2(135) Persons included and persons excluded
52.3(135) Child vision screening components
52.4(135) Timeline for valid vision screening
52.5(135) Proof of child vision screening
52.6(135) Child vision screening reporting
52.7(135) School requirements
52.8(135) Iowa’s child vision screening database module and follow-up
52.9(135) Referral requirements

CHAPTER 53
Reserved

CHAPTER 54
CONCUSSION OR OTHER BRAIN INJURY RETURN-TO-PLAY PROTOCOL

54.1(280) Definitions
54.2(280) Return-to-play protocol

CHAPTER 55
Reserved

CHAPTER 56
BRAIN INJURY SERVICES PROGRAM

56.1(135) Definitions
56.2(135) Waiver-eligible component
56.3(135) Cost-share component
56.4(135) Application process
56.5(135) Service providers and reimbursement
56.6(135) Available services/service plan

56.7(135) Redetermination
56.8(135) Appeal rights

CHAPTERS 57 to 66
Reserved

CHAPTER 67
BLOOD LEAD TESTING
67.1(135) Definitions
67.2(135) Persons included
67.3(135) Persons excluded
67.4(135) Records

CHAPTER 68
CONTROL OF LEAD-BASED PAINT HAZARDS
68.1(135) Definitions
68.2(135) EBL inspections required
68.3(135) Refusal of admittance
68.4(135) Lead hazard reduction required
68.5(135) Retaliation prohibited
68.6(135) Enforcement
68.7(135) Hearings
68.8(135) Variances
68.9(135) Injunction
68.10(135) Effective date

CHAPTERS 69 to 71
Reserved

CHAPTER 72
CHILDHOOD LEAD POISONING
PREVENTION PROGRAM
72.1(135) Definitions
72.2(135) Approved programs

CHAPTERS 73 and 74
Reserved

CHAPTER 75
DISTRIBUTION OF FEDERAL FUNDS RESTRICTIONS—PROVIDER
IDENTIFICATION AND ATTESTATION
75.1(88GA,ch85,90GA,ch19) Definitions
75.2(88GA,ch85,90GA,ch19) Identification numbers
75.3(88GA,ch85,90GA,ch19) Attestation

CHAPTER 76
MATERNAL AND CHILD HEALTH PROGRAM
76.1(135) Definitions
76.2(135) Client eligibility criteria
76.3(135) Client application procedures for MCH services

CHAPTER 77
LOCAL BOARDS OF HEALTH
77.1(137) Definitions
77.2(137) Local boards of health—roles and responsibilities
77.3(137) Organization of local boards of health
77.4(137) Expenses of local board of health members
77.5(137) Dissolution of city boards
77.6(137) Request to form district board of health
77.7(137) Review, approval or denial of district board of health formation

77.8(137) Adding to a district board of health
77.9(137) Withdrawal from a district board of health

CHAPTERS 78 and 79
Reserved

CHAPTER 80
LOCAL PUBLIC HEALTH SERVICES

80.1(135) Definitions
80.2(135) Contractor assurances
80.3(135) Utilization of LPHS contract funding
80.4(135) LPHS funds

CHAPTERS 81 to 87
Reserved

CHAPTER 88
VOLUNTEER HEALTH CARE PROVIDER PROGRAM

88.1(135) Definitions
88.2(135) Eligibility for the volunteer health care provider program
88.3(135) Sponsor entity and protected clinic
88.4(135) Covered health care services
88.5(135) Defense and indemnification
88.6(135) Term of agreement
88.7(135) Reporting necessities and duties
88.8(135) Revocation of agreement
88.9(135) Procedure for revocation of agreement
88.10(135) Effect of suspension or revocation
88.11(135) Protection denied
88.12(135) Board notice of disciplinary action
88.13(135) Effect of eligibility protection
88.14(135) Reporting by a protected clinic or sponsor entity

CHAPTER 89
PARENTAL NOTIFICATION OF INTENT TO
TERMINATE A PREGNANCY THROUGH ABORTION

89.1(135L) Definitions
89.2(135L) Notification of parent prior to the performance of abortion on a pregnant minor
89.3(135L) Notification procedures in the event of an exception

CHAPTER 90
STATE MORTALITY REVIEW COMMITTEE

90.1(135) Definitions
90.2(135) Agency
90.3(135) Membership
90.4(135) Officers
90.5(135) Subcommittees
90.6(135) Liaisons
90.7(135) Meetings
90.8(135) Duties and responsibilities
90.9(135) Disclosure of information
90.10(135) Immunity and liability

CHAPTERS 91 to 93
Reserved

CHAPTER 94
CHILD PROTECTION CENTER GRANT PROGRAM

94.1(135) Definitions
94.2(135) Goals

94.3(135) Review process
94.4(135) Eligibility and criteria
94.5(135) Appeals

CHAPTER 95
VITAL RECORDS: GENERAL ADMINISTRATION

95.1(144) Definitions
95.2(144) Vital records and statistics
95.3(144) Forms—property of department
95.4(144) Information by others
95.5(144) Handling of vital records
95.6(144) Fees
95.7(144) General public access of vital records in the custody of the county registrar
95.8(144) Direct tangible interest in and entitlement to a vital record
95.9(144) Search and issuance of a certified copy of a vital record
95.10(144) Search and issuance for genealogy or family history
95.11(144) Registrars' responsibility for maintenance of confidentiality
95.12(144) Disclosure of data
95.13(144) Preparation of certified copies
95.14(144) Access to original certificate of birth prior to adoption
95.15(144) Certificate of nonviable birth
95.16(144) Cancellation of fraudulent records
95.17(144) Unlawful acts
95.18(144) Enforcement assistance

CHAPTER 96
BIRTH REGISTRATION

96.1(144) Definitions
96.2(144) Forms—property of department
96.3(144) Standard birth registration—up to seven days
96.4(144) Standard birth registration—seven days to one year
96.5(144) Birthing institutions
96.6(144) Non-birthing institutions
96.7(144) Non-institution birth
96.8(144) Gestational surrogate arrangement birth registration
96.9(144) Foundling birth registration
96.10(144) Newborn safe haven registration
96.11(144) Birth registration following a foreign-born adoption
96.12(144) Birth registration fees
96.13(144) Fee collection
96.14(144) Waivers
96.15(144) Fee deposit
96.16(144) Responsibilities of institutions
96.17(144) Responsibility for births occurring in non-institutions and non-birthing institutions
96.18(144) Delayed birth registration—one year or more after event

CHAPTER 97
DEATH REGISTRATION AND DISPOSITION OF DEAD HUMAN BODIES

97.1(144) Definitions
97.2(144) Forms—property of department
97.3(144) Standard registration of death—up to one year
97.4(144) Standard registration of fetal death—up to one year
97.5(144) Preparation of the certificate of death or fetal death
97.6(144) Medical certification of death
97.7(144) Medical certification of fetal death
97.8(144) Medical certifier
97.9(144) Report of autopsy findings
97.10(144) Extension of time
97.11(144) Removal of a dead human body or fetus

97.12(144) Burial-transit permit
97.13(144) Transportation and disposition of a dead human body or fetus
97.14(144) Disinterment permits
97.15(144) Delayed death registration—one year or more after event
97.16(144) Registration of presumptive death
97.17(144) Release or final disposition of a dead human body or fetus by an institution
97.18(144) Additional record by funeral director

CHAPTER 98
MARRIAGE REGISTRATION

98.1(144,595) Definitions
98.2(144,595) Forms—property of department
98.3(144,595) Standard registration of marriage—up to one year
98.4(144,595) Application for a license to marry in Iowa
98.5(144,595) License to marry
98.6(144,595) Certificate of marriage
98.7(144,595) Delayed registration of marriage—one year or more after date of event
98.8(144,595) Dissolution of marriage or annulment

CHAPTER 99
VITAL RECORDS MODIFICATIONS

99.1(144) Definitions
99.2(144) Forms—property of department
99.3(144) Forms used in the establishment of new records
99.4(144) Corrections of minor errors in vital record—within one year of event
99.5(144) Amendment of certificate of live birth to add first or middle given name—within one year of event
99.6(144) Amendment of vital record—one year or more after the event
99.7(144) Method of amendment of vital records
99.8(144) Correction or amendment of same item more than once
99.9(144) Other amendments to certificate of live birth
99.10(144) Correction or substitution of medical certification of cause of death
99.11(144) Correction or amendment to a certificate of marriage
99.12(144) Correction to a report of dissolution of marriage or annulment
99.13(144) Minimum information required to establish a new certificate of live birth
99.14(144) Establishment of new certificate of live birth following adoption
99.15(144) Establishment of new certificate of live birth following a birth by gestational surrogate arrangement
99.16(144) Certificate of live birth following voluntary paternity affidavit
99.17(144) Certificate of live birth following court determination of paternity
99.18(144) Certificate of live birth following rescission of paternity affidavit or disestablishment of paternity
99.19(144) Certificate of live birth following court-ordered change of name
99.20(144) Disestablishment of parentage

CHAPTER 100
VITAL RECORDS REGISTRIES AND REPORTS

100.1(144) Definitions
100.2(144) Forms—property of department
100.3(144) Declaration of paternity registry established
100.4(144) Mutual consent voluntary adoption registry established
100.5(144) Statistical report of termination of pregnancy report

CHAPTERS 101 to 106
Reserved

CHAPTER 107
BOARD-CERTIFIED BEHAVIOR ANALYST AND BOARD-CERTIFIED ASSISTANT BEHAVIOR ANALYST (BCBA/BCaBA) GRANTS PROGRAM

107.1(135) Definitions

107.2(135) Eligibility criteria
107.3(135) Priority in grant awards
107.4(135) Amount of a grant
107.5(135) Use of funds
107.6(135) Review process

CHAPTER 108
Reserved

CHAPTER 109
PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM

109.1(135M) Definitions
109.2(135M) Eligibility criteria for program participation by medical facilities and pharmacies
109.3(135M) Standards and procedures for accepting donated prescription drugs and supplies
109.4(135M) Standards and procedures for inspecting and storing donated prescription drugs and supplies
109.5(135M) Standards and procedures for dispensing donated prescription drugs and supplies
109.6(135M) Eligibility criteria for individuals to receive donated prescription drugs and supplies
109.7(135M) Forms and recordkeeping
109.8(135M) Handling fee
109.9(135M) List of drugs and supplies program will accept
109.10(135M) Prescription drug donation repository in disaster emergencies

CHAPTERS 110 to 112
Reserved

CHAPTER 113
PUBLIC HEALTH RESPONSE TEAMS

113.1(135) Definitions
113.2(135) Public health response team members
113.3(135) Public health response team
113.4(135) Legal and other protections
113.5(135) Reporting requirements and duties

CHAPTERS 114 to 125
Reserved

CHAPTER 126
STATE MEDICAL EXAMINER

126.1(144,331,691) Definitions
126.2(691) Fees for autopsies and related services and reimbursement for related expenses
126.3(691) Fees for tissue recovery

CHAPTER 127
COUNTY MEDICAL EXAMINERS

127.1(144,331,691) Definitions
127.2(331,691) Duties of medical examiners—jurisdiction over deaths that affect the public interest
127.3(331,691) Autopsies
127.4(331,691) Fees
127.5(144,331,691) Death certificates—deaths affecting the public interest
127.6(331,691) Cremation
127.7(331,691) County medical examiner investigators
127.8(331,691) Deputy county medical examiners
127.9(331,691) Failure to comply with rules
127.10(331,691,22) Confidentiality
127.11(331,691,670) Indemnification

CHAPTERS 128 to 130
Reserved

CHAPTER 131
EMERGENCY MEDICAL SERVICES—PROVIDERS—INITIAL CERTIFICATION—RENEWAL AND REACTIVATION—AUTHORITY—COMPLAINTS AND INVESTIGATIONS

131.1(147A,147D,272C) Definitions
131.2(147A,272C) Initial certification
131.3(147A) Background check results
131.4(147A) Authority
131.5(147A) Renewal standards, reactivation procedures, fees, and continuing education
131.6(147A,272C) Discipline—denial, citation and warning, probation, suspension, or revocation of certificates or renewal
131.7(147A) Certification denial
131.8(147A) Emergency adjudicative proceedings
131.9(147A) Complaints, investigations and appeals

CHAPTER 132
EMERGENCY MEDICAL SERVICES—SERVICE PROGRAM AUTHORIZATION

132.1(147A) Definitions
132.2(147A) Service program—authorization and renewal procedures and inspections
132.3(147A) Service program operations
132.4(147A) Waivers
132.5(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal

CHAPTER 133
WHITE FLASHING LIGHT AUTHORIZATION

133.1(321) Definitions
133.2(321) Purpose
133.3(321) Application
133.4(321) Approval, denial, probation, suspension and revocation of authorization

CHAPTER 134
TRAUMA CARE FACILITY CATEGORIZATION AND VERIFICATION

134.1(147A) Definitions
134.2(147A) Trauma care facility categorization and verification
134.3(147A) Complaints, investigations and appeals

CHAPTER 135
TRAUMA TRIAGE AND TRANSFER PROTOCOLS

135.1(147A) Definitions
135.2(147A) Trauma triage and transfer protocols
135.3(147A) Offenses and penalties

CHAPTER 136
TRAUMA REGISTRY

136.1(147A) Definitions
136.2(147A) Trauma registry
136.3(147A) Offenses and penalties

CHAPTER 137
TRAUMA EDUCATION AND TRAINING

137.1(147A) Definitions
137.2(147A) Initial trauma education requirements
137.3(147A) Continuing trauma education requirements

CHAPTER 138
Reserved

CHAPTER 139
EMERGENCY MEDICAL SERVICES—TRAINING PROGRAMS—STUDENTS—COMPLAINTS AND INVESTIGATIONS

139.1(147A) Definitions
139.2(147A) Initial application, renewal application, inspection and approval
139.3(147A) Training program standards, student requirements and waivers
139.4(147A) Out-of-state training programs
139.5(147A) Failure to comply with rules
139.6(147A) Temporary waivers
139.7(147A) Continuing education providers—approval, recordkeeping and inspection
139.8(147A) Discipline—denial, citation and warning, probation, suspension, or revocation of training program approval or renewal
139.9(147A) Complaints, investigations and appeals

CHAPTER 140
EMERGENCY MEDICAL SERVICES SYSTEM DEVELOPMENT GRANTS FUND

140.1(135) Definitions
140.2(135) County EMS associations
140.3(135) County EMS system development grants

CHAPTER 141
Reserved

CHAPTER 142
OUT-OF-HOSPITAL DO-NOT-RESUSCITATE ORDERS

142.1(144A) Definitions
142.2(144A,147A) Responsibilities of the department
142.3(144A,147A) EMS providers
142.4(144A) Guidelines for non-EMS health care providers, patients, and organizations
142.5(144A) Revocation of the out-of-hospital do-not-resuscitate order
142.6(144A) Personal wishes of family members or other individuals who are not authorized to act on the patient's behalf
142.7(144A) Transfer of patients
142.8(144A) Application to existing orders

CHAPTER 143
AUTOMATED EXTERNAL DEFIBRILLATOR MAINTENANCE

143.1(613) Definition
143.2(613) AED maintenance

CHAPTERS 144 and 145
Reserved

CHAPTER 146
STROKE CARE REPORTING

146.1(135) Definitions
146.2(135) Stroke care reporting
146.3(135) Method and frequency of reporting
146.4(135) Confidentiality
146.5(135) Penalties and enforcement

CHAPTERS 147 to 149
Reserved

CHAPTER 150
IOWA REGIONALIZED SYSTEM OF PERINATAL HEALTH CARE

150.1(135) Participation and designation
150.2(135) Definitions
150.3(135) Duties of statewide perinatal care team

150.4(135) Duties of the department
150.5(135) Maternal and neonatal levels of care—categorization and verification
150.6(135) Levels of maternal care
150.7(135) Maternal-fetal transport—all levels
150.8(135) Levels of neonatal care
150.9(135) Grant or denial of certificate of verification; and offenses and penalties
150.10(135) Prohibited acts
150.11(135) Construction of rules

CHAPTERS 151 and 152
Reserved

CHAPTER 153
SMOKEFREE AIR

153.1(142D) Definitions
153.2(142D) Duties of employers, owners, operators, managers, and persons having custody or control of a public place, place of employment, area declared nonsmoking pursuant to Iowa Code chapter 142D or outdoor areas where smoking is prohibited
153.3(142D) Leases
153.4(142D) Complaints and enforcement
153.5(142D) Limitation of rules

CHAPTER 154
MEDICAL CANNABIDIOL PROGRAM

154.1(124E) Definitions

REGISTRATION CARDS

154.2(124E) Health care practitioner certification—duties and prohibitions
154.3(124E) Medical cannabidiol registration card—application and issuance to patient
154.4(124E) Medical cannabidiol registration card—reciprocity
154.5(124E) Medical cannabidiol registration card—application and issuance to primary caregiver
154.6(124E) Denial and cancellation
154.7(124E) Appeal
154.8(124E) Duplicate card
154.9(124E) Renewal
154.10(124E) Confidentiality
154.11(124E) Registration card fees
154.12(124E) Consumption of medical cannabidiol
154.13(124E) Allowable forms of medical cannabidiol

MANUFACTURER AND DISPENSARY LICENSING

154.14(124E) Notice to law enforcement
154.15(124E) Manufacturer and dispensary licensure
154.16(124E) Collection of fees in competitive licensing
154.17(124E) Licensure renewal
154.18(124E) Suspension or revocation of a manufacturing or dispensary license
154.19(124E) Assessment of penalties
154.20(124E) Closure of operations
154.21(124E) Manufacturer and dispensary security requirements
154.22(124E) Advertising and marketing
154.23(124E) Sales and inventory tracking system
154.24(124E) Financial transactions
154.25(124E) Inspection by department or independent consultant

MANUFACTURING

154.26(124E) Manufacturer operations
154.27(124E) Recordkeeping requirements
154.28(124E) Recall of medical cannabidiol products
154.29(124E) Quality assurance and control
154.30(124E) Packaging and labeling
154.31(124E) Transportation of medical cannabidiol and plant material
154.32(124E) Disposal of medical cannabidiol and plant material

154.33(124E) Production requirements
154.34(124E) Supply and inventory

DISPENSING

154.35(124E) Duties of the department
154.36(124E) Dispensary operations
154.37(124E) Recordkeeping requirements
154.38(124E) Storage
154.39(124E) Dispensing
154.40(124E) Transportation of medical cannabidiol
154.41(124E) Disposal of medical cannabidiol
154.42(124E) Inventory
154.43(124E) Quality assurance and control

MEDICAL CANNABIDIOL BOARD

154.44(124E) Purpose and duties of board
154.45(124E) Organization of board and proceedings
154.46(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases

LABORATORY TESTING

154.47(124E) Requirements of the department
154.48(124E) Requirements of a laboratory
154.49(124E) Requirements of a manufacturer
154.50(124E) Content testing
154.51(124E) Reporting requirements
154.52(124E) Recordkeeping requirements
154.53(124E) Quality control
154.54(124E) Security requirements

CHAPTER 155
LICENSURE STANDARDS FOR SUBSTANCE USE DISORDER AND PROBLEM GAMBLING TREATMENT PROGRAMS

155.1(125,135) Definitions
155.2(125,135) Licensing
155.3(125,135) Types of licenses
155.4(125,135) Nonassignability
155.5(125,135) Application procedures
155.6(125,135) Technical assistance
155.7(125,135) Inspection of applicants
155.8(125,135) License—approval
155.9(125,135) Written corrective action plan
155.10(125,135) Grounds for denial of license
155.11(125,135) Denial, suspension or revocation of a license
155.12 to 155.14 Reserved
155.15(125,135) Issuance of a license after denial, suspension or revocation
155.16(125,135) Complaints and investigations
155.17(125,135) License revision
155.18(125,135) Deemed status
155.19(125,135) Funding
155.20(125,135) Inspection
155.21(125,135) General standards for all programs
155.22(125,135) Inpatient and residential program facilities
155.23(125,135) Specific standards for inpatient and residential programs
155.24(125,135) Specific standards for inpatient and residential programs licensed to provide services to juveniles
155.25(125,135) Specific standards for substance use assessment and OWI evaluation-only programs
155.26 to 155.33 Reserved
155.34(125,135) Specific standards for enhanced treatment services
155.35(125,135) Specific standards for opioid treatment programs

TUBERCULOSIS (TB) SCREENING: HEALTH CARE WORKERS AND RESIDENTS

155.36 Reserved

155.37(125,135) Definitions
155.38(125,135) Tuberculosis screening of staff and residents

CHAPTER 156
CONSUMABLE HEMP PRODUCTS

156.1(204) Definitions
156.2(204) Registration and posting
156.3(204) Testing requirements and documentation
156.4(204) Packaging and labeling
156.5(204) Applicability of other laws and regulations
156.6(204) Prohibitions
156.7(204) Violations and enforcement
156.8(204) Denial, suspension, or revocation of registration
156.9(204) Inspection and access to records
156.10(204) Public examination of records
156.11(204) Appeals

CHAPTER 157
STANDARDS FOR SUBSTANCE ABUSE TREATMENT AND ASSESSMENT PROGRAMS AND THE OPERATING A MOTOR VEHICLE WHILE INTOXICATED (OWI) LAW

157.1(125) Definitions
157.2(125) Screening, evaluation, treatment, and drinking drivers course
157.3(125) Screening, evaluation, treatment, and drinking drivers course completion
157.4(125) Cost of evaluation and treatment
157.5(125) Timeliness
157.6(125) Confidentiality
157.7(125) Records
157.8(125) Reciprocity

CHAPTERS 158 to 176
Reserved

CHAPTER 177
HEALTH DATA

177.1(76GA,ch1212) Definitions
177.2(76GA,ch1212) Description of data to be submitted
177.3(76GA,ch1212) Fees
177.4(76GA,ch1212) Patient confidentiality

CHAPTERS 178 to 191
Reserved

CHAPTER 192
CHILD SUPPORT NONCOMPLIANCE

192.1(252J) Definitions
192.2(252J) Denial of issuance or renewal of a license or suspension or revocation of a license
192.3(17A,22,252J) Sharing of information

CHAPTER 193
Reserved

CHAPTER 194
NONPAYMENT OF STATE DEBT

194.1(272D) Definitions
194.2(272D) Denial of issuance or renewal of a license or suspension or revocation of a license
194.3(272D) Sharing of information

CHAPTER 195
Reserved

CHAPTER 196
EMERGENCY MEDICAL SERVICES—MILITARY SERVICE, VETERAN RECIPROCITY, AND SPOUSES OF ACTIVE DUTY SERVICE MEMBERS

196.1(272C) Definitions
196.2(272C,147D) Military education, training, and service credit
196.3(272C,147D) Veteran and active duty military spouse privilege to practice

CHAPTER 1
REPORTABLE DISEASES, POISONINGS AND CONDITIONS, AND QUARANTINE AND ISOLATION

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/17/29

641—1.1(139A) Definitions. For the purpose of these rules, the following definitions will apply:

"AIDS" means the same as defined in Iowa Code chapter 141A.

"Area quarantine" means the same as defined in Iowa Code chapter 139A.

"Business" means the same as defined in Iowa Code chapter 139A.

"Care provider" means the same as defined in Iowa Code chapter 139A.

"Case" means an individual who has confirmatory evidence of disease.

"Clinical laboratory" means any laboratory performing analyses on specimens taken from the body of a person in order to assess that person's health status.

"Communicable disease" means the same as defined in Iowa Code chapter 139A.

"Congenital or inherited disorder" means any congenital disorder as defined in Iowa Code chapter 136A or any inherited disorder as defined in Iowa Code chapter 136A.

"Disease surveillance" means the ongoing, systematic collection, analysis, and interpretation of health-related data essential for planning, implementation, and evaluation of public health programs and practices.

"Exposure" means contact with an agent in a manner that could cause disease or infection.

"HBV" means the same as defined in Iowa Code chapter 139A.

"Health care facility" means the same as defined in Iowa Code chapter 139A.

"Health care provider" means the same as defined in Iowa Code chapter 139A.

"HIV" means the same as defined in Iowa Code chapter 141A.

"Hospital" means the same as defined in Iowa Code chapter 135B.

"IDSS" means the Iowa disease surveillance system, a secure electronic statewide disease reporting and surveillance system.

"Infectious disease" means a disease caused by the entrance into the body of organisms, including but not limited to bacteria, protozoans, fungi, prions, or viruses that grow and multiply.

"Infectious tuberculosis" means pulmonary or laryngeal tuberculosis as evidenced by:

1. Isolation of M. tuberculosis complex (positive culture) from a clinical specimen or positive nucleic acid amplification test, or

2. Both radiographic evidence of tuberculosis, such as an abnormal chest X ray, CT, PET or MRI scan, and clinical evidence, such as a positive skin test or whole blood assay test for tuberculosis infection, coughing, sputum production, fever, or other symptoms compatible with infectious tuberculosis that lead a health care provider to diagnose infectious tuberculosis according to currently acceptable standards of medical practice and to initiate treatment for tuberculosis.

"Investigation" means an inquiry conducted to determine the specific source, mode of transmission, and cause of a disease or suspected disease occurrence and to determine the specific incidence, prevalence, and extent of the disease in the affected or general population. "Investigation" may also include the application of scientific methods and analysis to institute appropriate control measures.

"Isolation" means the same as defined in Iowa Code chapter 139A.

"Local board" means the same as defined in Iowa Code chapter 139A.

"Local department" means the same as defined in Iowa Code chapter 139A.

"Placard" means the same as defined in Iowa Code chapter 139A.

"Poison control or poison information center" means any organization or program that has as one of its primary objectives the provision of toxicologic and pharmacologic information and referral services to the public and to health care providers (other than pharmacists) in response to inquiries about actual or potential poisonings.

"Public health disaster" means an incident as defined in Iowa Code section 135.140.

"Quarantinable disease" means any communicable disease that presents a risk of serious harm to public health and that may require isolation or quarantine to prevent its spread. "Quarantinable disease"

includes but is not limited to cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, novel influenza, and severe acute respiratory syndrome (SARS).

"Quarantine" means the same as defined in Iowa Code chapter 139A.

"Reportable cancers" means those cancers included in the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program.

"Reportable disease" means any disease or condition approved by the state epidemiologist or medical director and designated by this chapter.

"Sexually transmitted disease or infection" or *"STI"* means a disease or infection as identified by this chapter that is transmitted through sexual practices. "Sexually transmitted disease or infection" includes but is not limited to acquired immunodeficiency syndrome (AIDS), chlamydia, gonorrhea, hepatitis B, hepatitis C, human immunodeficiency virus (HIV), human papillomavirus, and syphilis.

"Suspected case" means an individual who presents with clinical signs or symptoms indicative of a reportable or quarantinable disease.

"Toxic agent" means any noxious substance in solid, liquid or gaseous form capable of producing illness in humans including but not limited to pesticides as defined in Iowa Code chapter 206, heavy metals, organic and inorganic dusts and organic solvents. Airborne toxic agents may be in the form of dusts, fumes, vapors, mists, gases or smoke.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24]

641—1.2(139A) Authority. The director is the principal officer of the state to administer disease, poisoning and condition, and incident reporting and control. The Iowa Cancer Registry, administered by the Department of Epidemiology of the College of Public Health at the University of Iowa, is a public health authority for purposes of collecting cancer data in accordance with this chapter.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24]

641—1.3(139A,141A) Reportable communicable and infectious diseases, poisonings or conditions, and cancers. Reportable communicable and infectious diseases, poisonings and conditions under this chapter are those listed in Appendices A and B. The director may also designate any disease, poisoning or condition or syndrome temporarily reportable for the purpose of a special investigation.

1.3(1) *Cancer.* Pursuant to Public Law 92-218 and Public Law 102-515, each occurrence of a reportable cancer that is diagnosed or treated in an Iowa resident or occurs in a nonresident who is diagnosed or treated in an Iowa facility shall be reported to the Iowa Cancer Registry.

1.3(2) *Congenital and inherited disorders.* Each occurrence of a congenital and inherited disorder that is diagnosed or treated in an Iowa resident or occurs in a nonresident who is diagnosed or treated in an Iowa facility is a reportable condition pursuant to Iowa Code chapter 136A, and records of these congenital and inherited disorders shall be abstracted and maintained in a central registry. Congenital and inherited disorder surveillance shall be performed to determine the occurrence and trends of congenital and inherited disorders, to conduct thorough and complete epidemiological surveys, to assist in the planning for and provision of services to children with congenital and inherited disorders and their families, and to identify environmental and genetic risk factors for congenital and inherited disorders.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24]

641—1.4(135,139A) Reporting requirements.

1.4(1) *Who is required to report.*

a. Communicable and infectious diseases, and poisonings.

(1) Health care providers, hospitals, and clinical laboratories and other health care facilities are required to report cases of reportable diseases, poisonings and conditions. Health care providers and hospitals are exempted from reporting communicable and infectious disease laboratory results and blood lead testing if the health care provider or hospital ensures that the laboratory performing the analysis provides a report containing the required information to the department.

(2) School nurses are required to report suspected cases of a reportable disease, poisoning or condition occurring among the children supervised.

(3) Poison control and poison information centers are required to report inquiries about cases of a reportable disease, poisoning or condition received by them.

(4) Medical examiners are required to report their investigatory findings of any death that was caused by or otherwise involved a reportable disease, poisoning or condition.

(5) Occupational nurses are required to report cases of reportable diseases, poisonings and conditions.

(6) Hospitals, health care providers and clinical laboratories outside the state of Iowa shall immediately report any confirmed or suspected case of a reportable disease, poisoning or condition in an Iowa resident.

b. Reportable cancers. Health care providers, hospitals, clinical laboratories and health care facilities involved in the diagnosis, care or treatment of individuals are required to report individuals with a reportable cancer.

c. Congenital and inherited disorders. Health care providers, clinics, clinical laboratories and other health care facilities are required to report cases of a congenital or inherited disorder.

1.4(2) *What to report.* Each report will contain all information as listed in Iowa Code chapter 139A, in addition to:

a. For communicable and infectious diseases:

(1) The name of the reportable disease.

(2) The treatment provided for the reportable disease.

b. For poisonings:

(1) The analytical result.

(2) In the case of blood lead testing, whether the sample is a capillary or venous blood sample.

(3) For conditions not identified by a laboratory analysis, the date that the condition was diagnosed.

(4) In the case of occupational conditions, the name of the patient's employer.

c. For reportable cancers:

(1) Follow-up data.

(2) Demographic, diagnostic, prognostic, treatment, and other medical information.

d. For congenital and inherited conditions:

(1) Follow-up data.

(2) Demographic, diagnostic, treatment and other medical information.

(3) Tissue samples, which may also be submitted.

1.4(3) *How to report.* Information on when and how to report any of the diseases, conditions, or injuries included in this chapter can be found in Appendices A and B.

a. Immediate reporting by telephone of diseases identified as immediately reportable. A health care provider and a public, private, or hospital clinical laboratory will immediately report any confirmed or suspect case of a disease identified in Appendix A as immediately reportable to the department.

b. Other diseases that carry serious consequences or spread rapidly. A health care facility, health care provider and a public, private, or hospital clinical laboratory will immediately report any confirmed or suspected case of a common source epidemic or disease outbreak of unusual numbers.

c. Reporting to other public health authorities. The department may authorize hospitals, health care providers or clinical laboratories outside the state of Iowa to report any confirmed or suspect case of a reportable disease, poisoning, or condition to another public health authority for the purpose of facilitating a report to the department.

d. Cancers. The department has delegated to the Iowa Cancer Registry the responsibility for collecting cancer data.

(1) Those required to report shall submit required data to the Iowa Cancer Registry monthly, in an electronic format specified by the Iowa Cancer Registry. Those required to report may employ registrars with Iowa Cancer Registry-approved training, or contract with the Iowa Cancer Registry or an outside vendor to submit reportable cancer cases and required data elements to the Iowa Cancer Registry.

(2) As needed for SEER surveillance activities, the Iowa Cancer Registry shall have remote electronic access, where available, or physical access to all cancer-relevant medical records.

e. Congenital and inherited disorders. The department has delegated to the Iowa Registry for Congenital and Inherited Disorders the responsibility to maintain a central registry for congenital and inherited disorders. The Iowa Registry for Congenital and Inherited Disorders shall:

(1) Prior to collecting the data from health care providers, hospitals, clinics, clinical laboratories and other health care facilities, work with the reporting facility to develop a process for abstracting records that is agreeable to the reporting facility.

(2) Develop and distribute reporting forms where applicable.

(3) Develop an abstracting process for data to be supplemented with information obtained from records from hospitals, treatment centers, outpatient centers, clinics, pathology laboratories and physician offices.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24]

INVESTIGATION

641—1.5(135,139A) Investigation of reportable diseases.

1.5(1) A health care provider and a public, private, or hospital clinical laboratory will provide the department, local board, or local department with all information necessary to conduct the investigation, including but not limited to medical records; exposure histories; medical histories; contact information; and test results necessary to the investigation, including positive, pending, and negative test results.

1.5(2) Issuance of investigatory subpoenas.

a. The department may, upon the written request of a local board of health, the state public health medical director or the state public health epidemiologist or designee, subpoena records, reports, or any other evidence necessary to conduct a disease investigation. The subpoena will be signed by the department following review and approval of the written request for subpoena.

b. Process to challenge a subpoena. Any person who is aggrieved or adversely affected by compliance with the subpoena and who desires to challenge the subpoena shall follow 441—Chapter 2506.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24; Editorial change: IAC Supplement 6/10/26]

ISOLATION AND QUARANTINE

641—1.6(135,193A) Isolation and quarantine. Isolation and quarantine should be consistent with guidelines provided by the Centers for Disease Control and Prevention.

1.6(1) *General provisions.*

a. Voluntary confinement. Prior to instituting mandatory isolation or quarantine pursuant to this rule, the department or a local board of health may request that an individual or group of individuals voluntarily confine themselves to a private home or other facility.

b. Quarantine and isolation. The department and local boards of health are authorized to impose and enforce quarantine and isolation restrictions. Quarantine and isolation shall rarely be imposed by the department or by local boards of health. If a quarantinable disease occurs in Iowa, individuals with a suspected or active quarantinable disease and contacts to the case may be quarantined or isolated as the particular situation requires. Any quarantine or isolation imposed by the department or a local board of health shall be established and enforced in accordance with this rule.

1.6(2) *Issuance of isolation or quarantine orders.* The department or the local board of health may isolate or quarantine an individual or groups of individuals, and area quarantine in the rarest of instances, through a written order issued pursuant to this rule. The isolation or quarantine of an individual or group, whether during a declared state of emergency or not, shall be conducted as follows:

a. A written administrative order to isolate or quarantine an individual or group of individuals shall be issued when voluntary measures are deemed impracticable or ineffective. Orders shall become effective immediately upon issuance.

b. Orders for isolation and quarantine may include, without limitation, confinement in a residence or other private or public premises including medical and nonmedical facilities; conditions on travel or behavior; and exclusion of individuals or groups from certain places, including but not limited to school, workplace, public conveyances, and other places where members of the public may congregate; or a

requirement that a person self-monitor specified health conditions (e.g., body temperature) and report the findings.

c. Administrative orders to isolate or quarantine an individual or a group of individuals may be issued orally if delay in imposing the isolation or quarantine would pose a serious imminent danger to the public health. If an oral order is issued, a written order shall be issued as soon as is reasonably possible, but in no event later than 24 hours following the issuance of the oral order.

d. A copy of the written order shall be provided to the individual to be isolated or quarantined or, if that is not possible, by any means reasonably calculated to provide actual notice. If the order applies to a group of individuals and it is impractical to provide individual copies, the order shall be posted in a conspicuous place in the isolation or quarantine premises.

e. The order of isolation or quarantine shall include the following:

(1) Full name and address of person or description of the group subject to the order.

(2) The clinical grounds for believing that the individual or group is infected with, or may have been exposed to, a communicable disease.

(3) The location where the individual or group will be confined during the period of isolation or quarantine.

(4) The exact date and time when the period of isolation or quarantine will expire. If it is not possible to fix an exact date, the order should specify the conditions or circumstances under which the individual or group would no longer pose a threat to the public health and confinement would end (e.g., the disappearance or absence of specified clinical symptoms).

(5) The conditions under which the individual or group will be isolated or quarantined.

(6) Notice of right to challenge the isolation or quarantine.

f. When individuals or groups are isolated or quarantined, whether through an administrative order or through voluntary compliance, the department or county board of health shall determine what method and place of isolation or quarantine is appropriate based upon the suitability of an individual's home or other designated facility and the services available.

g. To the greatest extent that it is possible to do so without jeopardizing the integrity of the isolation or quarantine, the authority issuing the isolation or quarantine order shall preserve and facilitate the ability of isolated and quarantined individuals to communicate with the outside world and, in particular, to exchange confidential communications with legal and medical advisors of their choice.

h. A person diagnosed with or clinically suspected of having infectious tuberculosis shall complete voluntary treatment until, in the opinion of the health care provider or the state public health medical director and epidemiologist, the person's tuberculosis is cured or such person is no longer a threat to public health. If such person refuses to complete the course of voluntary treatment, the department or local board of health may issue an order compelling mandatory treatment. Such order shall include the identity of the person subject to the mandatory treatment order, a description of the treatment ordered, the medical basis upon which the treatment is ordered, and a description of the potential medical and legal consequences of violating such order. A person who violates a mandatory treatment order may be subject to the penalties provided in Iowa Code section 135.38 or 137.117 and may be placed under mandatory quarantine or isolation in accordance with the provisions of this chapter.

1.6(3) *Appeal from department order imposing isolation or quarantine.*

a. Individuals have the right to appeal an order imposing isolation or quarantine. Appeal procedures for department orders are as laid forth in 441—Chapter 2506.

b. A request for a hearing shall not stay an isolation or quarantine order unless by order of the issuing department or board, or by a district court.

1.6(4) *Appeal from a local board of health order imposing isolation or quarantine.*

a. Appeal. The subject of a board order imposing isolation or quarantine may appeal a written order by submitting a written appeal within ten days of receipt of the written order. The appeal shall be addressed to the issuing board. Unless stayed by order of the board or a district court, the written order for quarantine or isolation shall remain in force and effect until the appeal is finally determined and disposed of upon its merits.

b. Proceeding. The appeal proceeding shall be conducted in accordance with this rule and specific local board of health rules governing appeal proceedings. The proceeding shall be held as soon as is practicable and in no case later than ten days from the date of receipt of the appeal. The hearing may be held by telephonic or other electronic means if necessary to prevent additional exposure to the communicable or possibly communicable disease. In extraordinary circumstances and for good cause shown, the board may continue the proceeding date for up to ten days, giving due regard to the rights of the affected individuals, the protection of the public's health, and the availability of necessary witnesses and evidence. At the appeal proceeding, the subject of the appeal shall have the right to introduce evidence on all issues relevant to the order. The board, by majority vote, may modify, withdraw, or order compliance with the order under appeal.

c. Judicial review. The aggrieved party to the final decision of the board may petition for judicial review of that action by filing an action in the appropriate district court. Petitions for judicial review shall be filed within 30 days after the decision becomes final.

d. Immediate judicial review of board order. The board acknowledges that in certain circumstances the subject or subjects of a board order may desire immediate judicial review of a board order in lieu of proceeding with the board's appeal process. The board may consent to immediate jurisdiction of the district court when requested by the subject or subjects of a board order and justice so requires. Unless stayed by order of the board or a district court, the written order for quarantine or isolation shall remain in force and effect until the judicial review is finally determined and disposed of upon its merits.

1.6(5) *Implementation and enforcement of isolation and quarantine.*

a. Jurisdictional issues. The department has primary jurisdiction to isolate or quarantine individuals or groups of individuals if the communicable disease outbreak has affected more than one county or has multicounty, statewide, or interstate public health implications. When imposing isolation or quarantine, the department will coordinate with the local health department as appropriate. If isolation or quarantine is imposed by the department, a local board of health or local health department may not alter, amend, modify, or rescind the isolation or quarantine order.

b. Assistance of local boards of health and local health departments. If isolation or quarantine is imposed by the department, the local boards of health and the local health departments in the affected areas will assist in the implementation of the isolation or quarantine order.

c. Assistance of law enforcement. Pursuant to Iowa Code chapter 135, all peace officers of the state will enforce and execute a lawful department order for isolation or quarantine within their respective jurisdictions. The department will take all reasonable measures to minimize the risk of exposure to peace officers and others assisting with enforcement of an isolation or quarantine order.

d. Penalty. Violation of a lawful isolation or quarantine order will be subject to penalties pursuant to Iowa Code chapter 135.

e. Enforcement action. The department may file a civil action in the Polk County district court or in the district court for the county in which the individual resides or is located to enforce a department order for isolation or quarantine. Such action will be filed in accordance with the Iowa Rules of Civil Procedure.

1.6(6) *Control of isolation and quarantine premises.*

a. The department or local board of health may authorize physicians, health care workers, or others access to individuals in isolation or quarantine as necessary to meet the needs of isolated or quarantined individuals.

b. No person shall enter isolation or quarantine premises unless authorized to do so by the department or local board of health.

c. Any person entering isolation or quarantine premises may be required to wear personal protective equipment or receive vaccination or any other preventative care as appropriate.

d. Any person entering isolation or quarantine premises, with or without authorization, may be subject to an order of quarantine as deemed medically necessary.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24; Editorial change: IAC Supplement 6/10/26]

641—1.7(139A,22) Confidentiality. Reportable disease records and information, with the exception of AIDS and HIV records, that identify a person or a business named in a report may be disclosed under the following limited circumstances:

1.7(1) By and between department employees and agents who have a need for the record in the performance of their duties.

1.7(2) By and between department employees and agents and local boards of health and local health departments as necessary to conduct disease surveillance and investigation, to the extent necessary to protect the health or life of the named party, or to enforce a department order or an order of a local board of health.

1.7(3) By and between department employees and agents and health care providers, laboratories, and hospitals as necessary to conduct disease surveillance or an investigation, to the extent necessary to protect the health or life of the named party, or to enforce a department order or an order of a local board of health.

1.7(4) By and between department employees and agents and employees and agents of federal, state, and local agencies as necessary to conduct disease surveillance or an investigation or to enforce a department order or an order of a local board of health.

1.7(5) By and between department employees and agents and employees and agents of tribes and tribal public health authorities as necessary to conduct disease surveillance or an investigation or to enforce a department order or an order of a local board of health.

1.7(6) Reportable disease information may be included in an isolation or quarantine order or placard as necessary to prevent the spread of a quarantinable disease.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24]

STATE HYGIENIC LABORATORY

641—1.8(135,139A) Specimens for which the fee charged by the state hygienic laboratory will be waived. Pursuant to Iowa Code section 263.8, the state hygienic laboratory will waive testing fees for conditions deemed to be of public health significance by the department with approval from the state medical director or the state epidemiologist. A list of conditions and the criteria for which the fee is waived can be found on the HHS website.

[**ARC 8070C**, IAB 6/12/24, effective 7/17/24]

APPENDIX A

Iowa Department of Health and Human Services

Table of Reportable Communicable and Infectious Diseases

Report cases of the diseases listed in the following table to the department within the time frame specified in the When to Report column and by the reporting method in the How to Report column.

To report diseases immediately, use the 24/7 disease reporting telephone hotline: 1-800-362-2736.

IMMEDIATELY report diseases, syndromes, poisonings and conditions of any kind suspected or caused by a biological, chemical, or radiological agent or toxin when there is reasonable suspicion that the disease, syndrome, poisoning or condition may be the result of a deliberate act such as terrorism.

IMMEDIATELY report to the department outbreaks of any kind, diseases that occur in unusual numbers or circumstances, unusual syndromes, or uncommon diseases. Outbreaks may be infectious, environmental or occupational in origin and include food-borne outbreaks or illness secondary to chemical exposure (e.g., pesticides, anhydrous ammonia).

Report diseases by:
Entering into the Iowa Disease Surveillance System (IDSS): For IDSS-related questions, call the Center for Acute Disease Epidemiology (CADE) at 1-800-362-2736.

Fax: (515)281-5698

Mail:
Iowa Department of Health and Human Services
Center for Acute Disease Epidemiology
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319

Isolates or specimens shall be sent to:
State Hygienic Laboratory at the University of Iowa (SHL)
U of I Research Park
2490 Crosspark Road
Coralville, Iowa 52241-4721

For specimen submission questions, call (319)335-4500 or go to www.shl.uiowa.edu.

Diseases	When to Report	How to Report
Acquired immune deficiency syndrome (AIDS) and AIDS-defining conditions	7 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Phone (515)322-8819 or mail ● Health care providers: use the Pediatric or Adult Confidential Case Report Form ● Laboratories: send copy of lab report or the Iowa Confidential Report of Sexually Transmitted Disease & HIV Infection. Mark envelope “Attention 03”

Diseases	When to Report	How to Report
		For HIV/AIDS-related questions, call (515)322-8819
Acute Flaccid Myelitis (AFM)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Anthrax	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Botulism (including infant botulism)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Brucellosis (Brucella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Campylobacteriosis (Campylobacter)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Candida auris	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Carbapenemase-Producing Organisms (CPO)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Chlamydia	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Phone (515)281-3031, IDSS, fax (515)725-1278 or mail ● Use the Iowa Confidential Report of Sexually Transmitted Disease ● Mark envelope “Attention 00”
Cholera	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax Laboratories: send isolate or specimen to the SHL
Cronobacter invasive infection (in infants)	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax
Cryptosporidiosis	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Cyclospora	3 days	Report for Iowa residents. Phone, IDSS, fax or mail Laboratories: send isolate or specimen to the SHL
Cytomegalovirus (CMV)	3 days	Report for Iowa residents. IDSS or fax: 1-515-242-6013
Diphtheria	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Escherichia coli shiga toxin-producing and related diseases (includes HUS and TTP)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail Laboratories: send isolate or specimen to the SHL

Diseases	When to Report	How to Report
Giardiasis (Giardia)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Gonorrhea	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Phone (515)281-3031, IDSS, fax (515)725-1278 or mail ● Use the Iowa Confidential Report of Sexually Transmitted Disease ● Mark envelope "Attention 00"
Haemophilus influenzae type B invasive disease	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736 Laboratories send isolate or specimen to the SHL
Hansen's disease (leprosy)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Hantavirus syndromes	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Hepatitis A	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax
Hepatitis B, C, D, E	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Human immunodeficiency virus (HIV) cases Death of a person with HIV Perinatally exposed newborn and child (newborn and child who was born to an HIV-infected mother)	7 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Phone (515)322-8819 or mail ● Health care providers: use the Pediatric or Adult Confidential Case Report Form ● Laboratories: send copy of lab report or the Iowa Confidential Report of Sexually Transmitted Disease & HIV Infection. Mark envelope "Attention 03" **For HIV/AIDS-related questions, call (515)322-8819**
Legionellosis (Legionella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Listeria monocytogenes invasive disease	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax Laboratories: send isolate or specimen to the SHL
Malaria	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Measles (rubeola)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Meningococcal invasive disease	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa.

Diseases	When to Report	How to Report
		24/7 disease reporting telephone hotline: 1-800-362-2736 Laboratories: send isolate or specimen to the SHL
Mosquito-borne diseases (e.g., chikungunya, dengue, eastern equine encephalitis, Jamestown Canyon, La Crosse, St. Louis, Venezuelan equine encephalitis, West Nile, western equine encephalitis and Zika)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Mpox	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax
Mumps	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with COVID-19	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Pertussis	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Plague	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Poliomyelitis	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Psittacosis	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Q fever	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Rabies, animal	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Rabies, human	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Rubella (including congenital)	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax
Salmonellosis (Salmonella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail Laboratories: send isolate or specimen to the SHL
Severe acute respiratory syndrome (SARS)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Shigellosis (Shigella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail Laboratories: send isolate or specimen to the SHL

Diseases	When to Report	How to Report
Smallpox	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Syphilis	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Phone (515)281-3031, IDSS, fax (515)725-1278 or mail ● Use the Iowa Confidential Report of Sexually Transmitted Disease ● Mark envelope "Attention 00"
Tetanus	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Tickborne diseases (e.g., alpha-gal syndrome, anaplasmosis, babesiosis, Bourbon virus disease, ehrlichiosis, Heartland virus disease, Lyme disease, Powassan virus disease, spotted fever group rickettsioses and tickborne relapsing fever)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Tuberculosis, pulmonary and laryngeal (infectious)	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone (515)281-7504, IDSS or fax (515)281-4570
Tuberculosis, extrapulmonary	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone (515)281-7504, IDSS or fax (515)281-4570
Tularemia	3 days	Report for Iowa residents. Phone, IDSS or fax
Typhoid fever	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax
Vancomycin intermediate Staphylococcus aureus (VISA) and vancomycin-resistant Staphylococcus aureus (VRSA)	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax Laboratories: send isolate or specimen to the SHL
Viral hemorrhagic fever (VHF) (e.g., Lassa, Marburg, Ebola, and Crimean-Congo)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Yellow fever	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736

APPENDIX B

Iowa Department of Health and Human Services

Table of Reportable Poisonings and Conditions

Report cases of the poisonings and conditions listed in the following table to the department within the time frame specified in the When to Report column and by the reporting method in the How to Report column.

To report diseases immediately, use the 24/7 disease reporting telephone hotline: 1-800-362-2736.

IMMEDIATELY report diseases, syndromes, poisonings and conditions of any kind suspected or caused by a biological, chemical, or radiological agent or toxin when there is reasonable suspicion that the disease, syndrome, poisoning or condition may be the result of a deliberate act such as terrorism.

IMMEDIATELY report to the department outbreaks of any kind, diseases that occur in unusual numbers or circumstances, unusual syndromes, or uncommon diseases. Outbreaks may be infectious, environmental or occupational in origin and include food-borne outbreaks or illness secondary to chemical exposure (e.g., pesticides, anhydrous ammonia).

Mailing address:
Bureau of Environmental Health Services
Iowa Department of Health and Human Services
321 East 12th Street
Des Moines, Iowa 50319-0075

Telephone: 1-800-972-2026

Fax: (515)281-4529

Poisoning or Condition	Cases to Report	When to Report	How to Report
Arsenic poisoning	Blood arsenic values equal to or greater than 70 µg/L Urine arsenic values equal to or greater than 100 µg/g of creatinine	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Blood lead testing	All analytical results greater than or equal to 20 micrograms per deciliter (µg/dL) in a child under the age of 6 years or a pregnant woman	Daily	By telephone: 1-800-972-2026
	All other analytical values for all blood lead analyses	Weekly	Electronic format specified by the department
Cadmium poisoning	Blood cadmium values equal to or greater than 5 µg/L Urine cadmium values equal to or greater than 3 µg/g of creatinine	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Carbon monoxide (CO) poisoning	Blood carbon monoxide level equal to or greater than 10% carboxyhemoglobin or its equivalent with a breath analyzer test, or a clinical diagnosis of CO poisoning regardless of any test results	Daily	By telephone: 1-800-972-2026

Poisoning or Condition	Cases to Report	When to Report	How to Report
Hypersensitivity pneumonitis	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Mercury poisoning	Blood mercury values equal to or greater than 2.8 µg/dL Urine mercury values equal to or greater than 20 µg/L	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Methemoglobinemia	Blood analyses showing greater than 5% of total hemoglobin present as methemoglobin	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Microcystin toxin poisoning	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Noncommunicable respiratory illness	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Occupationally related asthma, bronchitis or respiratory hypersensitivity reaction	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Pesticide poisoning (including pesticide-related contact dermatitis)	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Severe skin disorder	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Toxic hepatitis	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.

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[Editorial change: IAC Supplement 6/10/26]

CHAPTER 2
HEPATITIS PROGRAMS

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/14/29

VIRAL HEPATITIS PROGRAM—VACCINATIONS AND TESTING

641—2.1(135) Definitions. For the purpose of these rules, the following definitions shall apply:

"Contracted agencies" means local health departments, clinics, and community-based organizations that are funded by the department to provide HCV testing and vaccination services.

"HCV" means the hepatitis C virus as defined by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"HIV" means the same as defined in Iowa Code section 141A.1.

"Viral hepatitis" means inflammation of the liver caused by one of several viruses: hepatitis A, B, C, D, and E.

[**ARC 8123C**, IAB 7/10/24, effective 8/14/24]

641—2.2(135) Exposure risks for hepatitis C virus. The following individuals are at increased risk of exposure to HCV as described by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services:

1. People living with HIV;
2. People who have ever injected drugs;
3. People with selected medical conditions, including those who ever received maintenance hemodialysis;
4. Recipients of clotting factors made before 1987;
5. Recipients of blood transfusions, blood products, and organ transplants that occurred before 1992;
6. Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood; and
7. Infants born to mothers living with HCV.

[**ARC 8123C**, IAB 7/10/24, effective 8/14/24]

641—2.3(135) Information for public distribution. The department will make available educational materials to the public on hepatitis C infection, transmission, and where to seek testing services as defined on the department's website.

[**ARC 8123C**, IAB 7/10/24, effective 8/14/24]

641—2.4(135) Hepatitis vaccination and testing program.

2.4(1) When sufficient state and federal funds are available, the department will maintain a vaccination and testing program. The program shall offer HCV testing and hepatitis A and B vaccinations through local health departments, clinics, and community-based organizations to individuals at an increased risk of exposure to viral hepatitis as described in the Viral Hepatitis Prevention and Testing Services Manual dated December 2023 and available on the department's website. Contracted agencies offering testing and vaccination services shall be required to provide integrated HIV, viral hepatitis, and sexually transmitted infection education; pretest and posttest counseling; and referral services.

2.4(2) Contracted agencies shall provide individuals presenting for testing or vaccination services with education explaining viral hepatitis and how to reduce the risk of acquiring it.

2.4(3) Contracted agencies shall provide individuals testing positive for viral hepatitis with information about the diagnosis and treatment options and with a referral list of health care providers to aid in seeking treatment, additional follow-up testing, and other hepatitis-related services.

[**ARC 8123C**, IAB 7/10/24, effective 8/14/24]

These rules are intended to implement Iowa Code section 135.19.

[Filed 11/14/07, Notice 10/10/07—published 12/5/07, effective 1/9/08]

[Filed ARC 8123C (Notice ARC 7373C, IAB 1/24/24), IAB 7/10/24, effective 8/14/24]

CHAPTER 3
EARLY HEARING DETECTION AND INTERVENTION (EHDI) PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 12/1/30

641—3.1(135) Definitions. For the purposes of this chapter, the following definitions will apply:

"Audiologist" means a person licensed pursuant to Iowa Code chapter 147 or certified by the Iowa board of educational examiners pursuant to 282—Chapter 14 or a person appropriately licensed in the state where the person practices.

"Audiology assistant" means a person who works under the supervision of an Iowa-licensed speech pathologist or audiologist, does not meet the requirements to be licensed as a speech pathologist or audiologist, and meets the minimum requirements set forth in 481—Chapter 781.

"Audiometrist" means a technician who has received special training in the use of pure-tone audiometry equipment. An audiometrist conducts the hearing tests selected and interpreted by an audiologist, who supervises the process.

"Birth center" means the same as defined in Iowa Code section 10A.711.

"Birthing hospital" means the same as defined in Iowa Code section 135.131.

"Congenital cytomegalovirus" or *"cCMV"* means an infection where cytomegalovirus is transmitted to the fetus in the prenatal period.

"Cytomegalovirus" or *"CMV"* means a kind of herpes virus that usually produces very mild symptoms in an infected person but may cause severe neurological damage in a person with a weakened immune system and in a newborn.

"Diagnostic audiologic assessment" means physiological or behavioral procedures completed by an audiologist to evaluate and diagnose hearing loss.

"Discharge" means a release from a birthing hospital to the parent or legal guardian of the child.

"Early ACCESS" means Iowa's Individuals with Disabilities Education Act (IDEA), Part C, program for infants and toddlers. It is a statewide, comprehensive, interagency system of integrated early intervention services that supports eligible children and their families as defined in 281—Chapter 120.

"Guardian" means a person who is not the parent of a minor child, but who has legal authority to make decisions regarding life or program issues for the child. A guardian may be a court or a juvenile court. "Guardian" does not mean conservator as defined in Iowa Code section 633.3, although a person who is appointed to be a guardian may also be appointed to be a conservator.

"Health care professional" means a licensed physician, nurse practitioner, physician associate, certified midwife, registered nurse, licensed practical nurse, patient care technician, certified nursing assistant, licensed audiologist, audiology assistant, audiometrist, hearing aid specialist, speech-language pathologist or other licensed or certified professional for whom hearing screening is within the professional's scope of practice.

"Hearing loss" means a permanent unilateral or bilateral hearing loss of greater than 30 dB hearing loss (HL) in the frequency region important for speech recognition (500-4000 Hz).

"Hearing screening" means a physiological measurement of hearing of a newborn or infant with a "pass" or "refer" result. Screening is used to determine the newborn's or infant's need for further testing and must be performed bilaterally, when applicable.

"Initial screening" or *"newborn hearing screening"* means a screening performed in a birthing hospital, birth center or facility other than a birthing hospital within the first month of life. This is a physiological test to separate those newborns with normal hearing from those newborns who may have hearing thresholds of greater than 30 dB HL in either ear in the frequency region important for speech recognition (500-4000 Hz).

"Normal hearing" means hearing thresholds in both ears of 30 dB HL or less in the frequency region important for speech recognition (500-4000 Hz).

"Parent" means:

1. A biological or adoptive parent of a child;
2. A guardian, but not the state if the child is a ward of the state;

3. A person acting in the place of a parent, such as a grandparent or stepparent with whom a child lives, or a person who is legally responsible for the child's welfare;

4. A surrogate parent who has been assigned in accordance with 281—120.422(34CFR303); or

5. A foster parent, if:

- A biological parent's authority to make the decisions required of parents under state law has been terminated; and
- The foster parent has an ongoing, long-term parental relationship with the child, is willing to make the decisions required of a parent, and has no interest that would conflict with the interests of the child.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Primary care provider" means a licensed physician, nurse practitioner, physician associate or certified midwife who undertakes primary pediatric care responsibility for an infant or child to provide ongoing medical care and referrals to promote overall health and well-being.

"Protocol" means a document that guides decision making and provides the criteria to be used regarding screening, diagnosis, management, and treatment of children related to hearing health care. Early hearing detection and intervention protocols not otherwise specified in this chapter are available on the department's website.

"Provider" means a licensed audiologist, otolaryngologist or hearing aid specialist who agrees to provide hearing aids or audiologic services to eligible patients.

"Rescreen" means a newborn hearing screening performed after two weeks of age on an infant who did not pass the initial screening.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25; Editorial change: IAC Supplement 6/10/26]

641—3.2(135) Program components.

3.2(1) The EHDI coordinator assigned within the department provides administrative oversight, including follow-up activities, for the EHDI program within Iowa.

3.2(2) The EHDI advisory committee represents the interests of the people of Iowa and assists in the development of programming that ensures the availability and access to quality hearing health care for Iowa children.

3.2(3) The EHDI program has an association with the Iowa Title V maternal and child health programs to promote comprehensive services for infants and children with special health care needs.

3.2(4) The EHDI program provides hearing screening surveillance and follow-up for infants and children under the age of three. Follow-up may include:

a. Contact with the parent or legal guardian of an infant who was not screened or does not pass the initial hearing screening, outpatient hearing screening or diagnostic audiologic assessment.

b. Contact with the infant's primary care provider to ensure the infant receives appropriate follow-up no later than the recommended timeline as outlined in the Joint Committee on Infant Hearing position statement at www.jcih.org as amended to August 1, 2025.

c. Contact with the birthing hospital or health care professional for inquiries on missing results, data entry discrepancies and recommendations for additional referrals.

d. Referrals to family support or early intervention service providers for infants or toddlers diagnosed with a hearing loss.

e. Technical assistance to birthing facilities, primary care providers and health care professionals regarding best practices related to newborn hearing screening, diagnosis and follow-up best practices.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.3(135) Screening the hearing of all newborns. All newborns and infants born in Iowa, except those born with a condition that is incompatible with life, shall be screened for hearing loss. The person required to perform the screening shall use at least one of the following procedures:

1. Automated or screening auditory brainstem response, or
2. Evoked otoacoustic emissions.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.4(135) Procedures required of birthing hospitals. Each birthing hospital in Iowa shall follow these procedures:

3.4(1) Each birthing hospital shall designate an employee of the hospital to be responsible for the newborn hearing screening program in that institution. If a birthing hospital contracts with a third party for newborn screening services, the hospital retains ultimate responsibility for screening and reporting.

3.4(2) Prior to the discharge of the newborn, each birthing hospital shall provide hearing screening to every newborn delivered in the hospital, except in the following circumstances:

a. The newborn is transferred for acute care prior to completion of the hearing screening.

b. The newborn is born with a condition that is incompatible with life.

3.4(3) If a newborn is transferred for acute care, the birthing hospital shall notify the receiving facility of the status of the hearing screening. The receiving facility shall then be responsible for completion of the newborn hearing screening prior to discharge of the newborn from the nursery.

3.4(4) Newborn hearing screening shall be performed by a health care professional.

3.4(5) The birthing hospital shall report newborn hearing screening results to the parent or guardian in written form.

3.4(6) The birthing hospital shall report newborn hearing screening results to the department pursuant to 641—3.7(135).

3.4(7) The birthing hospital shall report the results of the hearing screening to the primary care provider of the newborn or infant upon the newborn's or infant's discharge from the birthing hospital. If the newborn or infant was not tested prior to discharge, the birthing hospital shall report the status of the hearing screening to the primary care provider of the newborn or infant.

3.4(8) The birthing hospital shall follow the hearing screening protocols prescribed by the department.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.5(135) Procedures required of birth centers. Each birth center in Iowa shall follow these procedures:

3.5(1) Each birth center shall designate an employee of the birth center to be responsible for the newborn hearing screening program in that institution.

3.5(2) Prior to discharge of the newborn, each birth center shall refer every newborn delivered in the birth center to a health care professional for a newborn hearing screening. Before discharge of the newborn, the birth center shall arrange an appointment for the newborn hearing screening no more than 15 days from the date of discharge and report the appointment time, date and location to the parent.

3.5(3) The health care professional to whom the newborn is referred for screening shall complete the screening within 30 days of the newborn's discharge from the birth center, unless the parent fails to attend the appointment. If the parent fails to attend the appointment, the health care professional shall document such failure in the medical or educational record and shall report such failure to the department.

3.5(4) The health care professional who completes the newborn hearing screening shall report screening results to the parent in written form.

3.5(5) The health care professional who completes the newborn hearing screening shall report screening results to the department pursuant to 641—3.7(135).

3.5(6) The health care professional who completes the newborn hearing screening shall report the results of the hearing screening to the primary care provider of the newborn or infant.

3.5(7) The person who completes the screening shall follow the hearing screening protocols prescribed by the department.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.6(135) Procedures to ensure that children born in locations other than a birth center or birthing hospital receive a hearing screening.

3.6(1) The physician or other health care professional who undertakes primary pediatric care of a newborn delivered in a location other than a birthing hospital or birth center shall ensure a hearing screening is performed pursuant to Iowa Code section 135.131(5). The health care professional shall

arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date, and location.

3.6(2) The health care professional who completes the newborn hearing screening shall report screening results to the parent in written form.

3.6(3) The health care professional who completes the newborn hearing screening shall report screening results to the department pursuant to 641—3.7(135). If the parent fails to attend the appointment, the facility shall document such failure in the medical or educational record and shall report such failure to the department.

3.6(4) The health care professional who completes the newborn hearing screening shall report the results of the hearing screening to the primary care provider of the newborn or infant.

3.6(5) The person who completes the newborn hearing screening shall follow the hearing screening protocols prescribed by the department.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.7(135) Reporting hearing screening results and information to the department and child's primary care provider.

3.7(1) Any birthing hospital, birth center, physician, audiologist or other health care professional required to report information pursuant to Iowa Code section 135.131 shall report all of the following information to the department relating to each newborn's hearing screening within six working days of the birth of the newborn and within six working days of any hearing rescreen, utilizing the department's designated reporting system:

a. The name, date of birth, and sex of the newborn.

b. The name, address, and telephone number, if available, of the mother of the newborn. If the mother is not the person designated as legally responsible for the child's care, the name, address, and telephone number of the parent, as defined in 641—3.1(135), shall be reported.

c. The name of the primary care provider for the newborn upon the newborn's discharge from the birthing hospital or birth center.

d. The results of the newborn hearing screening, either "pass," "refer," or "not screened," for each ear separately.

e. The results of any rescreening, either "pass" or "refer," and the diagnostic audiologic assessment procedures used for each ear separately.

f. Known risk indicators for hearing loss of the infant or child.

3.7(2) If the parent fails to attend the appointment, the facility shall document such failure in the medical or educational record and shall report such failure to the department.

3.7(3) The person who completes the newborn hearing screening shall report the results of the hearing screening to the primary care provider of the infant or child.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.8(135) Conducting and reporting screening results and diagnostic audiologic assessments to the department and child's primary care provider. Any health care professional conducting newborn hearing screens, rescreens, or diagnostic audiologic assessments shall report the results within six working days for any child under three years of age to the department utilizing the department's designated reporting system. The health care professional shall conduct the diagnostic hearing assessment in accordance with the Pediatric Audiologic Diagnostic Protocol as amended to August 1, 2025, posted on the department's website. Results of a hearing screen, rescreen or diagnostic audiologic assessment shall be reported as follows.

3.8(1) Reports shall include:

a. The name, date of birth, and sex of the child.

b. The name, address, and telephone number, if available, of the mother of the child. If the mother is not the person designated as legally responsible for the child's care, the name, address, and telephone number of the parent, as defined in 641—3.1(135), shall be reported.

c. The name of the primary care provider for the child.

d. Known risk indicators for hearing loss.

e. The date the child is fit with a hearing aid(s) or a cochlear implant(s), if applicable.

f. The date of referral to early intervention, if applicable.

g. The date of referral to family support, if applicable.

3.8(2) Results of the newborn hearing screening shall be reported as either "pass" or "refer" for each ear separately.

3.8(3) Results of the hearing rescreen shall be reported as either "pass" or "refer" for each ear separately.

3.8(4) If an assessment results in a diagnosis of normal hearing for both ears, this shall be reported.

3.8(5) Any diagnosis of hearing loss shall also be reported except for transient conductive hearing loss lasting for less than 90 days in the professional judgment of the practitioner. This exception will apply only if the child passed the initial hearing screening or rescreening or had a diagnostic assessment resulting in normal hearing for both ears.

3.8(6) Diagnostic audiologic assessment results shall include a statement of the severity (mild, moderate, moderately severe, severe, profound, or undetermined) and type (sensorineural, conductive, mixed, or undetermined) of hearing loss.

3.8(7) Any health care professional conducting newborn hearing screens, rescreens, or diagnostic audiologic assessments shall report the results to the primary care provider of the infant or child.

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.9(135) Congenital cytomegalovirus (cCMV) testing for newborns who do not pass the initial newborn hearing screening. If the newborn hearing screen indicates potential hearing loss, as evidenced when a newborn does not pass the initial newborn hearing screening, the birthing hospital, birth center, physician, or other health care professional required to ensure that the hearing screening is performed shall follow the procedures related to cCMV testing outlined in Iowa Code section 135.131(9). If a parent objects to the testing, the birthing hospital, birth center, physician, or other health care professional required to ensure that the hearing screening is performed shall follow the procedures in 641—3.11(135).

[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.10(135) Information sharing and confidentiality. Reports, records, and other information collected by or provided to the department relating to a child's newborn hearing screening, rescreen, diagnostic audiologic assessment, and early intervention enrollment are confidential records pursuant to Iowa Code section 22.7.

3.10(1) Personnel of the department shall maintain the confidentiality of all information and records used in the review and analysis of newborn hearing screenings, rescreens, diagnostic audiologic assessments, and early intervention enrollment, including information which is confidential under Iowa Code chapter 22 or any other provisions of state law.

3.10(2) No individual or organization providing information to the department in accordance with this rule shall be deemed to be or held liable for divulging confidential information.

3.10(3) The department shall not release confidential information except to the following persons and entities under the following conditions:

a. The parent or guardian of an infant or child for whom the report is made.

b. A local birth-to-three coordinator with the Early ACCESS program or an agency under contract with the department to administer the children with special health care needs program.

c. A health care professional or primary care provider.

d. A representative of a federal or state agency, to the extent that the information is necessary to perform a legally authorized function of that agency.

e. A representative of a state agency, or an entity bound by that state, to the extent that the information is necessary to perform newborn hearing screening follow-up. The state agency or the entity bound by that state shall be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. The state agency or the entity bound by that state shall not use the information obtained from the department to market services to patients or nonpatients or identify patients for any purposes other than those expressly provided in this rule.

3.10(4) Research purposes. All proposals for research using the department's data to be conducted by persons other than program staff shall first be submitted to and accepted by the researchers' institutional review board. The department will then review and approve programs before research can commence.
[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.11(135) Procedure to accommodate parental objection. These rules will not apply if the parent objects to the hearing screening, diagnostic audiologic assessment, or cCMV testing.

3.11(1) If a parent objects to the screening, the birthing hospital, birth center, physician, or other health care professional shall obtain a written refusal from the parent or guardian on the department newborn hearing screening or diagnostic audiologic assessment refusal form and shall maintain the original copy of the written refusal in the newborn's, infant's or child's medical record.

3.11(2) The birthing hospital, birth center, physician, or other health care professional shall send a copy of the written newborn hearing screening or diagnostic audiologic assessment refusal form to the department within six days of the birth of the newborn.

3.11(3) If a parent objects to a hearing rescreen or diagnostic audiologic assessment orally to a department EHDI staff member during follow-up, the staff member shall document the refusal in the department's designated reporting system and mail to the parent or guardian the department newborn hearing screening or diagnostic audiologic assessment refusal form in an attempt to obtain a written refusal to be maintained in the newborn's, infant's or child's medical record.

3.11(4) If a parent objects to cCMV testing, the birthing hospital, birth center, physician, or other health care professional required to ensure cCMV testing shall obtain, on the department cCMV testing refusal form, a written refusal from the parent or guardian, shall maintain the original copy of the written refusal in the child's medical record, and shall send a copy of the written refusal to the department within 21 days of the child's birth.
[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

641—3.12(135) Civil/criminal liability. A person who acts in good faith in complying with these rules shall not be held civilly or criminally liable for reporting the information required.
[**ARC 9616C**, IAB 10/15/25, effective 12/1/25]

These rules are intended to implement Iowa Code section 135.131.

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CHAPTER 4
CONGENITAL AND INHERITED DISORDERS
[Prior to 7/29/87, Health Department[470]]

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/1/30

641—4.1(136A) Definitions. For the purposes of this chapter, the following definitions apply:

"Anonymized specimen" means a specimen that cannot be traced back to or linked with the particular individual from whom the specimen was obtained.

"Attending health care provider" means the same as defined in Iowa Code section 136A.2.

"Birth defect" means any major structural abnormality or metabolic disorder that may adversely affect a child's health and development. The abnormality or disorder must be diagnosed or its signs and symptoms must be recognized within the first two years of life.

"Birthing facility" means a private or public facility licensed pursuant to Iowa Code chapter 135B that has a licensed obstetric unit or is licensed to provide obstetric services.

"Central laboratory" means the state hygienic laboratory (SHL), which is designated as the screening laboratory to perform testing and reporting for the Iowa newborn screening and Iowa maternal prenatal screening programs.

"Central registry" means the Iowa registry for congenital and inherited disorders (IRCID).

"Congenital condition" means a condition that exists at birth and may be hereditary, result from an action or exposure occurring during pregnancy or at birth, or may be due to a combination of both factors.

"Consulting physician" means a physician designated by the center for congenital and inherited disorders to interpret screen results and provide consultation to a licensed health care provider.

"Council" means the council on health and human services.

"Critical congenital heart disease" or *"CCHD"* means the presence of one or more of the following specific heart lesions: hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"Discharge" means a release of an infant from a hospital or birth center.

"Early ACCESS" means the statewide, comprehensive, interagency system of integrated early intervention services that supports eligible children and their families as defined in 281—Chapter 120.

"Early hearing detection and intervention program" means Iowa's newborn hearing screening and follow-up program, which ensures that all newborns and toddlers with hearing loss are identified as early as possible and provided with timely and appropriate audiological, educational and medical intervention and family support.

"Follow-up program" means the services provided to follow up on an abnormal screening result.

"Guardian" means a person who is not the parent of a minor child, but who has legal authority to make decisions regarding life or program issues for the child.

"Health care provider" means a licensed physician, nurse practitioner, certified nurse midwife, registered nurse, or physician associate providing medical care to an individual.

"Iowa maternal prenatal screening program" or *"IMPSP"* means a program that provides a screening test designed to identify increased risk of having a baby with a congenital or inherited disorder or developing a problem later in pregnancy.

"Iowa newborn screening panel" or *"newborn screening panel"* means the list of disorders for which the department screens Iowa newborns.

"Iowa newborn screening program" or *"INSP"* means a program that provides screening of live-born Iowa newborns for the disorders listed on the Iowa newborn screening panel.

"Neuromuscular disorder" means Duchenne, Becker, congenital, distal, Emery-Dreifuss, facioscapulohumeral, limb-girdle, myotonic, and oculopharyngeal muscular dystrophy.

"Newborn critical congenital heart disease (CCHD) screening" means the screening of newborns for seven targeted heart conditions (hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot,

total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus) using pulse oximetry or other means to detect blood oxygen saturation levels.

"Primary health care provider" means a licensed physician, physician associate, nurse practitioner, or certified nurse midwife providing ongoing primary medical care to a patient.

"Receiving facility" means the facility receiving an infant from a birthing facility.

"Residual maternal prenatal serum screening specimen" means the portion of the specimen that may be left over after all necessary activities of the Iowa maternal prenatal screening program are completed.

"Residual newborn screening specimen" means the portion of the dried blood spot specimen that may be left over after all activities necessary for the Iowa newborn screening program are completed.

"Specialty genetics provider" means a medical geneticist, genetic nurse, genetic physician associate, genetic nurse practitioner, or genetic counselor.

"State hygienic laboratory" or *"SHL"* means the designated central testing laboratory.

"Stillbirth" means the same as defined in Iowa Code section 136A.2.

"Transferring facility" means the birthing facility that transfers the infant to another facility.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25; Editorial change: IAC Supplement 6/10/26]

641—4.2(136A) Iowa newborn screening program (INSP). This program provides comprehensive newborn screening services for hereditary and congenital disorders for the state.

4.2(1) *Newborn screening policy.*

a. All newborns and infants born in the state of Iowa shall be screened for all congenital and inherited disorders on the Iowa newborn screening panel as specified by the department.

b. As new disorders are recognized and new technologies and tests become available, the department will develop and follow protocols for the addition of disorders to or the deletion of disorders from the screening panel.

c. The department may monitor individuals identified as having a genetic or metabolic disorder for the purpose of conducting public health surveillance or intervention and for determining whether early detection, treatment, and counseling lead to the amelioration or avoidance of the adverse outcomes of the disorder. Birthing facilities and health care providers shall provide patient data and records to the department upon request to facilitate the monitoring. Any identifying information provided to the department shall remain confidential pursuant to Iowa Code section 22.7(2).

d. For purposes of newborn screening, the department will collect newborn screening specimens and data, test the specimens for disorders on the universal screening panel, conduct follow-up on abnormal screening results, conduct quality improvement and quality assurance activities, and store specimens for a time period determined by its policies.

4.2(2) *Newborn blood spot screening procedure for facilities and providers.*

a. Educating parent or guardian. Before a specimen from an infant is obtained, a parent or guardian will be informed of the type of specimen, how it is obtained, the nature of the disorders for which the infant is being screened, the consequences of treatment and nontreatment, and the retention, use and disposition of residual specimens.

b. Refusal of screening. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening form. The birthing facility or attending health care provider shall submit the signed refusal of screening form to the INSP within six days of the refusal. The birthing facility or attending health care provider may submit refusal forms via the courier service established for the transportation of newborn screening specimen collection forms or via secure fax.

c. Collection of specimens. A filter paper blood specimen shall be collected from the infant between 24 to 48 hours after the infant's birth. A specimen shall not be collected from an infant less than 24 hours after birth except as follows:

(1) A blood specimen must be collected before any initial transfusion, even if the infant is less than 24 hours old.

(2) A blood specimen must be collected before the infant leaves the hospital, whether by discharge or by transfer to another hospital, even if the infant is less than 24 hours old.

d. Submission of specimens. All specimens shall be delivered to the SHL via courier service or, if courier service is not available, overnight postage, overnight express delivery service, or other appropriate means within 24 hours after collection.

4.2(3) *Primary health care provider responsibility.*

a. The health care provider or a designee shall ensure that infants under the provider's care are screened.

b. Procedures for specimen collection for newborn blood spot screening shall be followed in accordance with subrule 4.2(2).

c. A physician or other health care professional who undertakes primary pediatric care of an infant delivered in Iowa shall arrange for the newborn screening if a newborn screening result is not in the infant's medical record.

d. The primary care provider of an infant delivered in Iowa shall discuss the newborn screening results with the parent or guardian of the newborn, including follow-up on abnormal results.

4.2(4) *Birthing facility.* The birthing facility shall ensure that all infants receive newborn screening.

a. Designee. Each birthing facility shall designate an employee to be responsible for the newborn screening program in that institution.

b. Procedures for specimen collection for newborn screening shall be followed in accordance with subrule 4.2(2).

c. Transfer. The following apply if an infant is transferred:

(1) If an infant is transferred within the hospital for acute care, the newborn nursery shall notify the acute care unit of the status of the newborn screening. The acute care unit shall then be responsible for the status of the newborn screening prior to discharge of the infant.

(2) If the infant is transferred to another facility within the state, the facility shall notify the receiving facility of the status of the newborn screening. The receiving facility shall then be responsible for completion of the newborn screening prior to discharge of the infant.

d. Discharge. Each birthing facility shall collect a newborn screening specimen on every infant prior to discharge, including under the following circumstances:

(1) The infant is discharged or transferred to another facility before the infant is 24 hours old.

(2) The infant is born with a condition that is incompatible with life.

(3) The infant has received a transfusion.

e. Notification. The birthing facility shall report the newborn screening results to the health care provider who has undertaken ongoing primary pediatric care of the infant.

4.2(5) *SHL responsibility.* The SHL will:

a. Contract with a courier service to provide transportation and delivery of newborn screening specimens.

b. Contact all birthing facilities to provide education on ordering specimen transport from the courier.

c. Process specimens within 24 hours of receipt.

d. Notify the submitting health care provider, birthing facility, or drawing laboratory of an unacceptable specimen and the need for another specimen.

e. Report a presumptive positive screen result within 24 hours to the consulting physician or the physician's designee.

f. Distribute specimen collection forms, specimen collection procedures, refusal of newborn screening forms, and other materials to drawing laboratories, birthing facilities, and health care providers.

g. Report normal and abnormal screening results to the submitting facility or provider.

h. Submit a written annual report of the previous calendar year to the department by July 1 of each year. This report will include:

(1) Number of infants screened,

(2) Number of repeat screens,

(3) Number of presumptive positive results by condition and disorder,

(4) Number of rejected specimens,

(5) Number of waivers,

(6) Results of quality assurance testing, including any updates to the INSP quality assurance policies, and

(7) Screening and educational activity details.

i. In collaboration with the program consulting physicians, submit a proposed budget and narrative justification for the upcoming state fiscal year by January 31 of each year.

j. Act as fiscal agent for program expenditures encompassing the analytical, technical, administrative, educational, and follow-up costs for the screening program.

k. Submit a fiscal expenditures report to the department within 90 days after the end of the state fiscal year.

4.2(6) *Follow-up program responsibility.* Follow-up programs will be available for all individuals identified by the newborn screening as having an abnormal screen result.

a. The follow-up activities will include care coordination, consultation, genetic counseling or recommendations for treatment when indicated, case management, education and quality assurance.

b. The follow-up programs shall submit a written annual report of the previous calendar year by July 1 of each year. The report shall include:

(1) The number of presumptive positive results and confirmed positive results by condition and disorder,

(2) Number of confirmed cases receiving follow-up,

(3) A written summary of educational and follow-up activities.

c. In collaboration with the SHL, the follow-up programs shall submit a proposed budget and narrative justification for the upcoming fiscal year to the department by January 31 of each year.

d. The follow-up programs shall submit a fiscal expenditures report to the department within 90 days of the end of the state fiscal year.

4.2(7) *Information sharing and confidentiality.* Reports, records, and other information collected by or provided to the Iowa newborn screening program relating to an infant's newborn screening results and follow-up information are confidential records pursuant to Iowa Code sections 22.7 and 136A.7. INSP data may be retained for 19 years.

a. Personnel of the program shall maintain the confidentiality of all information and records used in the review and analysis of newborn screening and follow-up, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. The program shall not release confidential information, except to the following persons and entities under the following conditions:

(1) The parent or guardian of an infant or child or the adult individual for whom the report is made.

(2) A primary health care provider, birthing facility, or submitting laboratory.

(3) A representative of a state or federal agency or agents of tribes and tribal public health authorities to the extent that the information is necessary to perform a legally authorized function of that agency or the department. No data shall be furnished to state or federal agencies or agents of tribes or tribal public health agencies until the department has prepared in writing the conditions under which the data may be used and has received an agreement signed by a responsible agent of the state or federal agency agreeing to meet and conform to such conditions.

(4) A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.

c. Newborn screening information shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

4.2(8) *Retention, use and disposition of residual newborn screening specimens.*

a. A newborn screening specimen collection form consists of a filter paper containing the dried blood spots (DBS) specimen and the attached requisition that contains information about the infant and birthing facility or drawing laboratory. The DBS specimen can be separated from the information contained in the requisition form. The INSP is the custodian of the specimens and related data for purposes of newborn screening, quality improvement and quality assurance activities.

(1) The residual DBS specimen shall be held for five years in a locked area at the SHL.

(2) The residual DBS specimen shall be stored for the first year at –75 to –80 degrees C.

(3) After one year, the residual DBS specimen shall be archived for four additional years at room temperature.

(4) The residual DBS specimen shall be incinerated after completion of the retention period.

b. The program shall not release a residual newborn screening specimen except to the following persons and entities:

(1) The parent or guardian of the infant or the individual adult upon whom the screening was performed.

(2) A health care provider acting on behalf of the patient.

(3) A medical examiner authorized to conduct an autopsy on a child or an investigation into the death of a child.

(4) A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.

(5) The newborn screening program, for operations as provided in this rule.

c. Research. A residual newborn screening specimen may be released for research purposes only if written consent has been received by the researcher from a parent or guardian of the child, or the individual adult upon whom the screening was performed, and each of the following conditions is satisfied:

(1) Investigators shall submit proposals to use residual newborn screening specimens to the department. Any intended use of the requested specimens as part of the research study must be clearly delineated in the proposal.

(2) Before research can commence, proposals shall be approved by the researcher's institutional review board and the department.

(3) Research on residual newborn screening specimens shall be allowed only in instances where research would further: newborn screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; general medical knowledge for existing public health surveillance activities; public health purposes; or medical knowledge to advance the public health.

d. Newborn screening program operations. Residual newborn screening specimens and related data may be used for activities, testing, and procedures directly related to the operation of the newborn screening program, including confirmatory testing, laboratory quality control assurance and improvement, equipment calibration, evaluation and improvement of the accuracy of newborn screening tests, and equipment and screening methods validation, and for the use of linked specimens in feasibility studies approved by the council for the purpose of incorporating new tests or evaluating new test methodologies.

e. Prohibited uses. A residual newborn screening specimen shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

f. Return or destruction of specimens. A parent or guardian may request return or destruction of the parent's or guardian's newborn's residual newborn screening specimen by contacting the department.

4.2(9) *Newborn screening for critical congenital heart disease.* All newborns and infants born in Iowa shall receive newborn screening for CCHD, by pulse oximetry or other means in accordance with subparagraph 4.2(9)*"b"*(3). The purpose of newborn screening for CCHD is to identify newborns with structural heart defects usually associated with hypoxia in the newborn period that could have significant morbidity or mortality early in life with the closing of the ductus arteriosus or other physiological changes early in life.

a. Newborn CCHD screening procedure for providers and facilities.

(1) Educating parent or guardian. Before newborn screening for CCHD on an infant is conducted, a parent or guardian shall be informed of the type of screening, how it is performed, the nature of the conditions and disorders for which the infant is being screened, and the follow-up procedure for an abnormal screen result.

(2) Refusal. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening form. The birthing facility or attending health care provider shall submit the signed refusal form to the central laboratory within six days of the refusal. The birthing facility or attending health care provider may submit refusal

forms via the courier service established for the transportation of newborn screening specimen collection forms or via secure fax.

b. Newborn CCHD screening for newborns in low-risk or intermediate nurseries or out-of-hospital births.

(1) Screening should not begin until the newborn is at least 24 hours of age, or as late as possible if earlier discharge is planned, and should be completed on the second day of life.

(2) Screening shall be conducted using pulse oximeters or other means in accordance with subparagraph 4.2(9)*"b"*(3). Pulse oximeters shall:

1. Be motion tolerant;
2. Report functional oxygen saturation;
3. Be validated in low-perfusion conditions;
4. Be cleared by the Food and Drug Administration (FDA) for use on newborns; and
5. Have a 2 percent root-mean-square accuracy.

Disposable or reusable probes may be used. Reusable probes must be appropriately cleaned between uses according to manufacturer's instructions.

(3) Newborn CCHD screening shall be conducted by pulse oximetry or other means in accordance with the most recently published guidelines, algorithms, and protocols as outlined by the American Academy of Pediatrics, the American College of Cardiology Foundation and the American Heart Association, or subsequent guidance by the organizations listed in this subparagraph. Materials are available on the department's website.

c. Newborn CCHD screening for high-risk newborns in neonatal intensive care unit (NICU). Until such time that an evidence-based protocol for CCHD screening in infants discharged from the NICU is available, the attending health care provider shall conduct a comprehensive examination of the newborn to screen the infant for CCHD prior to discharge.

d. Primary health care provider responsibility. The health care provider shall ensure that infants under the provider's care are screened.

e. Reporting results of newborn CCHD screening. Results of newborn CCHD screening shall be reported in a manner consistent with other newborn screening reporting.

4.2(10) *INSP and IMPSP fees.*

a. In consultation with the department, the SHL shall establish the newborn screening fee schedule in a manner sufficient to support the newborn screening system of care, including but not limited to laboratory screening costs, short-term and long-term follow-up program costs, the newborn screening developmental fund, and the cost of the department's newborn screening data system.

b. The SHL shall include as part of the INSP fee an amount to fund the provision of special medical formula and foods for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the programs.

c. Funds collected through newborn screening fees will be used for newborn screening program activities only.

d. Funds collected through maternal prenatal screening fees will be used for maternal prenatal screening activities only.

e. In order to support newborn and maternal prenatal screening activities, the department will authorize the expenditure and exchange of newborn screening and maternal prenatal screening developmental funds between the SHL (as designated fiscal agent) and the department.

f. A portion of INSP and IMPSP fees will be distributed to the department to support activities of the INSP and the IMPSP.

4.2(11) *Special medical formula and foods program.*

a. A special medical formula and foods program for individuals with inherited diseases of amino acids and organic acids who are identified through the Iowa newborn screening program is provided by the University of Iowa.

b. Payments received from clients based on third-party payment, sliding fee scales and donations shall be used to support the administration of and the purchase of special medical formula and foods.

c. The funding allocation from the Iowa newborn screening program fee will be used as the funder of last resort after all other available funding options have been pursued by the special medical formula and foods program.

d. Provisions of special medical formula and foods through this funding allocation shall be available to an individual only after the individual has shown that all benefits from third-party payers, including but not limited to health insurers; health maintenance organizations; Medicare; Medicaid; Special Supplemental Food Program for Women, Infants and Children program (WIC); and other government assistance programs have been exhausted. In addition, a full fee and a sliding fee scale shall be established and used for those persons able to pay all or part of the cost. Income and resources shall be considered in the application of the sliding fee scale. Individuals whose income is at or above 185 percent of the federal poverty level shall be charged a fee for the provision of special medical formula and foods. Placement of individuals on the sliding fee scale shall be determined and reviewed at least annually.

e. The SHL will act as the fiscal agent.

f. The University of Iowa Health Care Medical Center under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.3(136A) Iowa maternal prenatal screening program (IMPSP). This program provides comprehensive maternal prenatal screening services for the state.

4.3(1) *Maternal screening.* The IMPSP provides a risk assessment for certain congenital or inherited conditions and disorders of a newborn. The department will identify the minimum conditions included in the assessment on the department's website.

a. If a patient desires this screening test, the health care provider shall direct that a specimen be drawn and submitted to the SHL or a laboratory with the capacity to provide screening for the minimum type of prenatal screening services.

b. As new technologies and tests become available, the department will develop and follow protocols for the addition or deletion of conditions and disorders from the screening program.

4.3(2) *Maternal screening procedure.*

a. *Specimen collection.* A serum or clotted blood specimen shall be collected from the patient within the appropriate gestational range indicated by the requested screen.

b. *Specimen processing.* The SHL will test specimens within three working days of receipt.

c. *Reporting abnormal results.* Abnormal screen results shall be reported within 24 hours to the consulting physician or the physician's designee, who shall then notify the primary health care provider. On the next working day, this initial report shall be followed by a written report to the primary health care provider.

4.3(3) *Consulting physician responsibility.* A consulting physician shall be designated by the department to provide interpretation of screen results and consultation to the submitting health care provider. This physician shall provide consultation for abnormal screen results, assist with questions about management of identified cases, provide education and assist with quality assurance measures. The screening program, with assistance from the consulting physician, shall:

a. In collaboration with the SHL, submit a proposed budget and narrative justification for the upcoming fiscal year to the department by January 31 of each year, and

b. Submit a written annual report of the previous calendar year's activity to the department by July 1 of each year. The report will include:

(1) Number of persons screened,
(2) Number of repeat screens,
(3) Number of abnormal results by condition and disorder,
(4) Number of rejected specimens,
(5) Results of quality assurance testing, and
(6) Screening and educational activity details.

4.3(4) *SHL responsibility.* The SHL will:

a. Contract with a courier service to provide transportation and delivery of maternal prenatal serum specimens.

b. Contact all entities submitting specimens to recommend use of the courier service to transport specimens to the SHL.

c. Test specimens within seven working days of receipt.

d. Distribute specimen collection kits and other materials to health care provider offices and drawing facilities as required.

e. Inform the submitting health care provider or drawing facility of an unacceptable specimen and request another specimen.

f. Provide educational materials concerning specimen collection procedures to health care provider offices.

g. Have available for review a written quality assurance program covering all aspects of its screening activity.

h. Act as a fiscal agent for program charges encompassing the analytical, technical, administrative, educational and follow-up costs for the screening program.

4.3(5) *IMPSP fee determination.* The department will annually review and determine the fee to be charged for all activities associated with the IMPSP. The review and determination of the fee will be completed at least one month prior to the beginning of the fiscal year.

4.3(6) *Information sharing and confidentiality.* Reports, records, and other information collected by or provided to the IMPSP relating to a patient's maternal prenatal screening results and follow-up information are confidential records pursuant to Iowa Code section 22.7.

a. Personnel of the program shall maintain the confidentiality of all information and records used in the review and analysis of maternal serum screening and follow-up, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. The program shall not release confidential information except to the following persons and entities, under the following conditions:

(1) The patient for whom the report is made.

(2) A primary health care provider or submitting laboratory.

(3) A representative of a state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency will be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa.

c. Maternal prenatal information shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

4.3(7) *Retention, use and disposition of residual maternal prenatal screening specimens.* The residual serum specimens shall be held for a specified period of time in a locked area at the SHL in accordance with SHL policy and procedures.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.4(136A) Regional genetic consultation service (RGCS). This program provides comprehensive genetic and genomic services statewide through outreach clinics.

4.4(1) Provision of comprehensive genetic and genomic services. The department will contract with the division of medical genetics and genomics within the department of pediatrics at the University of Iowa to provide genetic and genomic health care and education outreach services for individuals and families within Iowa.

4.4(2) The University of Iowa Health Care Medical Center under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.5(136A) Neuromuscular and other related genetic disease program (NMP). This program provides comprehensive services statewide for individuals and families with neuromuscular disorders through outreach clinics and statewide, active surveillance for selected neuromuscular disorders.

4.5(1) Comprehensive service provision. The department will contract with the department of pediatrics at the University of Iowa to provide neuromuscular health care, case management and education outreach services for individuals and families within Iowa.

4.5(2) The University of Iowa Health Care Medical Center under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.
[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.6(136A) Iowa registry for congenital and inherited disorders (IRCID). This program provides active statewide surveillance for congenital and inherited conditions and disorders. These may include birth defects, neuromuscular disorders, metabolic disorders, and all stillbirths. The program also may conduct active statewide surveillance of live births without a reportable congenital or inherited condition or disorder to serve as controls for epidemiological surveys. Surveillance activities for specific congenital and inherited conditions and disorders and maternal and congenital infections will be conducted for the period of time that adequate financial support is available.

A reportable congenital or inherited condition or disorder occurring in a miscarriage or pregnancy may be included in the IRCID.

4.6(1) *Surveillance policy.*

a. Congenital conditions and disorders, including birth defects, occurring in Iowa are reportable conditions, and records will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Congenital conditions and disorders surveillance will be performed in order to determine the occurrence and trends of such conditions and disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for congenital conditions and disorders, to contribute to prevention strategies, and to assist in the planning for and provision of services to children with congenital conditions and disorders and their families.

b. Records for neuromuscular disorders will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Neuromuscular disorders surveillance for individuals of all ages shall be performed to determine the occurrence and trends of the selected neuromuscular disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys through annual long-term follow-up, and to assist in the planning for and provision of services to individuals with selected neuromuscular disorders and their families.

c. Stillbirths occurring in Iowa are reportable conditions, and records of these stillbirths will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Stillbirth surveillance will be performed to determine the occurrence and trends of stillbirths, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for stillbirths, and to assist in the planning for and provision of services to prevent stillbirths.

4.6(2) *IRCID activities.*

a. The department will establish an agreement with the University of Iowa to implement the activities of the IRCID.

b. The IRCID will use the birth defects, neuromuscular disorders, and stillbirth coding schemes developed by the Centers for Disease Control and Prevention (CDC).

c. The IRCID staff will review hospital records, clinical charts, physician's records, vital records, prenatal records, and fetal death evaluation protocols pursuant to rule 641—1.3(139A), information from the INSP, RGCS, NMP, and the IMPSP, and any other information that the IRCID deems necessary and appropriate for congenital and inherited conditions and disorders surveillance.

4.6(3) *Department responsibility.*

a. When a live infant's medical records are ascertained by the IRCID, the department or its designee will inform the parent or legal guardian by letter that this information has been collected and provide the parent or guardian with information about services for which the child and family may be eligible.

b. The department and the IRCID will annually release aggregate medical and epidemiological information to medical personnel and appropriate state and local agencies for the planning and monitoring of services for children with congenital or inherited conditions and disorders and their families.

4.6(4) *Confidentiality and disclosure of information.* Reports, records, and other information collected by or provided to the IRCID relating to a person known to have or suspected of having a congenital or inherited condition or disorder are confidential records pursuant to Iowa Code sections 22.7 and 136A.7.

a. Personnel of the IRCID and the department shall maintain the confidentiality of all information and records used in the review and analysis of congenital or inherited conditions and disorders, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. IRCID staff are authorized pursuant to rule 641—1.3(139A) to gather all information relevant to the review and analysis of congenital or inherited conditions and disorders. IRCID staff are permitted to review hospital records, clinical charts, physician's records, vital records, and prenatal records, information from the INSP, RGCS, NMP, and IMPSP and any other information the IRCID deems necessary and appropriate for live births without a reportable congenital or inherited condition and disorder to serve as controls for epidemiological surveys.

c. No individual or organization providing information to the IRCID in accordance with this rule shall be deemed or held liable for divulging confidential information.

4.6(5) *Access to information in the IRCID.* The IRCID and the department shall not release confidential information except to the following, under the following conditions:

a. The parent or guardian of an infant or child for whom the report is made and who can demonstrate that the parent or guardian has received the notification letter.

b. An Early ACCESS service coordinator or an agency under contract with the department to administer the children with special health care needs program, upon receipt of written consent from the parent or guardian of the infant or child.

c. A local health care provider, upon receipt of written consent from the parent or guardian of the infant or child.

d. A representative of a federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The information provided shall not include the personal identifiers of an infant or child with a reportable congenital or inherited condition or disorder.

e. Researchers. All proposals for research using the IRCID data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher's institutional review board. Proposals shall then be reviewed and approved by the department before research can commence.

f. A representative of a state agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state agency will be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

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

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CHAPTER 5
MATERNAL DEATHS
[Prior to 7/29/87, Health Department[470]]
Rescinded **ARC 8970C**, IAB 2/19/25, effective 4/1/25

CHAPTER 6
VENEREAL DISEASE PROPHYLACTICS
[Prior to 7/29/87, Health Department[470]]
Rescinded IAB 6/2/10, effective 7/7/10

CHAPTER 7
IMMUNIZATION AND IMMUNIZATION EDUCATION: PERSONS ATTENDING ELEMENTARY OR SECONDARY SCHOOLS, LICENSED CHILD CARE CENTERS OR INSTITUTIONS OF HIGHER EDUCATION

[Prior to 7/29/87, Health Department[470]]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/3/29

641—7.1(139A) Definitions.

"Admitting official" means the superintendent of schools or the superintendent's designated representative if a public school; if a nonpublic school or licensed child care center, the governing official of the school or child care center.

"Advanced registered nurse practitioner" or *"ARNP"* means an advanced registered nurse practitioner as defined in 655—Chapter 7.

"Applicant" means any person seeking enrollment in a licensed child care center or elementary or secondary school.

"Certified medical assistant" means a person who is certified to practice as a certified medical assistant following completion of a postsecondary medical assistant program accredited by the Commission on Accreditation of Allied Health Education Programs or the Accrediting Bureau of Health Education Schools and successful completion of the certification examination and who is directed by a supervising physician, physician associate, or nurse practitioner.

"Competent private instruction" is as defined in Iowa Code section 299A.1.

"Elementary school" means kindergarten if provided, and grades one through eight or grades one through six when grades seven and eight are included in a secondary school.

"Eligible postsecondary institution" means an institution of higher learning under the control of the state board of regents, a community college established under Iowa Code chapter 260C, or an accredited private institution as defined in Iowa Code section 256.183.

"Enrolled user" means a user of the registry who has completed an enrollment form that specifies the conditions under which the registry can be accessed and who has been issued an identification code and password by the department.

"Health screening" means a vision screen, dental screen, or refugee health screen.

"Immunization registry" or *"registry"* means the department of health and human services' database of confidential, population-based, immunization and health screening records.

"Institution of higher education" means a postsecondary school.

"Nurse" means a person licensed to practice as a nurse pursuant to Iowa Code chapter 152.

"On-campus residence hall or dormitory" means campus housing for students that is owned or leased by the institution of higher education and located on a recognized campus site.

"Pharmacist" means a person licensed to practice pharmacy pursuant to Iowa Code chapter 155A.

"Physician" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to Iowa Code chapter 148.

"Physician associate" means a person licensed to practice as a physician associate pursuant to Iowa Code chapter 148C.

"Postsecondary student" means a person who has officially registered with a postsecondary school, as determined by the school, and who physically attends class on the school's campus. For purposes of these rules, "postsecondary student" does not include a person who is exclusively registered in a correspondence course or continuing education class or who attends class exclusively by means of distance learning or through other means that do not require the person's physical presence on the school's campus.

"Screening provider" means an ophthalmologist, optometrist, physician, free clinic, child care center, local public health department, public or accredited nonpublic school, community-based organization, advanced registered nurse practitioner (ARNP), physician associate, dentist or dental hygienist.

"Secondary school" means:

1. A junior high school comprising grades 7, 8 and 9, and a senior high school;

2. A combined junior-senior high school comprising grades 7 through 12;
3. A junior high school comprising grades 7 and 8 and a high school comprising grades 9 through 12;
4. A high school comprising grades 9 through 12.

"Signature" means an original signature or the authorized use of a stamped signature or electronic signature.

"Student" means an individual who is enrolled in a licensed child care center, elementary school or secondary school.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24; Editorial change: IAC Supplement 6/10/26]

641—7.2(139A) Persons included. The immunization requirements specified elsewhere in these rules apply to all persons enrolled or attempting to enroll in a licensed child care center or a public or nonpublic elementary or secondary school in Iowa including those who are provided competent private instruction.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24]

641—7.3(139A) Persons excluded. Exclusions to these rules are permitted on an individual basis for medical and religious reasons pursuant to Iowa Code section 139A.8. Applicants approved for medical or religious exemptions shall submit to the admitting official a valid department certificate of immunization exemption.

7.3(1) To be valid, a medical certificate of immunization exemption shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) exempted, and an expiration date (if applicable) and shall bear the signature of a physician, nurse practitioner, or physician associate. Language included on the medical certificate of immunization exemption referencing rule 641—7.3(139A) cannot be altered. Any edits or alterations to the medical certificate of immunization exemption referencing rule 641—7.3(139A) will invalidate the certificate.

a. A medical exemption may apply to a specific vaccine(s) or all required vaccines. If, in the opinion of the physician, nurse practitioner, or physician associate issuing the medical exemption, the exemption should be terminated or reviewed at a future date, an expiration date shall be recorded on the certificate of immunization exemption; or

b. A medical exemption may apply when the administration of the required vaccine would violate minimum interval spacing and the exemption shall apply only to an applicant who has not received prior doses of the exempted vaccine. An expiration date, not to exceed 60 calendar days, and the name of the vaccine exempted shall be recorded on the medical certificate of exemption.

7.3(2) A religious exemption may be granted to an applicant if immunization conflicts with a genuine and sincere religious belief. To be valid, a religious certificate of immunization exemption for religious reasons shall contain, at a minimum, the applicant's last name, first name, and date of birth and shall bear the signature of the applicant or, if the applicant is a minor, of the applicant's parent or guardian and shall attest that immunization conflicts with a genuine and sincere religious belief and that the belief is in fact religious and not based merely on philosophical, scientific, moral, personal, or medical opposition to immunizations. Language included on the religious certificate of immunization exemption referencing rule 641—7.3(139A) cannot be altered. Any edits or alterations to the religious certificate of immunization exemption referencing rule 641—7.3(139A) will invalidate the certificate.

7.3(3) Medical and religious exemptions do not apply in times of emergency or epidemic pursuant to Iowa Code section 139A.8.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24; Editorial change: IAC Supplement 6/10/26]

641—7.4(139A) Required immunizations.

7.4(1) Applicants enrolled or attempting to enroll shall have received the following vaccines in accordance with the doses and age requirements below:

IMMUNIZATION REQUIREMENTS

Applicants enrolled or attempting to enroll shall have received the following vaccines in accordance with the doses and age requirements listed below. If, at any time, the age of the child is between the listed ages, the child must have received the number of doses in the "Total Doses Required" column.

Institution	Age	Vaccine	Total Doses Required
Licensed Child Care Center	Less than 4 months of age	This is not a recommended administration schedule, but contains the minimum requirements for participation in licensed child care. **Routine vaccination begins at 2 months of age.**	
	4 months through 5 months of age	Diphtheria/Tetanus/Pertussis	1 dose
		Polio[1]	1 dose
		haemophilus influenzae type B	1 dose
		Pneumococcal	1 dose
	6 months through 11 months of age	Diphtheria/Tetanus/Pertussis	2 doses
		Polio[1]	2 doses
		haemophilus influenzae type B	2 doses
		Pneumococcal	2 doses
	12 months through 18 months of age	Diphtheria/Tetanus/Pertussis	3 doses
		Polio[1]	2 doses
		haemophilus influenzae type B	2 doses; or 1 dose received at 15 months of age or older.
		Pneumococcal	3 doses; or 2 doses if both doses were received at 12 months of age or older.
	19 months through 23 months of age	Diphtheria/Tetanus/Pertussis	4 doses
		Polio[1]	3 doses
		haemophilus influenzae type B	3 doses if a dose was received on or after 12 months of age; or 2 doses if the first dose was received on or after 12 months of age; or 1 dose if the dose was received at 15 months of age or older.
		Pneumococcal	4 doses if a dose was received on or after 12 months of age; or 3 doses if 1 or more doses were received on or after 12 months of age; or 2 doses if both doses were received at 12 months of age or older.
		Measles/Rubella	1 dose; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Varicella	1 dose; or the applicant has a reliable history of natural disease.
	24 months of age and older	Diphtheria/Tetanus/Pertussis	4 doses
		Polio[1]	3 doses
		haemophilus influenzae type B	3 doses if a dose was received on or after 12 months of age; or 2 doses if the first dose was received on or after 12 months of age; or 1 dose if the dose was received at 15 months of age or older. **Hib vaccine is not required for persons 60 months of age or older.**
		Pneumococcal	4 doses if a dose was received on or after 12 months of age; or 3 doses if 1 or more doses were received on or after 12 months of age; or 2 doses if the first dose was received on or after 12 months of age; or 1 dose if the dose was received on or after 24 months of age. Pneumococcal vaccine is not required for persons 60 months of age or older.
		Measles/Rubella	1 dose; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Varicella	1 dose; or the applicant has a reliable history of natural disease.
Elementary or Secondary School (K-12)	4 years of age and older	Diphtheria/Tetanus/Pertussis[2]	5 doses with at least 1 dose received on or after 4 years of age; or 4 doses if the fourth dose was received on or after 4 years of age; and 1 dose of tetanus/diphtheria/acellular pertussis-containing vaccine (Tdap) received on or after 10 years of age for applicants in grades 7 and above, regardless of the interval since the last tetanus/diphtheria-containing vaccine.
		Polio[1]	4 doses, with at least 1 dose received on or after 4 years of age; or 3 doses if the third dose was received on or after 4 years of age.
		Measles/Rubella	2 doses; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Hepatitis B	3 doses
		Varicella	2 doses; or the applicant has a reliable history of natural disease.
		Meningococcal (A, C, W, Y)	1 dose received on or after 10 years of age for applicants in grades 7 through 11; and 2 doses with 1 dose received on or after 16 years of age for applicants in grade 12; or 1 dose for applicants in grade 12 if the dose was received on or after 16 years of age.

[1] Doses of oral polio vaccine (OPV) administered on or after April 1, 2016, are not valid doses and do not count toward the polio vaccine requirement.

[2] Applicants 7 through 18 years of age who received the first dose of diphtheria/tetanus/pertussis-containing vaccine at 12 months of age or older should receive a total of 3 doses, with one dose received on or after 4 years of age.

7.4(2) Vaccine doses administered less than or equal to four days before the minimum interval or age shall be counted as valid. Doses administered greater than or equal to five days earlier than the minimum interval or age shall not be counted as valid doses and shall be repeated as appropriate.

7.4(3) For vaccine administration, the minimum age and intervals recommended by the advisory committee on immunization practices shall be followed.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24]

641—7.5(139A) Required education. An institution of higher education with an on-campus residence hall or dormitory shall provide vaccination information on meningococcal disease to enrolled students on a student health form pursuant to Iowa Code section 139A.26. For purposes of this rule, student health form(s) means a document(s) prepared by an institution of higher education that contains, at a minimum, information on meningococcal disease, vaccination information and any recommendations issued by the national Centers for Disease Control and Prevention regarding meningococcal disease. The student health form(s) shall also include space for the postsecondary student to indicate whether or not the postsecondary student has received vaccination against meningococcal disease, including, at a minimum, the date of vaccination. The student health form(s) shall also include space for the postsecondary student to indicate whether or not the postsecondary student has received information on meningococcal disease and benefits of vaccine. If a traditional student health form is not utilized by the institution of higher education, any document(s) containing the above information is acceptable.
[**ARC 8041C**, IAB 5/29/24, effective 7/3/24]

641—7.6(139A) Proof of immunization.

7.6(1) A valid department certificate of immunization shall be submitted by the applicant or, if the applicant is a minor, by the applicant's parent or guardian to the admitting official of the school or licensed child care center in which the applicant wishes to enroll. To be valid, the certificate shall be the certificate of immunization issued by the department, a computer-generated copy from the immunization registry, or a certificate of immunization that has been approved in writing by the department. The certificate shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) administered, the date(s) given, and the signature of a physician, a physician associate, a nurse, or a certified medical assistant. A faxed copy, photocopy, or electronic copy of the valid certificate is acceptable. The judgment of the adequacy of the applicant's immunization history should be based on records kept by the person signing the certificate of immunization or on that person's personal knowledge of the applicant's immunization history, or comparable immunization records from another person or agency, or an international certificate of vaccination, or the applicant's personal health records. If personal health records are used to make the judgment, the records shall include the vaccine(s) administered and the date given. Persons validating the certificate of immunization are not held responsible for the accuracy of the information used to validate the certificate of immunization if the information is from sources other than their own records or personal knowledge.

7.6(2) Persons wishing to enroll who do not have a valid department certificate of immunization available to submit to the admitting official shall be referred to a physician, a physician associate, a nurse, or a certified medical assistant to obtain a valid certificate.
[**ARC 8041C**, IAB 5/29/24, effective 7/3/24; Editorial change: IAC Supplement 6/10/26]

641—7.7(139A) Provisional enrollment.

7.7(1) Applicants may be granted provisional enrollment pursuant to Iowa Code section 139A.8. A valid department provisional certificate of immunization shall be submitted by the applicant or, if the applicant is a minor, by the applicant's parent or guardian to the admitting official of the school or licensed child care center in which the applicant wishes to enroll. To qualify for provisional enrollment, applicants shall have received at least one dose of each of the required vaccines or be a transfer student from another school system. A transfer student is an applicant seeking enrollment from one United States elementary or secondary school into another. To be valid, the certificate shall be the certificate of immunization issued by the department, a computer-generated copy from the immunization registry, or a certificate of immunization that has been approved in writing by the department. The certificate shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) administered, the date(s) given, the remaining vaccine(s) required, the reason that the applicant qualifies for provisional enrollment, and the signature of a physician, a physician associate, a nurse, or a certified medical assistant. Persons validating the provisional certificate of immunization are not held responsible for the accuracy of the information used to validate the provisional certificate of immunization if the information is from sources other than their own records or personal knowledge. Persons signing the provisional certificate

of immunization shall certify that they have informed the applicant or, if the applicant is a minor, the applicant's parent or guardian of the provisional enrollment requirements.

a. Any applicant seeking provisional enrollment who does not have a valid department provisional certificate of immunization to submit to the admitting official shall be referred to a physician, a physician associate, a nurse, or a certified medical assistant to obtain a valid certificate.

b. Reserved.

7.7(2) The amount of time allowed for provisional enrollment shall be as soon as medically feasible but shall not exceed 60 calendar days. The period of provisional enrollment shall begin on the date the provisional certificate is signed. The person signing the provisional certificate shall assign an expiration date to the certificate and shall indicate the remaining immunizations required to qualify for a certificate of immunization.

7.7(3) The applicant or parent or guardian shall ensure that the applicant receives the necessary immunizations during the provisional enrollment period and shall submit a certificate of immunization to the admitting official by the end of the provisional enrollment period.

7.7(4) If at the end of the provisional enrollment period the applicant or parent or guardian has not submitted a certificate of immunization, the admitting official shall immediately exclude the applicant from the benefits, activities, and opportunities of the school or licensed child care center until the applicant or parent or guardian submits a valid certificate of immunization.

7.7(5) If at the end of the provisional enrollment period the applicant has not completed the required immunizations due to minimum interval requirements, a new department provisional certificate of immunization shall be submitted to the admitting official. The admitting official must maintain all issued certificates of provisional immunization with the original provisional certificate until the applicant submits a certificate of immunization.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24; Editorial change: IAC Supplement 6/10/26]

641—7.8(139A) Records and reporting.

7.8(1) It shall be the duty of the admitting official of a licensed child care center or elementary or secondary school to ensure that the admitting official has a valid department certificate of immunization, certificate of immunization exemption, or provisional certificate of immunization on file for each student by the first day of attendance.

a. The admitting official shall keep the certificates on file in the school or licensed child care center in which the student is enrolled and assist the student or parent or guardian in the transfer of the certificate to another school or licensed child care center upon the transfer of the student to another school or licensed child care center.

b. Unless otherwise requested by the applicant, or parent or guardian, the admitting official shall retain the department certificate of immunization, or certificate of immunization exemption, or provisional certificate of immunization for three years commencing upon the transfer or graduation of the applicant, or the school may choose to provide the permanent immunization record to the student at time of graduation. Included with the immunization record a letter should state that this is an important document that will be needed by the student for college or employment and should be permanently retained.

7.8(2) It shall be the duty of the local boards of health to audit the department certificates of immunization, certificates of immunization exemption, and provisional certificates of immunization in the schools within their jurisdiction to determine compliance with Iowa Code section 139A.8. The local boards of health shall furnish the department within 60 days of the first official day of school a report of the audit. The report shall be submitted for each school within the local board of health's jurisdiction and shall include the enrollment by grade, and the number of department certificates of immunization, certificates of immunization exemption, and provisional certificates of immunization by grade.

7.8(3) The local board of health and the department shall have the right to have access to the department certificates of immunization, certificates of immunization exemption, and the provisional certificates of immunization of children enrolled in elementary and secondary schools and licensed child care centers within the constraints of the privacy rights of parents and students.

7.8(4) The admitting official of an institution of higher education shall provide to the department by December 1 each year aggregate data regarding compliance with Iowa Code section 139A.26. The data

shall be forwarded to the department within 30 days. The data shall include, but not be limited to, the total number of incoming postsecondary freshmen students living in a residence hall or dormitory who have:

a. Enrolled in the institution of higher education; and

b. Been provided information on meningococcal disease; and

c. Been immunized with meningococcal vaccine.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24]

641—7.9(139A) Compliance. Applicants not presenting proper evidence of immunization or exemption are not entitled to enrollment in a licensed child care center or elementary or secondary school under the provisions of Iowa Code section 139A.8. It shall be the duty of the admitting official to deny enrollment to any applicant who does not submit proper evidence of immunization and to exclude a provisionally enrolled applicant in accordance with this chapter.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24]

641—7.10(22) Statewide registry.

7.10(1) *Statewide registry.* The department shall maintain a statewide immunization and health screening registry.

7.10(2) *Purpose and permitted uses of registry.*

a. The registry shall contain immunization and health screening information, including identifying and demographic data, to allow enrolled users to maintain and access a database of immunization and health screening histories for purposes of ensuring patients are fully immunized and screened.

b. The registry may be used to track inventory or utilization of pharmaceutical agents identified by the department to prepare for or respond to an emergency event.

c. Enrolled users shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purpose other than those expressly provided in this rule.

d. The registry shall contain health screening data, including screening results and follow-up information.

7.10(3) *Release of information to the registry.* Enrolled users shall provide immunization and health screening information, including identifying and demographic data, to the registry. Information provided may include, but is not limited to, the following:

a. Name of patient;

b. Sex of patient;

c. Date of birth;

d. Race;

e. Ethnicity;

f. Birth state and birth country;

g. Address;

h. Parents' names;

i. Mother's maiden name;

j. Type of vaccination administered;

k. Dose or series number of vaccine;

l. Date vaccination was administered;

m. Lot number;

n. Date of health screening;

o. Health screening results;

p. Source of health screening;

q. Health screening follow-up information;

r. Patient comments;

s. Provider name, license, and business address; and

t. Patient history, including previously unreported doses.

7.10(4) *Confidentiality of registry information.* Immunization and health screening information, including identifying and demographic data maintained in the registry, is confidential and may not be disclosed except under the following limited circumstances:

a. The department may release information from the registry to the following:

(1) The person or the parent or legal guardian of the person immunized or screened.

(2) Enrolled users of the registry who have completed a department enrollment form that specifies the conditions under which the registry can be accessed.

(3) Persons or entities requesting immunization or health screening data in an aggregate form that does not identify an individual either directly or indirectly.

(4) Agencies that complete an agreement with the department that specifies conditions for access to registry data and how that data will be used. Agencies shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purposes other than those expressly provided in this rule.

(5) A representative of a state or federal agency, or entity bound by that state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency is subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. State or federal agencies shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purposes other than those expressly provided in this rule.

(6) The admitting official of a licensed child care center, elementary school, secondary school, or postsecondary school; or medical or health care providers providing continuity of care.

(7) Users from other states or jurisdictions who have signed and completed enrollment in the state's or jurisdiction's immunization registry.

b. Users shall not release data obtained from the registry except to the person or the parent or legal guardian of the person immunized or screened, admitting officials of licensed child care centers and schools, medical or health care providers providing continuity of care, and other enrolled users of the registry.

7.10(5) *Suspend or terminate access.* The department will approve, suspend, terminate, and reinstate user access in accordance with this chapter and department policy.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24; **ARC 9617C**, IAB 10/15/25, effective 12/1/25]

641—7.11(22) Release of immunization and health screening information.

7.11(1) *Between a physician, physician associate, nurse, certified medical assistant, pharmacist, or screening provider and the elementary, secondary, or postsecondary school or licensed child care center that the student attends.* A physician, a physician associate, a nurse, a certified medical assistant, a pharmacist, or a screening provider shall disclose a student's or patient's immunization or health screening information, including the name, date of birth, and demographic information; vaccine(s) administered and the month, day and year of administration; health screening results; and clinic source and location, to an elementary, secondary, or postsecondary school or a licensed child care center upon written or verbal request from the elementary, secondary, or postsecondary school or licensed child care center. Written or verbal permission from a student or parent is not required to release this information to an elementary, secondary, or postsecondary school or licensed child care center that the student attends.

7.11(2) *Among physicians, physician associates, nurses, certified medical assistants, pharmacists or screening providers.* Immunization or health screening information, including the student's or patient's name, date of birth, and demographic information; vaccine(s) administered and the month, day and year of administration; health screening results; and clinic source and location, shall be provided by a physician, physician associate, nurse, certified medical assistant, pharmacist, or screening provider to another health care provider without written or verbal permission from the student, parent, guardian or patient.

7.11(3) *Among an elementary school, secondary school, postsecondary school, and licensed child care center that the student attends.* An elementary school, secondary school, postsecondary school, and licensed child care center shall disclose a student's immunization or health screening information, including the student's name, date of birth, and demographic information; vaccine(s) administered and the month, day and year of administration; health screening results; and clinic source and location, to

another elementary school, secondary school, postsecondary school, and licensed child care center that the student attends. Written or verbal permission from a student, or if the student is a minor, the student's parent or guardian, is not required to release this information to an elementary school, secondary school, postsecondary school, and licensed child care center that the student attends.

7.11(4) *Among the department and a physician, physician associate, nurse, certified medical assistant, pharmacist, screening provider, elementary school, secondary school, postsecondary school, and licensed child care center.* A student's or patient's immunization or health screening information, including name, date of birth, grade, and demographic information; vaccine(s) administered and the month, day and year of administration; and health screening results, clinic source, and location, all in a format specified by the department, shall be disclosed upon written or verbal request among the department, physicians, physician associates, nurses, certified medical assistants, pharmacists, screening providers, elementary schools, secondary schools, postsecondary schools, and licensed child care centers. Written or verbal permission from a student, patient, parent, or guardian is not required to release this information.

7.11(5) *Among the department and physicians, physician associates, nurses, resettlement agencies, federal, state, and local government agencies, and certified medical assistants conducting refugee health screenings.* Refugee health screenings shall be disclosed only as indicated in this rule. Immunization or health screening information, including the patient's name, date of birth, and demographic information; the vaccine(s) administered and the month, day, and year of administration; health screening results; and clinic source and location, shall be disclosed upon written or verbal request among the department, physicians, physician associates, nurses, certified medical assistants, resettlement agencies, federal, state, and local government agencies, or screening providers to another health care provider or the department. Written or verbal permission from the parent, guardian or patient is not required to release this information.

[**ARC 8041C**, IAB 5/29/24, effective 7/3/24; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code sections 139A.8, 139A.26 and 22.7(2).

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[Editorial change: IAC Supplement 6/10/26]

◊ Two or more ARCs

CHAPTER 8
IOWA CARE FOR YOURSELF (IA CFY) PROGRAM
[Prior to 4/4/12, see 641—Chapter 37]
Rescinded **ARC 9557C**, IAB 9/17/25, effective 11/1/25

CHAPTER 9
OUTPATIENT DIABETES EDUCATION PROGRAMS
[Prior to 7/29/87, Health Department[470], Ch 9]
Rescinded **ARC 9558C**, IAB 9/17/25, effective 11/1/25

CHAPTER 10
IOWA GET SCREENED: COLORECTAL CANCER PROGRAM
Rescinded **ARC 9559C**, IAB 9/17/25, effective 11/1/25

CHAPTER 11
HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Chapter rescission date pursuant to Iowa Code section 17A.7: 1/1/30

641—11.1(139A,141A) Definitions.

"AIDS" means the same as defined in Iowa Code section 141A.1.

"AIDS-related condition" means the same as defined in Iowa Code section 141A.1.

"Alleged offender" means the same as defined in Iowa Code section 915.40.

"Benefits and drug assistance program" or *"BDAP"* means the Iowa benefits and drug assistance program, a component of the Ryan White program administered by the health and human services department (department).

"Blood bank" means a facility for the collection, processing, or storage of human blood or blood derivatives, or from which or by means of which human blood or blood derivatives are distributed or otherwise made available.

"Blood-borne viral hepatitis" means hepatitis B or hepatitis C.

"Care provider" means the same as defined in Iowa Code section 139A.2.

"CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

"Certification of a significant exposure report" means the determination by an authorized infection preventionist, occupational health professional, or other personnel trained in infection control or infectious disease medicine and designated by a facility to review significant exposure reports that the incident described by the exposed care provider meets the definition of a significant exposure as defined in this rule.

"Confirmed positive test" means a reactive result or detectable quantity on any HIV-related test, including an antibody test, an antigen test, a culture, a nucleic acid amplification test, or other test or combination of tests that is considered to be confirmatory according to prevailing medical technology and algorithms or guidance from CDC. When the confirmed positive test involves more than one test, all test results should be included in any reports to the department.

"Contagious or infectious disease" means hepatitis in any form, meningococcal disease as defined in these rules, AIDS or HIV as defined in Iowa Code section 141A.1, tuberculosis as defined in these rules, and any other disease determined to be life-threatening to a person exposed to the disease based upon a determination by the state epidemiologist or medical director and in accordance with guidelines of the CDC.

"Department of corrections" means the Iowa department of corrections.

"Designated representative" means a person who is designated by a department, agency, division, or service organization to act on behalf of the exposed care provider as a liaison with the facility that received the source patient when the exposure occurred in the field or during patient transport.

"Director of a plasma center, blood bank, clinical laboratory, organ procurement organization, or public health laboratory" means the person responsible for direction and operation of the facility, the medical director, or the person designated by the director or medical director to ensure compliance with applicable regulations and requirements.

"Emergency medical services personnel" means "emergency medical care provider" as defined in Iowa Code section 147A.1.

"Exposure" means the same as defined in Iowa Code section 139A.2.

"HBV" means hepatitis B virus.

"Health care facility" means the same as defined in Iowa Code section 139A.2.

"Health care provider" means the same as defined in Iowa Code section 141A.1.

"Health facility" means the same as defined in Iowa Code section 141A.1.

"HIV" means the same as defined in Iowa Code section 141A.1.

"HIV infection" means having acquired the human immunodeficiency virus.

"HIV-related test" means the same as defined in Iowa Code section 141A.1.

"Home health services" means health care services provided by a care provider in a patient's home or other residence.

"Identifiable third party" means a sexual partner of or a person who shares drug injecting equipment with a person who has been diagnosed with HIV infection.

"Infectious bodily fluids" means bodily fluids capable of transmitting HIV as listed in "Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis," dated September 25, 2013, and updated May 23, 2018, published by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia 30333, on its website. To prevent HIV and blood-borne viral hepatitis disease transmission, this reference indicates that standard precautions should be followed for exposure to the following infectious bodily fluids: blood, amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, vaginal secretions, and saliva contaminated with blood. HIV and blood-borne viral hepatitis disease transmission has not occurred from feces, nasal secretions, sputum, sweat, tears, urine, vomitus, and saliva when it is not contaminated with blood.

"Laboratory" means a clinical or public health laboratory, a plasma center, or a blood bank inside or outside the boundaries of Iowa.

"Meningococcal disease" means acute infectious bacterial meningococcal infection presenting as invasive disease characterized by one or more clinical syndromes, including bacteremia, sepsis, or meningitis. "Meningococcal disease" does not include nasopharyngeal colonization by *Neisseria meningitidis*.

"Payer of last resort" means a requirement to coordinate services and seek payment from all other sources before Ryan White program funds are used.

"Physician" means a person currently licensed pursuant to Iowa Code chapter 148.

"Physician associate" means a person currently licensed under Iowa Code chapter 148C.

"Plasma center" means a facility that conducts plasmapheresis.

"Plasmapheresis" means the removal of blood from a human being to obtain plasma with the subsequent reinfusion of the remaining formed elements into the donor but excludes such a procedure performed for the purpose of improving the health of the donor.

"Public health laboratory" means a laboratory operated by an agency of city, county or state government for the purpose of supporting disease control activities.

"Respite care services" means health care services provided by a care provider in a patient's home or other residence on a short-term, temporary basis as relief to those who are caring for family members.

"Ryan White program" means the Ryan White part B program administered by the department, which provides case management, behavioral health, and other supportive services, and assistance with the costs of housing, health insurance, and treatment medications for eligible low-income individuals diagnosed with HIV.

"Sexually transmitted disease or infection" means "sexually transmitted disease or infection" as defined in rule 641—1.1(139A).

"Significant exposure" means a situation in which there is a risk of contracting disease through exposure to a patient's infectious bodily fluids in a manner capable of transmitting an infectious agent as determined by CDC. Exposure includes contact with blood or other infectious bodily fluids to which standard precautions apply through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membranes during the performance of normal job duties. Significant exposures include:

1. Transmission of blood, bloody fluids, or other infectious bodily fluids of the source patient onto a mucous membrane (mouth, nose, or eyes) of the care provider.

2. Transmission of blood, bloody fluids, or other infectious bodily fluids of the source patient onto an open wound or lesion with significant breakdown in the skin barrier, including a needle puncture with a needle contaminated with blood, bloody fluids, or other infectious bodily fluids.

"Significant exposure report" means the Report of Exposure to HIV or Other Infectious Disease form provided by the department. This is the only form authorized to be used to document a significant exposure to infectious bodily fluids such that the source patient is deemed to consent to a test to determine if the

patient has a contagious or infectious disease and is deemed to consent to notification of the care provider of the results of the test pursuant to Iowa Code section 139A.19.

"Tuberculosis" means infectious tuberculosis as defined in rule 641—1.1(139A).

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25; Editorial change: IAC Supplement 6/10/26]

641—11.2(141A) HIV testing—obtaining consent—voluntary HIV-related tests for adults who are not pregnant.

11.2(1) Prior to conducting a voluntary HIV-related test on an adult, the health care provider requesting the test shall provide information to the subject of the test concerning HIV testing and where to obtain additional information regarding HIV infection and risk reduction.

11.2(2) Patient consent for testing must be obtained as detailed in Iowa Code section 141A.6.

11.2(3) Once an adult has been informed of a confirmed positive HIV-related test, no HIV-specific consent for medical procedures and tests shall be required for subsequent medical procedures and tests involved in the care or treatment of the adult with HIV infection.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.3(139A,141A) HIV testing—obtaining consent—voluntary HIV-related tests for minors who are not pregnant.

11.3(1) Patient consent for testing must be obtained as detailed in Iowa Code section 141A.6. A minor shall have the legal capacity to act and give consent pursuant to Iowa Code section 139A.35.

11.3(2) Prior to conducting a voluntary HIV-related test on a minor, the health care provider requesting the test shall provide information to the subject of the test concerning HIV testing and where to obtain additional information regarding HIV infection and risk reduction.

11.3(3) A minor shall be informed prior to testing of requirements for health facilities to inform the minor's legal guardian of a positive test result pursuant to Iowa Code section 141A.7.

11.3(4) Prior to the test, a minor shall give written consent for performance of the HIV-related test and to the notification of the legal guardian should the test be confirmed as positive.

11.3(5) Once a minor has been informed of a confirmed positive HIV-related test and the legal guardian has been notified, no HIV-specific consent for medical procedures and tests shall be required for subsequent medical procedures and tests involved in the care or treatment of a minor with HIV infection.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.4(141A) HIV testing—obtaining consent—voluntary HIV-related tests for pregnant women.

11.4(1) Health care providers that offer prenatal care to women shall provide HIV testing to all pregnant women as described in Iowa Code section 141A.4. No written or oral consent shall be required.

11.4(2) The testing shall occur as early as possible during each pregnancy.

11.4(3) The health care provider requesting the test shall make information available about HIV prevention, risk reduction, and treatment to all pregnant women pursuant to Iowa Code section 141A.4.

11.4(4) A pregnant woman who is a minor shall be informed prior to testing of requirements for health facilities to inform the minor's legal guardian of a positive test result as described in Iowa Code section 141A.7.

11.4(5) If a pregnant woman declines the test, the decision shall be documented as described in Iowa Code section 141A.4. A health care provider shall encourage women who decline the test early in prenatal care to be tested at a subsequent visit.

11.4(6) Once a pregnant woman has been informed of a confirmed positive HIV-related test and, if the pregnant woman is a minor, the legal guardian has been notified, no HIV-specific consent for medical procedures and tests shall be required for subsequent medical procedures and tests involved in the care or treatment of a pregnant woman with HIV infection.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.5(141A) HIV test results—posttest counseling. Upon informing the subject of an HIV-related test of a confirmed positive test result, the health care provider who requested the test or other designated personnel shall initiate counseling concerning the emotional and physical health effects of HIV infection as described in Iowa Code section 141A.7.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.6(141A) Reporting of diagnoses and HIV-related tests, events, and conditions to the department.

11.6(1) The following constitute reportable events related to HIV infection:

a. A test result indicating HIV infection, including:

(1) Confirmed positive results on any HIV-related test or combination of tests, including antibody tests, antigen tests, cultures, and nucleic acid amplification tests.

(2) A positive result or report of a detectable quantity on any other HIV detection (non-antibody) tests, and results of all viral loads, including nondetectable levels.

(3) Results of genotypic resistance assays.

b. AIDS and AIDS-related conditions, including all levels of CD4+ T-lymphocyte counts.

c. Birth of an infant to an HIV-infected mother (perinatal exposure) or any (positive, negative, or undetectable) non-antibody detection test (antigen test, viral culture, viral load, or qualitative nucleic acid amplification test) on an infant 18 months of age or younger.

d. Death resulting from an AIDS-related condition or death of a person with HIV infection.

11.6(2) Reportable events as described in this rule shall be reported to the department pursuant to Iowa Code section 141A.6. The following reporting requirements are in addition to those described in Iowa Code section 141A.6.

a. Within seven days of the receipt of a person's confirmed positive test result indicating HIV infection, the director of a plasma center, organ procurement organization, or public health laboratory that performed the test or that requested the confirmatory test shall make a report to the department.

b. Within seven days of the birth of an infant to a mother diagnosed with HIV or a receipt of a laboratory result (positive, negative, or undetectable) of a non-antibody detection test (antigen test, viral culture, viral load, or qualitative nucleic acid amplification test) on an infant 18 months of age or younger, the attending physician shall make a report to the department.

11.6(3) The report shall be made on a form provided by the department that includes those form fields described in Iowa Code section 141A.6 unless approval from the department has been obtained for use of other reporting formats.

11.6(4) All persons who experience a reportable event while receiving services in the state, regardless of state of residence, shall be reported.

Rules 641—11.1(139A,141A) through 641—11.6(141A) are intended to implement Iowa Code sections 139A.35, 141A.4, 141A.6, and 141A.7.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.7(141A) Confidentiality of information. In addition to the entities described in Iowa Code section 141A.9, medical information secured pursuant to Iowa Code section 141A.9(1) may be shared between employees and agents of the department and employees and agents of tribes and tribal public health authorities that have a need for the information in the duties related to HIV prevention, disease surveillance, or care of persons with HIV, only as necessary to administer the program for which the information is collected or to administer a program in the tribe or tribal public health authority. Confidential information transferred to other persons or entities under this rule shall continue to maintain its confidential status as described in Iowa Code section 141A.9.

This rule is intended to implement Iowa Code section 141A.9.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.8(135) HIV and AIDS training programs where occupational exposure to blood or other potentially infectious materials may occur.

11.8(1) *Personnel covered by the rule.*

a. Nonemergency personnel. All supervisory and patient care personnel of any agency listed below:

(1) A licensed hospice,

(2) A homemaker-home health aide provider agency that receives state homemaker-home health aide funds, or

(3) An agency that provides respite care services.

b. Emergency and law enforcement personnel. All personnel from the following agencies:

(1) Emergency medical services.

(2) Fire services.

(3) Law enforcement.

11.8(2) *Topics covered.* Training programs must address the following topics, consistent with standards from the Occupational Safety and Health Administration of the U.S. Department of Labor:

a. Symptoms and modes of transmission of blood-borne diseases, including human immunodeficiency virus and viral hepatitis,

b. Location and handling of personal protective equipment,

c. Information on the hepatitis B vaccine, and

d. Follow-up procedures in the event of an exposure.

11.8(3) *Timing of training.* Training must occur before an initial assignment of tasks where occupational exposure to blood or other potentially infectious materials may take place and at least annually thereafter.

This rule is intended to implement Iowa Code section 135.11.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.9(139A,141A) Partner notification program.

11.9(1) The department will maintain a partner notification program for persons known to have tested positive for sexually transmitted diseases or infections pursuant to the procedures described in Iowa Code sections 141A.5 and 139A.33.

11.9(2) Services provided include but are not limited to counseling about the disease or infection, risk reduction techniques, linkage to medical care and treatment, assessment and referral to social and prevention services, and elicitation of exposed partners' names and contact information for referral to testing, as described in the Partner Services Program Manual dated December 2023, adopted and incorporated by this reference. The manual contains the policies and procedures utilized in the implementation of the program. The manual is updated annually. A copy of the manual is available on the department website.

11.9(3) The department may delegate its partner notification duties under this rule for persons who have tested positive for HIV or other sexually transmitted diseases to a local health authority or a physician or other health care provider unless the authority or physician or other health care provider refuses or neglects to conduct the partner notification program in a manner deemed to be effective by the department.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.10(141A) Direct notification of an identifiable third party by a physician, physician associate or the department.

11.10(1) Direct notification shall be used when a person diagnosed with HIV is having continuing contact with a sexual or needle-sharing partner who is unaware of the person's infection and when both of the following situations exist:

a. A physician or physician associate for the person diagnosed with HIV is of the good-faith opinion that the nature of the continuing contact through sexual intercourse or the sharing of drug injecting equipment poses an imminent danger of HIV transmission to the third party.

b. When the physician or physician associate believes in good faith that the person diagnosed with HIV, despite strong encouragement, has not and will not warn the third party and will not participate in the voluntary partner notification program.

11.10(2) The department or a physician or a physician assistant may reveal the identity of a person diagnosed with HIV pursuant to this rule only to the extent necessary to protect a third party from the direct threat of transmission. Notification of a person pursuant to this rule shall be made confidentially. Nothing in this rule shall be interpreted to create a duty to warn third parties of the danger of exposure to HIV through contact with a person diagnosed with HIV.

11.10(3) When the physician or physician associate is of the good-faith opinion and belief that third-party notification should be performed, notification of a person pursuant to this rule shall be made:

a. Directly by the physician or physician associate, or

b. By the department at the request of the physician or physician associate.

11.10(4) Notification by the physician or physician associate. Prior to notification of a third party by the physician or physician associate of a person diagnosed with HIV, the physician or physician associate shall make reasonable efforts to inform, in writing, the person diagnosed with HIV. The written information shall state that, due to the nature of the person's continuing contact through sexual intercourse or the sharing of drug injecting equipment with the third party and the physician's or physician associate's belief that the person diagnosed with HIV, despite strong encouragement, has not and will not warn the third party and will not participate in the voluntary partner notification program, the physician or physician associate is forced to take action to provide notification to the third party. The physician or physician associate, when reasonably possible, shall provide the following information to the person diagnosed with HIV:

a. The nature of the disclosure and the reason for the disclosure.

b. The anticipated date of disclosure.

c. The name of the party or parties to whom disclosure is to be made.

NOTE: Reasonable efforts to inform, in writing, the person diagnosed with HIV shall be deemed satisfied when the physician or physician associate delivers the written notice in person or directs a written notice to the diagnosed person's last-known address by restricted certified mail, return receipt requested, at least five days prior to the anticipated date of disclosure to the third party.

11.10(5) When performed by the diagnosed person's physician or physician associate, notification of the third party and any disclosure concerning the purpose of that notification shall be made in person. However, initial contact with the third party may be made by telephone, mail, or other electronic means to arrange the meeting with the physician or physician associate at the earliest opportunity to discuss an important health matter. The nature of the health matter to be discussed shall not be revealed in the telephone call, letter, or other electronic message.

11.10(6) Notification by the department.

a. The physician or physician associate attending the person diagnosed with HIV shall provide by telephone to the department any relevant information provided by the person diagnosed with HIV regarding any party with whom the person diagnosed with HIV has had sexual relations or has shared drug injecting equipment. The information may include the third party's name, address, telephone number, and any other locating information known to the physician or physician associate. The department shall use the information in accordance with procedures established for the voluntary partner notification program.

b. Notification of the third party and any disclosure concerning the purpose of that notification shall be made in person. However, initial contact with the third party may be made by telephone, mail, or other electronic means to arrange the meeting with the department representative. The nature of the matter to be discussed shall not be revealed in the telephone call, letter, or other electronic message.

11.10(7) *Confidentiality.* The physician or physician associate of the person diagnosed with HIV and the department shall protect the confidentiality of the third party and the person diagnosed with HIV. The identity of the person diagnosed with HIV shall remain confidential unless it is necessary to reveal it to the third party so that the third party may avoid exposure to HIV. If the identity of the person diagnosed with HIV is revealed, the third party shall be presented with a statement in writing at the time of disclosure that includes the following or substantially similar language: "Confidential information revealing the identity of a person diagnosed with HIV has been disclosed to you. The confidentiality of this information is protected by state law. State law prohibits you from making any further disclosure of the information without the specific written consent of the person to whom it pertains. Any breach of the required confidential treatment of this information subjects you to legal action and civil liability for monetary damages. A general authorization for the release of medical or other information is not sufficient for this purpose."

11.10(8) *Immunity.* A health care provider attending a person diagnosed with HIV has no duty to disclose to or to warn third parties of the dangers of exposure to HIV through contact with the person diagnosed with HIV and is immune from any liability, civil or criminal, for failure to disclose to or warn third parties of the condition of the person diagnosed with HIV.

Rules 641—11.9(139A,141A) through 641—11.10(141A) are intended to implement Iowa Code sections 139A.33 and 141A.5.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25; Editorial change: IAC Supplement 6/10/26]

641—11.11(139A,141A) Care provider notification upon exposure to contagious or infectious diseases—exposures in nonclinical settings.

11.11(1) If a care provider sustains a significant exposure from a patient while rendering health care or other services, other than home-health or respite care services, outside of a health care facility or hospital, the care provider shall file a significant exposure report as soon as reasonably possible following the exposure. When the exposure occurred outside a clinical setting, a care provider who has sustained a significant exposure should file this report with the infection control, occupational health, or other designated office of the facility to which the patient was transported.

11.11(2) The source patient to whom the care provider was exposed is deemed to consent to a test to determine if the patient has a contagious or infectious disease and is deemed to consent to notification of the care provider or the designated representative of the results of the test, upon submission of a significant exposure report and certification of the significant exposure by an authorized infection preventionist, occupational health professional, or other professional trained in infectious disease control. No further consent from the source patient is required. However, as soon as is practicable, the source patient shall be notified that an exposure has occurred and shall be told which specific tests have been performed to determine the presence of contagious or infectious diseases. If the source patient is a minor, the minor shall be informed that, upon positive confirmation of an HIV-related test result, the minor's legal guardian shall be informed of the positive result pursuant to Iowa Code section 141A.7(3).

11.11(3) Hospitals, clinics, or other health care facilities; institutions administered by the department of corrections; and jails shall have written policies and procedures pursuant to Iowa Code section 139A.19. In addition to those policies and procedures required by Iowa Code section 139A.19, hospitals, clinics, or other health care facilities; institutions administered by the department of corrections; and jails shall have written policies and procedures for reviewing and certifying significant exposure report forms, testing a source patient, and notifying a care provider who sustained a significant exposure while rendering health care services or other services to the source patient when the source patient is delivered to the facility and the exposure occurred prior to the delivery.

11.11(4) The hospital, clinic, or other health care facility to whom the source patient is delivered shall conduct the test. If the source patient is delivered to an institution administered by the department of corrections, the test shall be conducted by the staff physician of the institution. If the source patient is delivered to a jail, the test shall be conducted by the attending physician of the jail or the county medical examiner. If the source patient was deemed to consent upon certification of a significant exposure report, the sample and test results shall only be identified by a number.

11.11(5) If a test result is positive, the hospital, clinic, or other health care facility, or other person performing the test shall notify the source patient and make any required reports to the department pursuant to Iowa Code sections 139A.3 and 141A.6. The report to the department shall include the name of the source patient.

11.11(6) If a source patient is diagnosed or confirmed as having a contagious or infectious disease, the hospital, clinic, or other health care facility, or other person performing the test shall notify the care provider or the designated representative of the care provider who shall then notify the care provider. If the source patient is a minor and is diagnosed with HIV infection, the hospital, clinic, or other health facility, or other person performing the test shall notify the legal guardian of the minor.

11.11(7) The notification shall advise the care provider of possible exposure to a particular contagious or infectious disease and recommend that the provider seek medical attention. The notification shall be provided as soon as reasonably possible following determination that the source patient has a contagious or infectious disease. The notification shall not include the name of the source patient unless the patient consents. If the care provider who sustained a significant exposure determines the identity of a source patient who has been diagnosed or confirmed as having a contagious or infectious disease, the identity of the source patient shall be confidential information and shall not be disclosed by the care provider to any other person unless a specific written release is obtained from the source patient.

11.11(8) This rule does not preclude a hospital, clinic, other health care facility, or a health care provider from providing notification to a care provider under circumstances in which the hospital's, clinic's, other health care facility's, or health care provider's policy provides for notification of the

hospital's, clinic's, other health care facility's, or health care provider's own employees of exposure to a contagious or infectious disease that is not life-threatening if the notice does not reveal a source patient's name, unless the patient consents.

11.11(9) The infection control, occupational health, or other designated office of the facility shall maintain a record of all significant exposure reports it receives and shall retain each report for a period of five years.

11.11(10) The significant exposure report form is a confidential record pursuant to Iowa Code section 141A.9.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.12(139A,141A) Care provider notification upon exposure to contagious or infectious diseases—exposures in clinical settings.

11.12(1) If a care provider sustains a significant exposure from a patient while rendering health care services or other services within a hospital, clinic, or other health care facility or while delivering home-health or respite care services, the care provider shall file a report as soon as reasonably possible following the exposure. A care provider who has sustained a significant exposure should file the report with the infection control, occupational health, or other office designated by the facility in which the exposure occurred, or by the facility that has oversight for the delivery of home-health or respite care services.

a. If a general consent form was signed and in effect at the time of the significant exposure and the source patient is an adult, a significant exposure report form shall not be required to document the significant exposure. The health care facility or hospital may use an employee incident report or other similar form for this purpose. The source patient to whom the care provider was exposed is deemed to consent to a test to determine if the patient has a contagious or infectious disease and is deemed to consent to notification of the care provider or the designated representative of the results of the test, upon submission and review of an employee incident report and certification of the significant exposure by an authorized infection preventionist, occupational health professional, or other professional trained in infectious disease control. No further consent from the source patient is required. However, as soon as is practicable, the source patient shall be notified that an exposure has occurred and shall be told which specific tests have been performed.

b. If no consent form was signed or in effect at the time of the exposure, or if the source patient is a minor, the source patient is deemed to consent to a test to determine if the patient has a contagious or infectious disease and is deemed to consent to notification of the care provider or the designated representative of the results of the test upon submission of a significant exposure report form and certification of the significant exposure by an authorized infection preventionist, occupational health professional, or other professional trained in infectious disease control. As soon as is practicable, the source patient shall be notified that an exposure has occurred and shall be told which specific tests have been performed to determine the presence of contagious or infectious diseases. If the source patient is a minor, the minor shall be informed that, upon positive confirmation of an HIV-related test result, the minor's legal guardian shall be informed of the positive result pursuant to Iowa Code section 141A.7(3).

11.12(2) Hospitals, clinics, or other health care facilities; institutions administered by the department of corrections; and jails shall have written policies and procedures for reviewing and certifying significant exposure report forms or other employee incident report forms, testing a source patient, and notifying a care provider who sustained a significant exposure while rendering health care services or other services to a patient during the admission, care, or treatment of the patient at the facility or while delivering home-health or respite care services.

11.12(3) The hospital, clinic, or other health care facility where exposure occurred or that has oversight for the delivery of home-health or respite care services shall conduct the test. If a general consent form was signed and in effect and the source patient is an adult, the sample and test results shall be identified by name. If the source patient was deemed to consent to a test and to notification of the care provider upon certification of a significant exposure report pursuant to these rules because no general consent was signed and in effect at the time of the exposure or because the source patient is a minor, the sample and test results shall be identified only by a number.

11.12(4) If a test result is positive, the hospital, clinic, or other health care facility or other person performing the test shall notify the source patient and make any required reports to the department pursuant to Iowa Code sections 139A.3 and 141A.6. The reports to the department shall include the name of the source patient.

11.12(5) If a source patient is diagnosed or confirmed as having a contagious or infectious disease, the hospital, clinic, or other health care facility or other person performing the test shall notify the care provider or the designated representative of the care provider who shall then notify the care provider. If the source patient is a minor and is diagnosed with HIV infection, the hospital, clinic, or other health care facility or other person performing the test shall notify the legal guardian of the minor.

11.12(6) The notification shall advise the care provider of possible exposure to a particular contagious or infectious disease and recommend that the provider seek medical attention. The notification shall be provided as soon as reasonably possible following determination that the source patient has a contagious or infectious disease.

11.12(7) The infection control, occupational health, or other designated office of the facility shall maintain a record of all significant exposure reports it receives and shall retain each report for a period of five years.

11.12(8) The significant exposure report form is a confidential record pursuant to Iowa Code section 141A.9.

Rules 641—11.11(139A,141A) through 641—11.12(139A,141A) are intended to implement Iowa Code section 139A.19.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.13(915) Testing, reporting, and counseling of convicted or alleged sexual assault assailants.

11.13(1) Prior to ordering an HIV-related test on a convicted or alleged offender pursuant to Iowa Code sections 915.40 through 915.43, the physician or practitioner shall provide information to the subject of the test concerning testing and where to obtain additional information on HIV transmission and risk reduction pursuant to Iowa Code section 141A.6. The department may be contacted for brochures that may assist in meeting the requirements of Iowa Code section 141A.6.

11.13(2) At any time that the subject of an HIV-related test is informed of confirmed positive test results, the physician or other practitioner who ordered the test shall initiate counseling concerning the emotional and physical health effects of HIV infection, as required under Iowa Code section 141A.7, and shall make any required reports to the department pursuant to Iowa Code section 141A.6.

a. The physician or other practitioner shall encourage a person diagnosed with HIV to participate in the voluntary partner notification program pursuant to rule 641—11.9(139A,141A).

b. The physician or other practitioner may provide to the department any relevant information provided by the person diagnosed with HIV regarding any party with whom the person has had sexual relations or has shared drug injecting equipment.

This rule is intended to implement Iowa Code section 135.11(22).

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

641—11.14(141A) Ryan White program.

11.14(1) *General purpose and incorporation.* The Ryan White program is a state-administered program that provides support services and assistance with the costs of health insurance and treatment medications for eligible low-income individuals diagnosed with HIV when adequate state and federal funding is available for administration of the program.

a. The program is authorized under Part B of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). This legislation requires that the Ryan White program, including the benefits and drug assistance program, be the payer of last resort for HIV-related services. The Ryan White program is not an entitlement program and does not create a right to assistance. In the event that funding is exhausted or terminated or there are changes in state or federal guidelines, programs, or regulations that impact funding available to the program, the department reserves the right to close enrollment, cease to provide specific services, or alter eligibility criteria until such time that funding is again sufficient.

b. The Ryan White program will be administered in accordance with the Ryan White Part B Client Services Manual dated December 2023, adopted and incorporated by this reference. The manual contains the policies and procedures utilized in the implementation of the program. The manual is updated annually. A copy of the manual is available at the department website.

c. The benefits and drug assistance program will be administered in accordance with the Benefits and Drug Assistance Program Manual dated December 2023, adopted and incorporated by this reference. The manual contains the policies and procedures utilized in the implementation of the program. The manual is updated annually. A copy of the manual is available at the department website.

11.14(2) *Collaboration with Iowa Medicaid.* To ensure that the Ryan White program is the payer of last resort and to maximize the efficiency and effectiveness of HIV-related prevention and care services, Iowa Medicaid shall grant the department access to client information for persons enrolled in Medicaid.

11.14(3) *Confidentiality.* Applications, assessments, and all other client-level information received or maintained by the department in connection with the Ryan White program shall be considered confidential information in accordance with Iowa Code section 141A.9.

This rule is intended to implement Iowa Code section 141A.3.

[**ARC 8409C**, IAB 11/27/24, effective 1/1/25]

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CHAPTER 12
APPROVAL OF CONFIRMATORY LABORATORIES FOR PRIVATE SECTOR DRUG-FREE WORKPLACE TESTING

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—12.1(730) Definitions. For the purpose of these rules, the following definitions apply:

"Alcohol or drug testing" means analysis of a sample for the purpose of detecting the presence or absence of alcohol or other drugs, or their metabolites, in the sample tested.

"CLIA" means the Clinical Laboratory Improvement Amendments of 1988.

"CMS" means the Centers for Medicare and Medicaid Services.

"GC/MS" means gas chromatography/mass spectrometry.

"Laboratory" means a facility inside or outside the state of Iowa approved to conduct confirmatory testing of samples for the detection of alcohol or other drugs, or their metabolites.

"Sample," for the purpose of these rules, means the substances determined by the department to be samples from the human body capable of accurately and reliably revealing the presence of alcohol or other drugs, or their metabolites, including hair, urine, saliva, breath, and blood.

"SHL" means the state hygienic laboratory.

"Specimen" means a part taken from a sample to determine the character of the whole sample.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.2(730) Powers and duties. The department is responsible for the following actions:

12.2(1) Processing applications from laboratories requesting approval to conduct confirmatory testing pursuant to Iowa Code section 730.5(7)*"f."*

12.2(2) Developing an application package.

a. The department will make an application package available to all laboratories requesting approval to conduct confirmatory testing for alcohol or other drugs, or their metabolites.

b. The package will contain application procedures, a standardized application form and a self-inspection questionnaire.

c. The self-inspection questionnaire will assist the department in assessing the quality of a laboratory's performance as a confirmatory testing laboratory. This questionnaire will comprise the major but not the sole objective criteria used during the initial on-site inspection conducted by the SHL.

d. The package will be available from the department upon request.

12.2(3) Reviewing each application submitted and determining the adequacy for approval.

12.2(4) Designating the SHL to conduct an on-site inspection of each approved confirmatory laboratory at least once every two years. Inspection may be waived by the director if the laboratory has been inspected and accredited for forensic drug testing by the College of American Pathologists, or if the laboratory has been inspected and certified, licensed, or approved to conduct confirmatory testing by another state whose requirements are at least equal to Iowa's.

12.2(5) Maintaining and providing upon request an updated list of all approved confirmatory laboratories.

12.2(6) Providing written notice of approval and assigning an expiration date.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.3(730) Application procedures and requirements. Laboratories desiring to conduct confirmatory testing for Iowa's employers shall apply to the department for approval. Each laboratory requesting Iowa approval to conduct confirmatory testing shall provide the following to the department:

12.3(1) A completed laboratory survey checklist on a form provided by the department.

12.3(2) A completed self-inspection questionnaire provided by the department.

12.3(3) Proof of enrollment in a recognized proficiency testing program. Recognized programs include those approved by CMS.

12.3(4) Acceptable performance over a 12-month period in all appropriate areas of proficiency testing for alcohol or other drugs, or their metabolites, shall be documented and maintained on an ongoing basis. Acceptable performance is as follows:

a. Initial approval shall require at least 80 percent accuracy in the last two graded proficiency test cycles with no false positive results.

b. Renewal shall require at least 80 percent accuracy each year on graded proficiency surveys with no false positive results.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.4(730) Requirements of laboratory personnel involved in confirmatory testing for alcohol or other drugs, or their metabolites.

12.4(1) The laboratory director shall be a pathologist or doctoral level individual who qualifies as a clinical laboratory director under CLIA regulations.

12.4(2) Supervisors of analysts shall possess at least a bachelor of science degree in chemistry, medical technology, or comparable education and two years of analytical alcohol or drug testing experience. Supervisors must also have training in the theory and practice of laboratory procedures and an understanding of quality control concepts. Annual verification of the supervisor's skills must be documented by the laboratory director.

12.4(3) Analysts shall possess the necessary training and skills for assigned tasks. These individuals shall possess at least two years of college education in the physical or biological sciences. At a minimum, analysts shall be graduates of a medical laboratory technician program that is recognized by the department or have at least two years of college with a minimum of nine semester hours in chemistry.

12.4(4) Laboratory directors, supervisors and analysts involved in alcohol or drug testing shall annually complete at least one in-service continuing education program related to alcohol or drug testing. Continuing education programs include formal training programs where continuing education units are awarded, informal in-house training programs, and relevant correspondence courses. Dates, titles and subject matter for each completed course shall be documented and the information shall be available for review.

12.4(5) The following information about each of the laboratory staff involved in alcohol or drug testing shall be retained for two years from date of termination and shall be available for review:

a. Résumé of training and experience.

b. Certificate or license.

c. Job description.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.5(730) Quality assurance program and procedure manual requirements. All approved confirmatory laboratories shall have a written quality assurance program and a procedure manual that encompasses all aspects of the alcohol or drug testing process.

12.5(1) Approved laboratories shall have written procedures for performing alcohol or drug testing that shall include the following:

a. Sample acquisition.

b. Chain of custody.

c. Sample and report security.

d. Test performance.

e. Reporting of results.

f. Confidentiality.

12.5(2) The quality assurance program and procedure manuals shall be available for review during any on-site inspection.

12.5(3) Approved laboratories shall review their performance in each of the above areas every 12 months.

12.5(4) Approved laboratories are responsible for developing the criteria necessary to establish and maintain an effective quality assurance program for confirmatory testing of alcohol or other drugs, or their metabolites.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.6(730) Analytical quality control. The number and position of control specimens tested within a batch and the number of calibrators used for each batch of specimens shall be consistent with generally accepted laboratory practice for the methodology used to conduct confirmatory testing.

12.6(1) Positive and negative controls shall be used in testing each batch of specimens.

12.6(2) Procedures shall be implemented and documented to ensure that carryover from a positive specimen does not contaminate other subsequent specimens in that batch.

12.6(3) Approved laboratories shall develop criteria for the detection and rejection of adulterated samples.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.7(730) Sample security and confidentiality of test results. Samples and reports must never be left unattended or unsecured.

12.7(1) Complete chain of custody documentation shall be maintained for each sample from the time of collection from the employee or prospective employee to the time the sample is discarded. Each time the sample is handled or transferred, the individual receiving the sample, the time and date of transfer, and the recipient or destination of the sample shall be documented.

12.7(2) If the first portion of the sample yielded a confirmed positive test result, the laboratory shall store the second portion of that sample until receipt of a confirmed negative test result or for a period of at least 45 calendar days following the completion of the initial confirmatory testing. Urine and blood samples shall be retained in secure storage at freezing temperatures.

12.7(3) All samples for which a negative test result was reported shall be disposed of within five working days after issuance of the negative test result report.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.8(730) Confirmatory testing.

12.8(1) Reports for alcohol shall be confirmed by gas chromatography, or a test that is recognized by the department as an equivalent test before being reported as positive (or negative).

12.8(2) Reports for drugs or their metabolites, other than alcohol, shall not be issued in the absence of confirmation by GC/MS or a scientifically equivalent test approved by the department.

12.8(3) Complete chain of custody procedures shall be used for referred samples.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.9(730) Documentation of the confirmatory testing process. The following documents shall be retained for at least two years and, if requested, made available for inspection.

12.9(1) Chain of custody documentation shall be maintained for each sample tested with the identification of the sample, the person(s) handling and testing the sample, the storage of the sample, and the eventual disposal of the sample.

12.9(2) Documents regarding the following: analytical information for each batch assayed, instrument identification, calibration records, identification of reagent lot numbers and expiration dates, quality control results, and any other pertinent information.

12.9(3) Copies of proficiency testing results for ongoing monitoring and evaluation of laboratory performance. Approved confirmatory laboratories inspected by the SHL shall submit copies of proficiency testing results to the SHL or shall ensure that proficiency testing programs submit copies of proficiency testing results directly to the SHL on their behalf.

12.9(4) Current procedure manuals must be maintained for all procedures.

12.9(5) An annual review of manuals shall be performed and documented. Alterations and additions to procedures shall be incorporated into manuals and approved by the laboratory director before implementation.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.10(730) Reporting of confirmed positive test results to the medical review officer.

12.10(1) Each report shall identify the alcohol or other drugs, or their metabolites, being tested with the results of positive/negative or detected/nondetected clearly recorded.

12.10(2) Approved confirmatory laboratories shall have available a written summary of the established sensitivity levels used for the confirmatory tests conducted for alcohol or other drugs, or their metabolites. However, this information need not be issued with each report.

12.10(3) Approved confirmatory laboratories shall have written procedures for making both written and telephone reports to the medical review officer.

12.10(4) All test results must be reviewed and signed by the laboratory director, or a qualified designee, before being reported to the medical review officer.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.11(730) Reporting requirements to department. Pursuant to Iowa Code section 730.5(16), approved confirmatory laboratories shall file a report with the department by March 1 of each year. The report shall include the number of positive and negative drug or alcohol test results for the previous calendar year for the following if available to the laboratory:

1. Employees who work in non-safety-sensitive positions,
2. Employees who work in safety-sensitive positions,
3. Employees during and after completion of drug or alcohol rehabilitation,
4. Employees as a consequence of reasonable suspicion drug or alcohol testing,
5. Prospective employees,
6. As a consequence of federal law or regulation, or by law enforcement,
7. As a consequence of accident investigation in the workplace,
8. The types of drugs that were found in the positive drug tests,
9. All significant available demographic factors relating to the positive test pool, and
10. Total number of positive and negative drug or alcohol test results for the previous calendar year for all employees and prospective employees who were tested.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.12(730) Approval, renewal, and inspection fees. At the time of initial application and each year thereafter, laboratories shall remit to the department a fee in an amount sufficient to reimburse the department for expenses incurred in administering the confirmatory laboratory approval program. All fees shall be made payable to the department and are as follows:

12.12(1) *Approval.* An administration fee of $600 is required for new applications, including applicants seeking approval through reciprocity.

12.12(2) *Renewal.* An administration fee of $300 is required to renew laboratory approval.

12.12(3) *Inspections by the SHL.* Reimbursement for actual on-site inspection and related expenses shall be assessed to each laboratory after the completion of each inspection. Expenses related to the on-site inspection shall be reimbursed to the SHL. These expenses shall reflect the actual cost incurred for personnel time and travel expenses consistent with state of Iowa travel reimbursement policies and procedures. These expenses shall also include the time necessary for SHL inspection staff to:

a. Review the application and related laboratory materials in preparation for the on-site inspection,
b. Generate the written laboratory report regarding inspection findings,
c. Conduct postinspection follow-up activities, if any, and
d. Review proficiency test results on an ongoing basis.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.13(730) Renewal. Laboratories wishing to continue confirmatory testing for alcohol or other drugs, or their metabolites, in Iowa must renew their certification annually. The request for renewal shall include the following:

1. Name and address of laboratory.
2. Renewal fee.
3. Information that reflects any changes that occurred during the current approval period.

4. Copy of supporting documents if the laboratory is accredited for forensic drug testing by the College of American Pathologists or if it is certified, licensed, or approved through reciprocity.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.14(730) Reciprocity.

12.14(1) Confirmatory laboratories certified, licensed, or approved by another state to conduct testing for alcohol or other drugs, or their metabolites, may request Iowa approval through reciprocity by:

a. Completing and submitting the department's application package, and

b. Including a copy of their current certificate, license, or approval document from the state whose requirements are at least equal to Iowa's.

12.14(2) Laboratories approved through reciprocity that lose their certification, license or approval from another state shall notify the department within five working days.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.15(730) Changes during approval periods. The following changes that occur during an approval period shall be submitted to the department within five working days from the date the change took place:

1. Change in laboratory director.
2. Change of address.
3. Change in supervisor.
4. Change in confirmation procedures.
5. Change in proficiency testing program.
6. Addition or subtraction of alcohol or other drugs, or their metabolites, being tested.
7. Change of ownership.
8. Loss of accreditation for forensic drug testing by the College of American Pathologists.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.16(730) Enforcement. Upon a determination of noncompliance by the director that these rules have been violated, the director may immediately move to suspend, modify, or revoke any approval issued under these rules.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.17(730) Denial, suspension, modification or revocation of approval. Any one of the following can result in denial, suspension, modification or revocation of approval. Failure of the confirmatory laboratory to:

1. Remain in compliance with the requirements of these rules.
2. Provide required documentation, including documentation of laboratory personnel and proficiency test results.
3. Maintain confidentiality.
4. Meet proficiency testing criteria.
5. Provide correct information.
6. Satisfactorily complete the two most recent and relevant graded proficiency test reports from a recognized proficiency testing program (for initial approval).
7. Correctly represent facts on a self-inspection questionnaire or other application documents.
8. Pass an on-site inspection conducted by the College of American Pathologists for forensic drug testing, or by another state whose requirements are at least equal to Iowa's, or by the SHL.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.18(730) Restoration of approval. A confirmatory laboratory whose approval has been suspended, modified, or revoked may be reinstated within 90 days following the receipt of the following:

1. Documentation of actions that correct the reasons for suspension, modification, or revocation.
2. Documentation of a successful on-site inspection, if necessary, conducted by the College of American Pathologists for forensic drug testing, or by another state whose requirements are at least equal to Iowa's, or by the SHL.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

641—12.19(730) Appeals process.

12.19(1) *Denial, suspension, modification, or revocation.* The department will send written notice of denial, suspension, modification, or revocation by certified mail, return receipt requested, pursuant to 441—Chapter 16. The adverse action will become effective 30 days after receipt of the notice unless the applicant, within 90 days, gives written notice to the department requesting a hearing. In that event, the notice will be deemed to be suspended.

12.19(2) *Contested cases.* The procedures for contested cases as set out in Iowa Code chapter 17A and the rules adopted by the department in 441—Chapter 2506 will be followed in all cases where proper notice has been made to the department of the intent to formally contest any denial, suspension, modification, or revocation of approval.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25; Editorial change: IAC Supplement 6/10/26]

641—12.20(730) Complaints.

12.20(1) The department will accept complaints of alleged problems relating to confirmatory laboratory procedures. The information shall state in as specific a manner as possible the basis for the complaint. The complaint shall be presented to the department in writing, in person or by telephone.

12.20(2) Within 20 working days of the receipt of the complaint, the department will communicate with the laboratory director for initial evaluation of the specific matters alleged in the complaint. The complainant will be informed of the results of the action taken by the department.

[**ARC 9167C**, IAB 4/30/25, effective 7/1/25]

These rules are intended to implement Iowa Code section 730.5.

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[Editorial change: IAC Supplement 6/10/26]

CHAPTER 13
MILK AND MILK PRODUCTS
[Prior to 7/29/87, Health Department[470]]
Rescinded IAB 1/30/08, effective 3/5/08

CHAPTER 14
WATER TREATMENT SYSTEMS
Rescinded **ARC 6555C**, IAB 10/5/22, effective 1/1/23

CHAPTER 15
SWIMMING POOLS, SPAS, AND SPRAY PADS
Transferred to 481—Chapter 485, IAC Supplement 2/4/26

CHAPTER 16
GARBAGE AND REFUSE
[Prior to 7/29/87, Health Department[470] Ch 16]
Rescinded IAB 1/30/08, effective 3/5/08

CHAPTER 17
SANITATION OF HABITABLE BUILDINGS
[Prior to 7/29/87, Health Department[470] Ch 17]
Rescinded IAB 1/30/08, effective 3/5/08

CHAPTER 18
TOURIST CAMPS, TRAILER CAMPS, CABIN CAMPS, CONSTRUCTION CAMPS
AND SIMILAR ESTABLISHMENTS AND AREAS
[Prior to 7/29/87, Health Department[470] Ch 18]
Rescinded IAB 1/30/08, effective 3/5/08

CHAPTER 19
MASS GATHERINGS
[Prior to 7/29/87, Health Department[470]]
Rescinded IAB 1/30/08, effective 3/5/08

CHAPTER 20
COMMUNITY WATER FLUORIDATION GRANT PROGRAM
Rescinded **ARC 9268C**, IAB 5/14/25, effective 7/1/25

CHAPTER 21
CENTRAL REGISTRY FOR
BRAIN AND SPINAL CORD INJURIES
Rescinded **ARC 9560C**, IAB 9/17/25, effective 11/1/25

CHAPTER 22
PRACTICE OF TATTOOING
Transferred to 481—Chapter 492, IAC Supplement 4/2/25

CHAPTER 23
PLUMBING AND MECHANICAL SYSTEMS BOARD—LICENSEE PRACTICE
Transferred to 481—Chapter 431, IAC Supplement 4/2/25

CHAPTER 24
PRIVATE WELL TESTING, RECONSTRUCTION, AND PLUGGING—IOWA PRIVATE WELL GRANTS

[Prior to 3/29/06, see 567—Ch 47]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/3/29

641—24.1(455E,135) Grant procedures.

24.1(1) The department has adopted policies to administer the awarding of grants for the grants to counties program. Grants will be awarded pursuant to Iowa Code section 455E.11.

24.1(2) The department will:

a. Determine program objectives;

b. Set eligible and ineligible grant costs for which the department will reimburse county programs;

c. Define performance requirements for grant recipients that set minimum standards to be met by all county programs;

d. Develop a grant application and a grant application submission procedure;

e. Terminate a grant found to be obtained by fraud or misrepresentation regardless of whether grant moneys have already been given to the grantee;

f. Allow for an applicant to appeal the denial of a properly submitted grant application. Appeals shall be governed by 441—Chapter 2506.

This rule is intended to implement Iowa Code sections 455E.11 and 135.11(26).

[**ARC 8042C**, IAB 5/29/24, effective 7/3/24; Editorial change: IAC Supplement 6/10/26]

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CHAPTER 25
STATE PLUMBING CODE
[Prior to 7/29/87, see Health Department[470] Ch 25]
Transferred to 481—Chapter 425, IAC Supplement 4/2/25

CHAPTER 26
BACKFLOW PREVENTION ASSEMBLY TESTER REGISTRATION
Transferred to 481—Chapter 476, IAC Supplement 4/2/25

CHAPTER 27
PLUMBING AND MECHANICAL SYSTEMS BOARD—ADMINISTRATIVE AND REGULATORY AUTHORITY
Transferred to 481—Chapter 427, IAC Supplement 4/2/25

CHAPTER 28
PLUMBING AND MECHANICAL SYSTEMS BOARD—LICENSURE FEES
Transferred to 481—Chapter 428, IAC Supplement 4/2/25

CHAPTER 29
PLUMBING AND MECHANICAL SYSTEMS BOARD—APPLICATION, LICENSURE, AND EXAMINATION
Transferred to 481—Chapter 429, IAC Supplement 4/2/25

CHAPTER 30
CONTINUING EDUCATION FOR PLUMBING AND MECHANICAL SYSTEMS PROFESSIONALS
Transferred to 481—Chapter 432, IAC Supplement 4/2/25

CHAPTER 31
PLUMBING AND MECHANICAL SYSTEMS BOARD—WAIVERS FROM ADMINISTRATIVE RULES
Rescinded **ARC 7997C**, IAB 5/15/24, effective 6/19/24

CHAPTER 32
PLUMBING AND MECHANICAL SYSTEMS BOARD—LICENSEE DISCIPLINE
Transferred to 481—Chapter 434, IAC Supplement 4/2/25

CHAPTER 33
PLUMBING AND MECHANICAL SYSTEMS BOARD—CONTESTED CASES
Transferred to 481—Chapter 435, IAC Supplement 4/2/25

CHAPTER 34
PLUMBING AND MECHANICAL SYSTEMS BOARD—COMPLAINTS AND INVESTIGATIONS
Transferred to 481—Chapter 433, IAC Supplement 4/2/25

CHAPTER 35
PLUMBING AND MECHANICAL SYSTEMS BOARD—ALTERNATIVE LICENSURE PATHWAYS
Transferred to 481—Chapter 430, IAC Supplement 4/2/25

CHAPTER 36
PLUMBING AND MECHANICAL SYSTEMS BOARD—PETITIONS FOR RULE MAKING

Rescinded **ARC 8002C**, IAB 5/15/24, effective 6/19/24

CHAPTER 37
GENERAL PROVISIONS FOR RADIATION AND RADIATION PROTECTION STANDARDS

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/29/31

641—37.1(136C) General provisions.

37.1(1) Except as otherwise specifically exempted, the provisions of this chapter apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation. However, nothing in these rules shall apply to the extent that such persons are subject to regulation by the U.S. Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, byproduct 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 as amended to August 1, 2025.

37.1(2) All persons possessing radiation machines within the state shall be registered in accordance with this chapter, except as specifically exempted.

37.1(3) No person shall receive, possess, use, transfer, own, or acquire radioactive material, except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in these rules.

37.1(4) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the department. These rules are issued pursuant to the authority in Iowa Code sections 136C.3 and 136C.4.

37.1(5) The requirements of this chapter are designed to control the receipt, possession, use, transfer, and disposal of radiation sources by any licensee or registrant to ensure that the total radiation dose to any individual, excluding background radiation, does not exceed the standards for protection against radiation prescribed in this chapter.

37.1(6) The limits in this chapter do not apply to doses from background radiation, medical exposures for diagnosis or therapy, or voluntary participation in medical research. Nothing in this chapter shall be construed as limiting actions that may be necessary to protect public health and safety.

37.1(7) In addition to complying with the requirements set forth in this chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA).

37.1(8) The requirements of this chapter are in addition to, and not in substitution for, any other applicable provisions of 641—Chapters 38 through 42. Compliance with the most stringent applicable requirements, whether found in this chapter or in 641—Chapters 38 through 42, is required.

37.1(9) The provisions in this chapter pertaining to radioactive materials are consistent with the requirements of 10 CFR Parts 19 and 20 (as amended to August 1, 2025) and as referenced in 641—Chapter 39. Accordingly, the provisions of 641—Chapter 39 apply to corresponding rules and subrules of this chapter.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.2(136C) Definitions. Except as otherwise specifically provided within a chapter or rule, these definitions apply to 641—Chapters 37 through 42.

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

"Accelerator" or *"particle 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.

"Accelerator-produced material" means any material made radioactive by a particle accelerator.

"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.

"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). The state of Iowa is an agreement state as of January 1, 1986.

"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 10 CFR Part 20, Appendix A (as amended to August 1, 2025), 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" or *"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.

"Annual limit on intake" or *"ALI"* means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference person that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of 10 CFR Part 20, Appendix B, as amended to August 1, 2025.

"Annually" means at least once every 365 days.

"As low as is reasonably achievable" or *"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" or *"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.

"Authorization" means license, registration, certificate, permit, or any other document issued or received by the department that authorizes specific activities related to the possession and use of radioactive materials or radiation-producing machines in Iowa.

"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 department.

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

"Bioassay" or *"radiobioassay"* 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.

"Bone densitometry" means the use of ionizing radiation for diagnostic purposes utilizing a dual energy X-ray absorptiometry (DEXA) system. A DEXA system employs low-dose X-rays at two distinct energy levels to measure bone mineral density, and may also be used to assess lean tissue mass, total or regional body fat, or to perform other examinations as permitted by the system's intended use and the department.

"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.

"Byproduct 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 "byproduct 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
- 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 rule 641—37.11(11).

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year begins 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.

"Class," "lung class," or *"inhalation class"* means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W,

or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days.

"Code of Federal Regulations" or *"CFR"* means the codification of the general and permanent regulations promulgated by the executive departments and agencies of the federal government of the United States as amended to August 1, 2025, and all references to the CFR herein are amended as to August 1, 2025. It is the official legal print publication containing the rules published in the Federal Register.

"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" or *"HT,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" or *"HE,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 ($H_{E,50} = \Sigma w_T H_{T,50}$).

"Computed tomography" or *"CT"* means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

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

"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.

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

"Declared pregnant woman" means a woman who has voluntarily informed her licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

"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" or *"Hd,"* which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 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.

"Derived air concentration" or *"DAC"* means the concentration of a given radionuclide in air that if breathed by the reference person for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour) results in an intake of one ALI. DAC values are given in Table I, Column 3, of 10 CFR Part 20, Appendix B.

"Derived air concentration-hour" or *"DAC-hour"* means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed dose equivalent of 5 rem (0.05 Sv).

"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" or *"radiation 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.

"Dose equivalent" or *"HT"* 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" or *"limits"* means the permissible upper bounds of radiation doses established in accordance with these rules.

"Effective dose equivalent" or *"HE"* means the sum of the products of the dose equivalent to each organ or tissue (HT) and the weighting factor (wT) applicable to each of the body organs or tissues that is irradiated ($HE = \Sigma w_T H_T$).

"Embryo" or *"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) 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. For purposes of certification standards, "lower extremities" and "upper extremities" mean the same as defined in rule 641—38.7(136C).

"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.

"FDA" means the United States Food and Drug Administration.

"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, that 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 to August 1, 2025, 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" or *"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" or *"HVL"* means the thickness of a specified material that 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 that might be present initially in the beam concerned, is excluded.

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261 as amended to August 1, 2025.

"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 associates, 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 one 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 that exceeds:

1. 3,000 times the A1 value of the radionuclides as specified in 49 CFR 173.435 for special form Class 7 (radioactive) material;
2. 3,000 times the A2 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.

"Individual monitoring devices," "personnel dosimeter" or *"dosimeter"* means devices designed to be worn by a single individual for the assessment of dose equivalent. 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 department.

"Instrument traceability," "source traceability" or *"traceable to a national standard"* 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 that 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 producing machine" or *"radiation machine"* means any device capable of producing radiation when the associated control devices are operated, excluding devices that produce radiation only by the use of radioactive material.

"Iowa approved" means recognized or accepted by the department as meeting the training and experience requirements established by MQSA, CFR, or any additional criteria set forth by the department. This may include but is not limited to formal approval by the department based on documentation of education, training, certification, and clinical experience.

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"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" or *"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^2).

"License" means a license issued by the department in accordance with the rules adopted by the department.

"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 department.

"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 associate, and authorized to prescribe X-ray tests for the purpose of diagnosis or treatment.

"Licensee" means any person who is licensed by the department in accordance with these rules and Iowa Code chapter 136C.

"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 that has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"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.

"Mammography" means the radiography of the breast.

"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.

"Medical event" means the medical event:

1. In which, except for an event that results from patient intervention:

- The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:
  - 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
    - The total dose delivered differs from the prescribed dose by 20 percent or more;

♦ The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

♦ The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

o 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:

♦ An administration of the wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

♦ An administration of a radioactive drug containing byproduct material by the wrong route of administration;

♦ An administration of a dose or dosage to the wrong individual or human research subject;

♦ An administration of a dose or dosage delivered by the wrong mode of treatment; or

♦ A leaking sealed source.

o A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

♦ 50 rem (0.5 Sv) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

♦ 50 percent or more the expected dose from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration;

● For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

o The total source strength administered differing by 20 percent or more from the total source strength documented in the postimplantation portion of the written directive;

o The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the postimplantation portion of the written directive; or

o An administration that includes any of the following:

♦ The wrong radionuclide;

♦ The wrong individual or human research subject;

♦ Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the postimplantation portion of the written directive; or

♦ A leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

2. Resulting from intervention of a patient or human research subject in whom administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

"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.

"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.

"Monitoring, radiation monitoring" or *"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.

"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.

"Nonstochastic effect" or *"deterministic event"* means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect.

"Nuclear Regulatory Commission" or *"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 a dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material from voluntary participation in medical research programs, or as a member of the public.

"Online licensing portal" means the electronic system designated by the department through which applicants and credential holders shall submit applications, renewals, supporting documentation, and other required information for licensure, certification, credentialing, or registration.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

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

"PET/CT" means an imaging modality that uses positron emission tomography and computed tomography in one device to combine the structural anatomic information with functional data collected during the examination.

"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.

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

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"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" or *"PAPR"* means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"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 protective barrier" or *"barrier"* means the material, excluding filters, placed in the useful beam to reduce the radiation exposure (beyond the patient and cassette holder) for protection purposes.

"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, or from exposure to individuals administered sources of radiation or radioactive material and released from voluntary participation in medical research programs.

"Qualified expert" means an individual registered with the department as a radiation machines service provider, whether as an individual, as part of a corporation, or any other entity included in the definition of "person" under this chapter, having the knowledge and training to measure ionizing radiation, evaluate safety techniques, and provide guidance on radiation protection.

"Qualitative fit test" or *"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 assurance" means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

"Quality control" means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

"Quality factor" or *"Q"* means the modifying factor, listed in Tables I and II of subrule 37.5(1), that is used to derive dose equivalent from absorbed dose.

"Quantitative fit test" or *"QNFT"* means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"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" or *"ionizing radiation"* means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. 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 one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation detector" or *"detector"* means a device that 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 machine" means any device capable of producing radiation, except those devices with radioactive material as the only source of radiation.

"Radiation safety officer" or *"RSO"* 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 that emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radionuclide" means a radioactive element or a radioactive isotope.

"Reference person" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference person is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man" as amended to August 1, 2025.

"Registrant" means any person who is registered with the department or is legally obligated to register with the department pursuant to these rules and Iowa Code chapter 136C.

"Registration" means registration with the department in accordance with the rules adopted by the department.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100 through 180.

"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 radiation incident" means an occurrence involving the use of a radiation-producing machine that meets one or more of the criteria established in the Council of Radiation Control Program Director's (CRCPD) Suggested State Regulations, Part F.2 as amended to August 1, 2025, for medical events. This includes but is not limited to any of the following:

1. Unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rad);
2. Unintended dose other than skin dose in a single procedure greater than:

- 5 times the facility's established protocol, and > 0.5 Gy (50 rad) to any organ, or
- 5 times the facility's established protocol, and > 0.05 Sv (5 rem) effective dose;

3. Wrong patient or wrong site for entire procedure when the resultant dose is:

- Dose > 0.5 Gy (50 rad) to any organ, or
- Effective dose ≥ 0.05 Sv (5 rem).

4. This definition includes radiation incidents occurring during medical diagnostic and interventional X-ray procedures, as well as any other radiation machine-related incident that meets established reporting criteria. It also encompasses any additional incident deemed reportable by the department based on potential or actual deviation from intended use, dose, or safety standards.

"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 any previous state or federal licenses, rules, or regulations.

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"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 cannot 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 × 10-4 coulombs/kilogram of air.

"Sanitary sewerage" means a system of public sewers for carrying off wastewater and refuse, excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"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 the scattered radiation that 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.

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

"Service provider" means an individual or company engaged in equipment services included in this chapter.

"Shallow dose equivalent" or *"Hs,"* 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 mg/cm^2).

"Shutter" means a device attached to the tube housing assembly that can intercept the entire cross-sectional area of the useful beam and that 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 Sv = 100 rem).

"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:

a. Uranium or thorium, or any combination thereof, in any physical or chemical form; or

b. 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 byproduct material described in numbered paragraph "2" of the definition of "byproduct 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 that participates in continuing measurement quality assurance programs with the National Institute of Standards and Technology or other equivalent national or international program.

"SPECT/CT" means an imaging modality that uses single photon emission computed tomography and computed tomography in one device to combine the structural anatomic information with functional data collected during the examination.

"SSD" means the distance between the source and the skin entrance plane of the patient.

"Stochastic effect" or *"probabilistic effect"* means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

"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" or *"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.

"Termination of irradiation" means the stopping of irradiation in a fashion that 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 the rules contained within 641—Chapters 37 through 44.

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

"Total effective dose equivalent" or *"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" or *"TODE"* means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in rule 641—37.4(136C).

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

"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 A1 for special form radioactive material or A2 for normal form radioactive material as defined in 10 CFR 71.4 as amended to August 1, 2025.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity as defined in 10 CFR 71.4 as amended to August 1, 2025.

"Unrestricted area" or *"uncontrolled area"* means an area to which access is neither limited nor controlled by the licensee or registrant.

"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), all as amended to August 1, 2025.

"User seal check" or *"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 one 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 byproduct 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 byproduct material as described in paragraphs "2," "3" and "4" of the definition of "byproduct material."

"Week" means seven consecutive days starting on Sunday.

"Weighting factor" or *"wT"* for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of wT are:

ORGAN DOSE WEIGHTING FACTORS	
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, wT = 1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

"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 department and controlled by a licensee or registrant but does not include the licensee or registrant.

"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" or *"tube"* means any electron tube that 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 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.3(136C) General regulatory requirements.

37.3(1) *General provision.* The department may, upon application therefor or upon its own initiative, grant waivers from the requirements of the rules in 641—Chapters 37 through 42 as it determines are authorized by law and will not result in undue hazard to public health and safety or property. Waivers to administrative rules should be made in accordance with the process detailed in 441—Chapter 6.

37.3(2) *Persons using byproduct 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 as amended to August 1, 2025, 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 byproduct material for:

(1) The performance of work for a department at the United States government-owned or government-controlled site, including the transportation of byproduct 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 as amended to August 1, 2025, any prime contractor or subcontractor of the NRC is exempt from the requirements for a license set forth in Iowa Code chapter 136C 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 byproduct 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. Common and contract carriers, freight forwarders, warehouse employees, 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.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.4(136C) Records. 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.

37.4(1) *Electronic records.*

a. A record or signature cannot be denied legal effect or enforceability solely because it is in electronic form.

b. A contract cannot be denied legal effect or enforceability solely because an electronic record was used in its formation.

c. If a rule requires a record to be in writing, an electronic record will satisfy the rule.

d. If a rule requires a signature, an electronic signature will satisfy the rule.

37.4(2) *Inspections.*

a. Each licensee and registrant shall afford the department 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 department for inspection, upon reasonable notice, records maintained pursuant to these rules.

37.4(3) *Tests.* Each licensee and registrant shall perform upon instructions from the department, or shall permit the department to perform, such reasonable tests as the department 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;

d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.5(136C) Units of exposure and dose.

37.5(1) 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[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.

a. 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 Table 1 above, 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[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})
(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
	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

Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})
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

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

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

b. The department 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.

37.5(2) Reserved.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.6(136C) Prohibited uses. A hand-held fluoroscopic screen cannot 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 cannot be used. Radiation from radiation-emitting machines or radioactive materials cannot be used on humans for nonmedical purposes except as approved by the department for security-related purposes.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.7(136C) Communications. All communications and reports concerning these rules should be submitted electronically to radhealthinfo@hhs.iowa.gov or addressed to the department at its office located at the Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319.

37.7(1) Drafts of proposed regulations released to the department from the federal government that constitute essential information needed by the department to ensure compliance with federal regulations are not available for public examination.

37.7(2) 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.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.8(136C) Requirements for registrations.

1. Any persons applying for a permit to operate ionizing radiation producing machines or administer radioactive materials shall comply with the requirements of 641—Chapter 38.

2. Any persons applying for a radioactive materials license shall comply with the licensing requirements of 641—Chapter 39 and the requirements of this chapter.

3. All mammography facilities shall comply with the registration requirements of 641—Chapter 41 and the requirements of this chapter.

37.8(1) *Exemptions.*

a. The following are exempt from the requirements of this chapter:

(1) Electronic equipment that produces radiation incidental to its operation for other purposes, provided the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5

millirem (5 μSv) per hour at 5 centimeters from any accessible surface of such equipment. This exemption does not apply to the production, testing, or factory servicing of such equipment.

(2) Radiation machines while in transit or temporarily stored as part of the transit process. This exemption does not apply to the providers of radiation machines for mobile services. Facilities that have placed all radiation machines in storage, including on-site storage, and have notified the department in writing are exempt. This exemption is void if any radiation machine is energized and produces radiation.

(3) Domestic television receivers.

(4) Inoperable radiation machines. For the purposes of this chapter, "inoperable radiation machine" means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

(5) Financial institutions that take possession of radiation machines as the result of foreclosure, bankruptcy, or other default of payment, to the extent that the machines are demonstrated to be operable for the sole purpose of sale, lease, or transfer.

b. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in paragraph 37.8(3)*"c"* to the registrant's radiation machine facility until such person provides evidence that the person has been registered with the department as a provider of these services.

37.8(2) *Registration requirements for radiation machine facilities.* Each person having a radiation machine facility shall apply for registration of such facility with the department prior to the operation of a radiation machine facility.

a. Application for registration shall be submitted to the department through the online licensing portal using the application furnished by the department. The application shall:

(1) Contain complete and accurate information as required by the department;

(2) Include the appropriate fee specified in rule 641—37.9(136C).

b. The applicant shall designate on the application form the name of an individual who will be responsible for radiation protection.

(1) All radiation machine registrants shall designate an individual who has authority to make decisions and conduct assessments related to radiation protection and regulatory compliance at the facility.

(2) Healing arts. A practitioner licensed by the respective state board of examiners and responsible for directing the operation of radiation machines shall be designated on each healing arts application. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner (for example, hospitals, large clinics, or multipractitioner practices).

37.8(3) *Registration requirements for radiation machine service providers.* Each person who is engaged in the business of installing or offering to install radiation machines, or providing or offering to provide radiation machine servicing or services, within this state shall apply for registration with the department prior to installing, providing, or offering to provide such services.

a. Application. Registration shall be submitted to the department through the online licensing portal using the application furnished by the department. The application shall:

(1) Contain complete and accurate information as required by the department;

(2) Include the appropriate fee specified in rule 641—37.9(136C).

b. Contents. Each person applying for registration as a service provider shall specify:

(1) That the person has read and understands the requirements of these rules;

(2) The services for which he or she is applying for registration;

(3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;

(4) The type of measurement instrument to be used, frequency of calibration, and source of calibration;

(5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

c. Services requiring an application. Services requiring registration include but are not limited to:

(1) Installation and servicing of radiation machines and associated radiation machine components;

(2) Calibration of radiation machines or radiation measurement instruments or devices;

(3) Radiation protection or health physics consultations or surveys;
(4) Personnel dosimetry services;
(5) Provider of equipment;
(6) Shielding design and evaluation;
(7) Processor or processor servicing, or both;
(8) Calibration and compliance surveys of external beam radiation therapy units;
(9) Qualified expert services for CT equipment;
(10) Qualified expert services for e-brachytherapy;
(11) Qualified expert services for therapeutic machines.

37.8(4) *Registration requirements for qualified experts for services.* A qualified expert may perform services after registering as a radiation machines service provider, whether as an individual, as part of a corporation, or as any other entity included in the definition of "person" in this chapter.

a. Each qualified expert must possess the necessary knowledge and training to measure ionizing radiation, evaluate safety practices, and provide guidance on radiation protection. Examples of individuals who may qualify include:

(1) Persons certified in the appropriate field by the American Board of Radiology, American Board of Medical Physics, or American Board of Health Physics or those with equivalent qualifications.

(2) For calibration of radiation therapy equipment, persons who, in addition to the qualifications above, have training and experience in the clinical applications of radiation physics to radiation therapy, including individuals certified in therapeutic radiological physics, X-ray and radium physics by the American Board of Radiology, or those with equivalent qualifications.

b. Each qualified expert or registered radiation machines service provider must maintain documentation demonstrating that the training requirements for the services provided under this chapter have been met. This documentation must be retained and made available to the department upon request.

37.8(5) *Stated notice.* No persons shall perform services that are not specifically stated on the notice of registration issued by the department.

a. A registration may be revoked for violating or causing a facility to violate any of the rules in 641—Chapter 38 through 42.

b. Radiation therapy physicists providing services for therapeutic radiation machines must provide proof that the training requirements of rule 641—42.6(136C) have been met at the time of the application and upon request by the department.

c. Mammography physicists providing services for mammography radiation machines must provide proof that the training requirements of 641—Chapter 41 have been met at the time of the application and upon request by the department.

37.8(6) *Issuance of notice of registration.*

a. Upon a determination that an applicant meets the requirements of this chapter, the department will issue a notice of registration.

b. The department may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

37.8(7) *Expiration of notice of registration.* Each notice of registration will expire annually.

37.8(8) *Renewal of notice of registration.* An application for renewal of registration shall be submitted annually in accordance with the requirements of this chapter.

37.8(9) *Reinstatement of registration.*

a. An application for reinstatement of registration shall be submitted to the department when a registration has not been renewed within 30 days following the expiration date in accordance with this chapter.

b. The annual registration fee, as specified in Iowa Code section 39.9, shall be submitted to the department at the time of reinstatement.

c. A reinstatement fee of $100 shall be submitted to the department at the time of reinstatement, in addition to the annual registration fees.

37.8(10) *Report of changes.* The registrant shall notify the department in writing before making any change that would render the information contained in the application for registration or the notice of registration no longer accurate.

37.8(11) *Approval not implied.* No person, in any advertisement, shall refer to the fact that the person or the person's facility is registered with the department pursuant to the provisions of this chapter, and no person shall state or imply that any activity under such registration has been approved by the department.

37.8(12) *Assembler and transfer obligation.*

a. Any person registered under the requirements of this chapter who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the department in writing within 15 days following the completion of the service and shall include all of the following:

(1) The name and address of persons who have received these machines;

(2) The manufacturer, model, and serial number of each radiation machine transferred;

(3) The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, meet the requirements of 641—Chapters 38, 39, 40 and 41.

c. In the case of diagnostic X-ray systems that contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the department within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.9(136C) Fees. Fees are nonrefundable and are in amounts sufficient to defray the cost of administering the rules of this chapter.

37.9(1) *Radiation machines.* Each registrant shall, at the time of registration and annually thereafter, as long as the registrant owns the radiation machine, remit the applicable fee to the department in adherence with the fee schedule below:

a. Fee schedule. The fees to be paid shall be in the amount computed by the following schedule. Fees for radiation machines not listed in the schedule below cannot be less than $120 per unit/tube.

b. Annual fee schedule.

Type of radiation machine		Fee per tube	Maximum fee
1.	Medical	$120	$3,000
2.	Medical Cabinet X-ray Machine (Nonhuman Use)	$100	—
3.	Osteopathy	$120	$3,000
4.	Chiropractic	$120	$3,000
5.	Dentistry	$60	$1,550
6.	Podiatry	$75	$2,000
7.	Veterinary Medicine	$60	—
8.	Industrial/Nonmedical Use	$100	—
9.	Food Sterilization	$500	—
10.	Accelerators and Electronic Brachytherapy Units	$275	—
11.	Electron Microscope	$40	—
12.	DXA/Bone Densitometry	$55	—

37.9(2) *Radiation machine service providers and medical physicists.*

a. Radiation machine service providers.

(1) Each person who is engaged in the business of installing or offering to install radiation machines or providing or offering to provide radiation machine servicing or services within this state shall apply for registration with the department prior to installing, providing, or offering to provide such services.

(2) An application shall be submitted through the online licensing portal for both initial application and annual renewals thereafter. The application shall:

1. Contain complete and accurate information as required by the department;
2. Include an annual nonrefundable fee of $200.

(3) Reinstatement. Reinstatement applications shall be submitted through the online licensing portal when a registration has not been renewed within 30 days following the expiration date.

1. The annual registration fee described in this chapter shall be submitted to the department at the time of reinstatement.
2. A reinstatement fee of $100 shall be submitted to the department at the time of reinstatement, in addition to the annual registration fees.

b. Mammography medical physicist.

(1) Each person engaged in providing health physics services for mammography in Iowa who meets the requirements of 641—subrule 41.5(3) shall apply for Iowa approval with the department prior to providing such services.

(2) An application shall be submitted through the online licensing portal for both initial application and annual renewals thereafter. The application shall:

1. Contain complete and accurate information as required by the department;
2. Include an annual nonrefundable fee of $100.

(3) Reinstatement. Reinstatement applications shall be submitted through the online licensing portal when a registration has not been renewed within 30 days following the expiration date.

1. The annual registration fee described in this chapter shall be submitted to the department at the time of reinstatement.
2. A reinstatement fee of $100 shall be submitted to the department at the time of reinstatement, in addition to the annual registration fees.

c. Stereotactic medical physicist.

(1) Each person engaged in providing health physics services for stereotactic breast biopsy in Iowa who meets the requirements of 641—Chapter 41 shall apply for Iowa approval with the department prior to providing such services.

(2) An application shall be submitted through the online licensing portal for both initial application and annual renewals thereafter. The application shall:

1. Contain complete and accurate information as required by the department;
2. Demonstrate that the requirements for Iowa approval for mammography, as specified in this chapter, have been met prior to approval for stereotactic breast biopsy;
3. Not require a fee beyond the initial annual nonrefundable fee of $100 required for Iowa approval in mammography.

(3) Reinstatement. Reinstatement applications shall be submitted through the online licensing portal when a registration has not been renewed within 30 days following the expiration date.

d. Radiation therapy medical physicist.

(1) Each person engaged in providing health physics services for radiation therapy in Iowa who meets the requirements of 641—Chapter 42 shall apply for Iowa approval with the department prior to providing such services.

(2) An application shall be submitted through the online licensing portal for both initial application and annual renewals thereafter. The application shall:

1. Contain complete and accurate information as required by the department;
2. Include the annual nonrefundable fee of $200.

(3) Reinstatement. Reinstatement applications shall be submitted through the online licensing portal when a registration has not been renewed within 30 days following the expiration date.

1. The annual registration fee described in this chapter shall be submitted to the department at the time of reinstatement.

2. A reinstatement fee of $100 shall be submitted to the department at the time of reinstatement, in addition to the annual registration fees.

37.9(3) *Inspections/interpretation fees for radiation machines.* Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

a. Mammography and stereotactic breast biopsy.

(1) Mammography unit inspections fees:

1. $1,575 for the first unit and, if the facility has additional units at the address of the first unit, $375 for each additional unit; or

2. $1,575 per portable unit for each site; or

3. A dollar amount to be determined and justified by the department on a case-by-case basis for facilities that do not meet the above criteria; or

4. $675 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances; or

5. $1,575 for each stereotactic breast biopsy unit.

(2) All mammography facilities providing services in Iowa must submit a $150 annual authorization certification fee.

b. Accelerators and electronic brachytherapy.

(1) Industrial and oncology accelerator registrants and electronic brachytherapy registrants shall pay for each inspection a fee of $900 for the first unit and $225 for each additional unit.

(2) Industrial radiography X-ray units/walk-in cabinet radiography X-ray unit registrants shall pay for each inspection a fee of $450 for the first unit and $130 for each additional unit.

37.9(4) *Radioactive materials.* Fees associated with the possession and use of radioactive materials in Iowa cannot exceed those specified in 10 CFR 170.31 and 171.16.

a. The following fee schedule will apply:

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(3.L.)	01100	AAB	Academic Type A Broad	$5,400	1	$14,600
(8.A.)	03710	CD	Civil Defense	$2,500	5	$2,000
(3.E.)	03510	I1	Irradiators, Self-Shielding <10,000 Curies	$3,200	5	$2,600
(3.O.)	03320	IR1	Industrial Radiography – Temporary Job Sites	$3,100	1	$8,000
(3.P.)	03120	FG	Measuring Systems – Fixed Gauge	$3,400	5	$2,000
(3.P.)	03121	PG	Measuring Systems – Portable Gauge	$3,400	5	$2,000
(3.P.)	02410	IVL	*In-Vitro* Testing Laboratory	$3,400	5	$2,000
(7.C.)	02230	HDR	High Dose Rate Afterloader	$5,500	1	$5,100
(7.C.)	02120	M1	Medical – Diagnostic & Therapy	$5,500	3	$4,000
(7.C.)	02121	M2	Medical – Diagnostic Only	$5,500	4	$3,600
(7.C.)	02240	MET	Medical – Diagnostic, Therapeutic, Emerging Technologies	$5,500	2	$4,500
(3.S.)	03210	PET	Accelerator-Produced RAM	$7,500	1	$5,375
(3.C.)	02500	NP	Nuclear Pharmacy	$5,100	1	$7,700
(7.C.)	02231	NV1	Nuclear Medical Van	$4,140	2	$4,000
(7.C.)	22160	PMM	Pacemaker – Byproduct and/or SNM	$2,600	R	Note 6
(3.M.)	03620	RD2	Research & Development – Other	$4,375	3	$4,000
(2.C.)	11300	SM1	Source Material, Other, >150 Kilograms	$2,600	3	$4,000

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(1.D.)	22120	SNM2	SNM Plutonium – Neutron Source	$2,600	5	$3,750
(3.P.)	03221	CAL	Calibration and W/L Tests	$2,275	5	$3,900
(3.P.)	03122	XRF	X-Ray Fluorescent Analyzer	$2,275	5	$1,860
(3.P.)	02400	VMT	Veterinary Medicine – Therapy	$3,250	3	$3,900
(3.B.)	03214	MD	Manufacturing/Distribution	$3,500	3	$3,980

b. Additional fees for radioactive materials not listed in the above schedule include:

(1) Annual fees that are due no later than September 1 of each year.

(2) Licensees with more than two authorized locations of use will be charged an additional 10 percent of the annual fee, per location.

(3) A 10 percent reinstatement fee will be due when annual fees have not been submitted within 30 days following the annual due date.

(4) Inspections are included in the annual fee.

(5) A general license registration fee of $700 is due annually on the registration anniversary.

(6) A license amendment fee for all categories is $600.

(7) A reciprocity fee of $1,800 is due annually (180 days).

(8) Inspection priorities are based on NRC Inspection Manual Chapter 2800 as amended to August 1, 2025. Priority "R" is a remote contact and is not considered an inspection.

c. Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses with the department.

37.9(5) *Radioactive material transport fee schedule.* 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.

a. $1,800 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 this chapter 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.

b. $1,300 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 any material shipped in accordance with this chapter traversing the state or any portion thereof.

c. $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.

d. 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, motor vehicle division. Assistance may be obtained by calling the department. 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.

e. All fees received pursuant to subrule 37.9(5) shall be used for purposes related to transporting radioactive material, including enforcement and planning, developing, and maintaining a capability for emergency response.

37.9(6) *Additional fees.*

a. Owner-assessed expenses. In cases in which the department 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 department.

b. Environmental surveillance fee. A fee may be levied against any licensee, registrant, corporation, company, business, or individual for environmental surveillance activities that are necessary to assess the radiological impact of activities conducted by the licensee, registrant, corporation, company, business, or

individual. This fee will be sufficient to defray actual costs incurred by the department, including but not limited to salaries of department employees, per diem, travel, and costs of laboratory analysis of samples when required.

c. Returned check and late fees. Persons who fail to pay required fees to the department are subject to the following penalties:

(1) $40 for each payment received by the department in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the department.

(2) $100 reinstatement fee when a registration has not been renewed within 30 days following the expiration date. This fee is added to the unpaid annual registration fees.

d. Reciprocity. Fees paid for reciprocal recognition of out-of-state persons wishing to utilize radiation machines or radioactive materials in Iowa 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 department.

(1) Radiation machines. Any out-of-state person who wishes to bring an X-ray machine into the state to perform work or services shall register and pay a radiation machines fee in accordance with 641—subrule 38.8(1).

(2) Linear accelerators. Any out-of-state person who wishes to bring a linear accelerator into the state to perform work or services shall register and pay a fee of $500 in accordance with 641—subrule 38.8(1).

(3) 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. If a reciprocity fee is applicable, it will be assessed at the rate for reciprocity specified in the radioactive materials fee schedule available through the department for each 365-day reciprocity period. Additionally, the reciprocity requirements of 641—Chapter 39 shall apply.

e. 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 department. The waiver may only occur as a result of a 28E agreement or memorandum of understanding between the parties.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.10(136C) Administrative enforcement actions. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order; 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 department.

1. The term “regulated entity” as used in this rule refers to any facility, person, partnership, corporation or other organization that is regulated by the department by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation.

2. “Authorization” means license, registration, certificate, permit, or any other document issued or received by the department that authorizes specific activities related to the possession and use of radioactive materials or radiation-producing machines in Iowa.

3. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4.

37.10(1) *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 department or any order issued by the department, the department may serve on the regulated entity a written notice of violation; a separate notice may be omitted if an order pursuant to subrule 37.10(2) or demand for information pursuant to subrule 37.10(4) 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 that have been taken by the regulated entity and the results achieved;

(2) Corrective action that 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 department 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 department 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.

37.10(2) *Enforcement orders.*

a. The department 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 that 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 department 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 37.10(2)*"d,"* the answer may demand a hearing.

c. If the answer demands a hearing, the department 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 department and judicial review or to contest the validity of the order in any forum as to those matters that have been consented to or agreed to or on which a hearing has not been requested. An order that has been

consented to shall have the same force and effect as an order made after hearing by a presiding officer or the department and shall be effective as provided in the order.

37.10(3) *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.

37.10(4) *Demand for information.*

a. The department may issue to a regulated entity a demand for information for the purpose of determining whether an order under subrule 37.10(2) 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 department has issued a demand for information under subrule 37.10(4) 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 the 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 subparagraph 37.10(4)*"a"*(2), or if no answer is filed, the department may institute a proceeding pursuant to subrule 37.10(2) to take such action as may be proper.

d. An answer may consent to the entry of an order pursuant to subrule 37.10(2) in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in subrule 37.10(2).

37.10(5) *Civil penalties.*

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the department will serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to subrule 37.10(2). The notice of violation will:

(1) Specify the date or dates, facts, and nature of the alleged act or omission with which the person is charged;

(2) Identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation;

(3) State the amount of each proposed penalty;

(4) 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;

(5) Advise the person charged that upon failure to pay a civil penalty subsequently determined by the department, if any, unless compromised, remitted, or mitigated, the fee will 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 paragraph 37.10(5)*"b,"* an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in paragraph 37.10(5)*"a."*

d. If the person charged with violation files an answer to the notice of violation, the department, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or

remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the department 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 department dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The department may compromise any civil penalty, subject to the provisions of 641—paragraph 38.18(2)*"d."*

h. If the civil penalty is not compromised, or is not remitted by the presiding officer or the department, and if payment is not made within ten days following either the service of the order described in 641—paragraph 38.18(2)*"a"* or the expiration of the time for requesting a hearing described in 641—subparagraph 38.18(2)*"a"*(3), the department 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 Health and Human Services.

37.10(6) *Requests for action under this rule.*

a. Any person may file a request to institute a proceeding pursuant to rule 641—38.18(136C) 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 Health and Human Services, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319. The request 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.

b. Within a reasonable time after a request pursuant to 641—paragraph 38.18(2)*"b"* has been received, the bureau chief shall either institute the requested proceeding in accordance with this rule or 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. 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 department 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 department's supervisory power over delegated staff actions or the department's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.

d. No petition or other request for department review of a bureau chief's decision under this rule will be entertained by the department.

37.10(7) *Impounding.*

a. The department 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 department.

b. If department action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If department action is not necessary to protect the public health and safety, the department 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 department will issue an order designating the time and place of hearing.

c. At the department's direction, the impounded sources of radiation may be disposed of by any of the following:

(1) Returning the source of radiation to a properly licensed or registered owner who 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;

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

37.10(8) *Deliberate misconduct.*

a. 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, shall not:

(1) 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 department; or

(2) Deliberately submit to the department; a licensee, registrant, or 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 department.

b. A person who violates subparagraphs 37.10(8)*"a"*(1) and *"a"*(2) may be subject to enforcement action in accordance with the procedures in rule 641—38.17(136C).

c. For the purposes of this chapter, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) 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 department; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.11(136C) Standards for protection against radiation. The provisions in this rule pertaining to radioactive materials are consistent with the requirements of 10 CFR Parts 19 and 20, as incorporated by reference in 641—Chapter 39. Accordingly, the provisions of 641—Chapter 39 apply to corresponding rules and subrules of this chapter. The requirements of this chapter are in addition to, and not in substitution for, any applicable provisions of 641—Chapter 39.

37.11(1) *Implementation of standards for protection against radiation.*

a. Any existing license or registration condition that is more restrictive than this chapter remains in force until there is an amendment or renewal of the license or registration.

b. If a license or registration condition exempts a licensee or registrant from a provision of this chapter in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this chapter.

c. If a license or registration condition cites provisions of this chapter in effect prior to January 1, 1994, that do not correspond to any provisions of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

37.11(2) *Radiation protection programs.*

a. Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. Subrule 37.12(3) contains recordkeeping requirements relating to these programs.

b. The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are ALARA.

c. The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

d. To implement the ALARA requirements of 641—paragraph 40.4(9)*"b,"* and notwithstanding the requirements in subrule 37.11(12), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in subrule 37.13(4) and promptly take appropriate corrective action to ensure against recurrence.

e. The licensee or registrant shall, upon discovery of a reportable radiation incident or medical event, as described in this chapter, promptly take appropriate action in accordance with the rules within this chapter.

37.11(3) *Occupational dose limits for adults.*

a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to subrule 37.11(8), to the following dose limits:

(1) An annual limit, which is the more limiting of:

1. The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

2. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities that are:

1. A lens dose equivalent of 15 rem (0.15 Sv), and

2. A shallow dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime.

c. When the external exposure is determined by measurement with an external personal monitoring device, the deep dose equivalent must be used in place of the effective dose equivalent unless the effective dose equivalent is determined by a dosimetry method approved by the department. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

d. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of 10 CFR Part 20, Appendix B, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits set forth in this chapter.

e. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (footnote 3 of 10 CFR Part 20, Appendix B, contains more information).

f. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person as set forth in this chapter.

37.11(4) *Compliance with requirements for summation of external and internal doses.*

a. Monitor. If the licensee or registrant is required to monitor pursuant to subrule 37.11(14) the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subparagraph 37.11(14)*"a"*(1), or only pursuant to subparagraph 37.11(14)*"a"*(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to subrule 37.11(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation but are subject to separate limits.

b. Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation ALI for each radionuclide, or

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors (wT) and the committed dose equivalent (HT,50) per unit intake is greater than 10 percent of the maximum weighted value of H50 (wTHT,50) per unit intake for any organ or tissue.

c. Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

d. Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to subrule 37.11(4).

37.11(5) *Determination of external dose from airborne radioactive material.*

a. Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud (footnotes 1 and 2 of 10 CFR Part 20, Appendix B, contain more information).

b. Airborne radioactivity measurements and DAC values cannot be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

37.11(6) *Determination of internal exposure.*

a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to subrule 37.11(14), take suitable and timely measurements of:

(1) Concentrations of radioactive materials in air in work areas; or

(2) Quantities of radionuclides in the body; or

(3) Quantities of radionuclides excreted from the body; or

(4) Combinations of these measurements.

b. Unless respiratory protective equipment is used, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

c. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

(1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual’s record; and

(2) Upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(3) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent (10 CFR Part 20, Appendix B, contains more information).

d. If the licensee chooses to assess intakes of Class Y material, the licensee may delay the recording and reporting of the assessments for periods up to seven months unless otherwise required

by 641—Chapter 39. This delay permits the licensee to make additional measurements basic to the assessments.

e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(1) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from 10 CFR Part 20, Appendix B, for each radionuclide in the mixture; or

(2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

g. When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

(1) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subrule 37.11(11) and in complying with the monitoring requirements in subrule 37.11(13), and

(2) The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

(3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

h. When determining the committed effective dose equivalent, the following information may be considered:

(1) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rem (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of 10 CFR Part 20, Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in subparagraph 37.11(3)*"a"*(2) is met.

37.11(7) *Determination of prior occupational dose.*

a. For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to this rule, the licensee or registrant shall:

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of lifetime cumulative occupational radiation dose.

b. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(1) The internal and external doses from all previous planned special exposures;

(2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

(3) All lifetime cumulative occupational radiation dose.

c. In complying with the requirements of subrule 37.11(7), a licensee or registrant may:

(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year;

(2) Accept, as the record of lifetime cumulative radiation dose, a form signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

(3) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by

the licensee or registrant, by telephone, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

d. The licensee or registrant shall record the exposure history as required by subrule 37.11(14).

(1) The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the exposure history. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the report indicating the periods of time for which data are not available.

(2) Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this chapter in effect on or before January 1, 1994. Further, occupational exposure histories obtained and recorded on or before January 1, 1994, would not have included effective dose equivalent but may be used in the absence of specific information on the intake of radionuclides by the individual.

e. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

(1) In establishing administrative controls pursuant to subrule 37.11(3) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

f. The licensee or registrant shall retain the records in subrule 37.11(6) until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing any record for subrule 37.11(7) for three years after the record is made.

37.11(8) *Planned special exposures.* A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in subrule 37.11(8) provided that each of the following conditions is satisfied:

a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

b. The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

c. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

(1) Informed of the purpose of the planned operation;

(2) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose ALARA, considering other risks that may be present.

d. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by subrule 37.11(7) during the lifetime of the individual for each individual involved.

e. Subject to subrule 37.11(3), the licensee or registrant cannot authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(1) The numerical values of any of the dose limits in subrule 37.11(3) in any year; and

(2) Five times the annual dose limits in subrule 37.11(3) during the individual's lifetime.

f. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with subrule 37.12(7) and submits a written report in accordance with subrule 37.13(8).

g. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from

the date of the planned special exposure. The dose from planned special exposures cannot be considered in controlling future occupational dose of the individual.

37.11(9) *Occupational dose limits for minors.* The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in subrule 37.11(3).

37.11(10) *Dose equivalent to an embryo or fetus.* The licensee or registrant shall ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). Subrule 37.12(8) contains recordkeeping requirements.

a. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in subrule 37.12(8).

b. The dose equivalent to an embryo or fetus shall be taken as the sum of:

(1) The deep dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.

c. If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo or fetus has exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, the licensee or registrant shall be deemed to be in compliance with subrule 37.11(10) if the additional dose equivalent to the embryo or fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

d. The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo or fetus be received in any one month.

37.11(11) *Radiation dose limits for individual members of the public.*

a. Each licensee or registrant shall conduct operations so that:

(1) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage, and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

b. If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

c. A licensee, a registrant, or an applicant for a license or registration may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in this subrule;

(2) The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain the dose ALARA.

d. In addition to the requirements of this chapter, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 as amended to August 1, 2025, shall comply with those standards.

e. The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

f. Notwithstanding the requirements of this subrule a licensee may permit visitors to an individual who cannot be released under rule 641—39.11(136C) to receive a radiation dose greater than 0.1 rem (1 mSv) if:

(1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in rule 641—38.1(136C), has determined before the visit that it is appropriate.

37.11(12) *Compliance with dose limits for individual members of the public.*

a. The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in subrule 37.11(11).

b. A licensee or registrant shall show compliance with the annual dose limit in subrule 37.11(11) by:

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(2) Demonstrating that:

1. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of 10 CFR Part 20, Appendix B; and

2. If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

c. Upon approval from the department, the licensee or registrant may adjust the effluent concentration values in Table II of 10 CFR Part 20, Appendix B, for members of the public to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

37.11(13) *Surveys and monitoring—general.*

a. Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

(1) Are necessary for the licensee or registrant to comply with this chapter; and

(2) Are necessary under the circumstances to evaluate:

1. The magnitude and extent of radiation levels;

2. Concentrations or quantities of residual radioactivity; and

3. The potential radiological hazards of the radiation levels and residual radioactivity detected.

b. Notwithstanding subrule 37.12(4), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable part of these rules or a license condition.

c. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with subrule 37.11(3) with other applicable provisions of these rules or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

d. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

e. After replacement, each personnel dosimeter must be sent for processing as soon as possible.

37.11(14) *Conditions requiring individual monitoring of external and internal occupational dose.* Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter. As a minimum:

a. Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(1) Adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in subrule 37.11(3);

(2) Minors likely to receive, in one year from sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) Individuals entering a high or very high radiation area;

(4) Individuals working with medical fluoroscopic equipment; and

(5) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv).

b. Each licensee or registrant shall monitor, to determine compliance with subrule 37.11(6), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B;

(2) Minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

c. Location of individual monitoring devices. Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with subrule 37.11(14) wear individual monitoring devices in accordance with the dosimetry vendor specifications and processed in accordance with NVLAP-approved calculation methods. Additional requirements are as follows:

(1) An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman shall be located at the waist under any protective apron being worn by the woman;

(2) An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with subrule 37.11(3) shall be located at the neck (collar), outside any protective apron being worn by the monitored individual or at an unshielded location closer to the eye;

(3) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subrule 37.11(3), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

37.11(15) *Control of exposure from external sources in restricted areas; control of access to high radiation areas.*

a. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(1) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

(2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

b. In place of the controls required by subrule 37.11(15) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

c. The licensee or registrant may apply to the department for approval of alternative methods for controlling access to high radiation areas.

d. The licensee or registrant shall establish the controls required by paragraph 37.11(15)*"a"* in a way that does not prevent individuals from leaving a high radiation area.

e. The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

(1) The packages do not remain in the area longer than three days; and

(2) The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

f. The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this chapter and to operate within the ALARA provisions of the licensee's radiation protection program.

g. The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in subrule 37.11(15) if the registrant has met all the specific requirements for access and control specified in other applicable chapters.

37.11(16) *Control of exposure from external sources in restricted areas; control of access to very high radiation areas.*

a. In addition to the requirements in subrule 37.11(15), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in one hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to non-self-shielded irradiators.

b. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area if the registrant has met all the specific requirements for access and control specified in other applicable chapters.

37.11(17) *Control of exposure from external sources in restricted areas; control of access to very high radiation areas—irradiators.*

a. This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

b. Each area in which there may exist radiation levels in excess of 500 rad (5 Gy) in one hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(1) Each entrance or access point shall be equipped with entry control devices that:

1. Function automatically to prevent any individual from inadvertently entering a very high radiation area;

2. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

3. Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (1 mSv) in one hour.

(2) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subrule 37.11(17):

1. The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

2. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present,

familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(3) The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

1. The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

2. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(4) When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(5) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subparagraph 37.11(17)*"b"*(2).

(6) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

(7) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(8) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour.

(9) The entry control devices required in subrule 37.11(17) shall be tested for proper functioning as set forth in subrule 37.12(11) for recordkeeping requirements.

1. Testing shall be conducted prior to initial operation with the source of radiation on any day unless operations were continued uninterrupted from the previous day;

2. Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

3. The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems. The licensee or registrant cannot conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

4. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

c. Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of subrule 37.11(17) that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of subrule 37.11(17) such as those for the automatic control of radiation levels, may apply to the department for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in subrule 37.11(17). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

d. The entry control devices required by subrule 37.11(16) shall be established in such a way that no individual will be prevented from leaving the area.

37.11(18) *Security and control of licensed or registered sources of radiation.*

a. The licensee or registrant shall secure licensed or registered radioactive material that is stored in controlled or unrestricted areas from unauthorized removal or access.

b. The licensee or registrant shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

c. The registrant shall secure registered radiation machines from unauthorized removal.

d. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

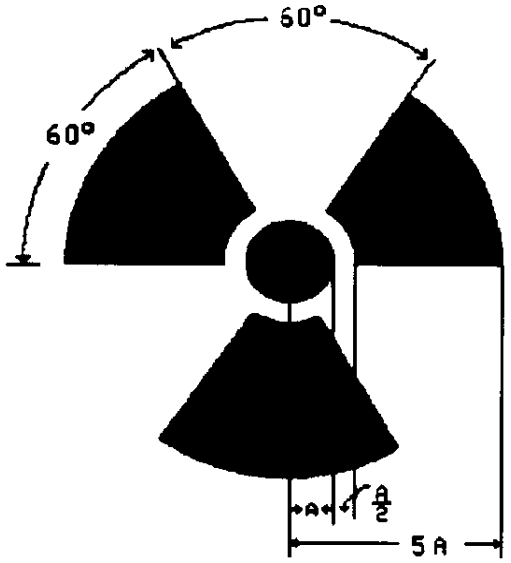
e. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever portable gauges are not under the control and constant surveillance of the licensee.

37.11(19) *Precautionary procedures; caution signs.* Unless otherwise authorized by the department, the symbol prescribed by this rule shall use the colors magenta, purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows.

a. Radiation symbol.

(1) Cross-hatched area is to be magenta, purple, or black, and

(2) The background is to be yellow.



b. Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of subrule 37.11(19), licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

c. Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this chapter, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

d. Improper posting or labeling. The licensee or registrant shall ensure that adequate measures are taken to prevent improper posting or labeling.

37.11(20) *Precautionary procedures; posting requirements.*

a. Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIATION AREA”.

b. Posting of high radiation areas. The licensee or registrant shall post in each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA”.

c. Posting of very high radiation areas. The licensee or registrant shall post in each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

d. Posting of airborne radioactivity areas. The licensee shall post in each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

e. Posting of areas or rooms in which licensed or registered material is used or stored. The licensee shall post in each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in 10 CFR Part 20, Appendix C, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

37.11(21) *Precautionary procedures; exceptions to posting requirements.*

a. A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours if each of the following conditions is met:

(1) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

(2) The area or room is subject to the licensee's or registrant's control.

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to subrule 37.11(21) provided that the patient could be released from licensee control.

c. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

d. A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis or simulation in the healing arts.

e. Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under subrule 37.11(21) if:

(1) Access to the room is controlled pursuant to subrule 37.11(17); and

(2) Personnel in attendance take necessary precautions to prevent an inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this chapter.

37.11(22) *Precautionary procedures; labeling radiation machines.* Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when it is energized.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.12(136C) Records.

37.12(1) *General provisions of measurement units.*

a. Each licensee or registrant shall use the special units curie, rad, rem and roentgen, counts per minute (cpm), disintegrations per minute (dpm), or the SI units becquerel, gray, sievert and coulomb per kilogram, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

b. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

c. In the records required by this chapter, the licensee may record quantities in SI units in parentheses following each of the units specified in subrule 37.12(1). However, all quantities must be recorded as stated in subrule 37.12(1).

d. Notwithstanding the requirements of subrule 37.12(1), when recording information on shipment manifests, information must be recorded in the International System of Units (SI) or in SI and units as specified in subrule 37.12(1).

e. Notwithstanding the requirements of subrule 37.12(1), records of removable radioactive surface contamination on packages shall be recorded in disintegrations per minute (dpm).

37.12(2) *Record retention of medical images.*

a. Medical images, whether stored digitally or on film, shall be retained for 7 years for patients 18 years of age or older, and for 7 years plus the difference between the patient's age and 18 for minors.

b. Facilities currently using hard-copy film may continue to retain imaging using this method throughout the retention period.

c. Facilities using both digital storage (computer media) and hard-copy storage may continue to retain imaging using both of these methods throughout the retention period. Digital data (computer media) should be backed up, or refreshed, at appropriate intervals as defined by the facility.

d. Facilities solely utilizing digital storage to store study information for which a report is generated must ensure the storage conditions prevent deterioration throughout the retention period required. The facility must maintain either retrieval or access or both to the stored images.

e. Facilities that have identified medical images as being involved in a legal case should immediately code the images appropriately and retain them for the required retention period defined in this paragraph or longer if required by the facility's internal policies or procedures. At the end of the retention period, the facility should follow its internal procedures and consult appropriate internal personnel for further disposition instructions as defined by the facility.

f. If records are temporarily transferred to any party, the facility should maintain appropriate information relating to location, date of release, and individual having custody of the records.

g. A facility that is ceasing operations must either transfer its medical image records to another facility or provide the records to its patients. The facility must send a certified letter as to the location, or disposition, of the records to notify the patients of the transferal.

h. Facilities performing mammography shall maintain mammography records in accordance with the requirements of 641—Chapter 41 and the requirements of this chapter. The retention period shall be the longer of the two durations specified, which is a minimum of seven years.

37.12(3) *Records of radiation protection programs.*

a. Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by this rule until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by subrule 37.12(1) for three years after the record is made.

37.12(4) *Records of surveys.*

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by subrule 37.11(13). The licensee or registrant shall retain these records for three years after the record is made.

b. The licensee or registrant shall retain each of the following records until the department terminates each pertinent license or registration requiring the record:

(1) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) Records showing the results of air sampling, surveys, and bioassays; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in subrule 37.12(4) or shall make provisions with the department for transfer to the department.

37.12(5) *Records of tests for leakage or contamination of sealed sources.* Records of tests for leakage or contamination of sealed sources shall be kept in units of microcurie or becquerel and maintained for inspection by the department for five years after the records are made.

37.12(6) *Records of prior occupational dose.*

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in subrule 37.11(7) until the department terminates each pertinent license or registration requiring this record.

b. The licensee or registrant shall retain records used in preparing the record required in subrule 37.12(6) for three years after the record is made.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in subrule 37.12(2) or shall make provisions with the department for transfer to the department.

37.12(7) *Records of planned special exposures.*

a. For each use of the provisions of subrule 37.12(7) for planned special exposures, the licensee or registrant shall maintain records that describe:

(1) The exceptional circumstances requiring the use of a planned special exposure;

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(3) What actions were necessary;

(4) Why the actions were necessary;

(5) What precautions were taken to ensure that doses were maintained ALARA;

(6) What individual and collective doses were expected to result; and

(7) The doses actually received in the planned special exposure.

b. The records shall be retained until the department terminates each pertinent license or registration requiring these records.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in subrule 37.12(7) or shall make provisions with the department for transfer to the department.

37.12(8) *Records of individual monitoring results.*

a. Recordkeeping requirements. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to subrule 37.11(14) and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect on or before January 1, 1994, need not be changed. These records shall include all of the following, when applicable:

(1) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(2) The estimated intake of radionuclides set forth in subrule 37.11(14);

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to calculate the committed effective dose equivalent pursuant to paragraph 37.11(6)*"c"*;

(5) The total effective dose equivalent when required by subrule 37.11(4);

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

b. Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in subrule 37.12(2) at intervals not to exceed one year.

c. Recordkeeping format. The licensee or registrant shall maintain the records specified in paragraph 37.12(8)*"a"* in clear and legible form.

d. Embryo or fetus records. The licensee or registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file but may be maintained separately from the dose records.

e. Retention during license or registration. The licensee or registrant shall retain each required form or record until the department terminates each pertinent license or registration requiring the record.

f. Retention after termination. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in this rule or shall make provision with the department for transfer to the department.

37.12(9) *Records of dose to individual members of the public.*

a. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public as set forth in subrule 37.11(3).

b. The licensee or registrant shall retain the records required by this rule until the department terminates each pertinent license or registration requiring the record.

37.12(10) *Records of waste disposal.*

a. Each licensee shall maintain records of the disposal of licensed materials and disposal or burial in soil.

b. The licensee shall retain the records until the department terminates each pertinent license or registration requiring the record.

37.12(11) *Records of testing entry control devices for very high radiation areas.*

a. Each licensee or registrant shall maintain records of tests made pursuant to subrule 37.11(17) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records for three years after the record is made.

37.12(12) *Form of records.*

a. Each record required by this chapter shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period, or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

b. The licensee or registrant shall retain the records required by this chapter until the department terminates each pertinent license or registration requiring the record.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.13(136C) Reports.

37.13(1) *Reports; stolen, lost, or missing licensed or registered sources of radiation.*

a. Telephone reports. Each licensee or registrant shall report to the department by telephone as follows:

(1) Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR Part 20, Appendix C, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas.

(2) Within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in quantity greater than ten times the quantity specified in 10 CFR Part 20, Appendix C, that is still missing.

(3) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

b. Written reports. Each licensee or registrant required to make a report pursuant to subrule 37.13(1) shall, within 30 days after making the telephone report, make a written report to the department setting forth the following information:

(1) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

(4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(5) Actions that have been, or will be, taken to recover the source of radiation;

(6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

c. Additional substantive information. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

d. Names of individuals. The licensee or registrant shall prepare any report filed with the department pursuant to subrule 37.13(1) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

37.13(2) *Reports; notification of incidents and reporting requirements for licensees.*

a. Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:

1. A total effective dose equivalent of 25 rem (0.25 Sv) or more;
2. A lens dose equivalent of 75 rem (0.75 Sv) or more;
3. A shallow dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more;

(2) The release of radioactive material inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) In addition to the requirements of paragraph 37.13(2)*"a,"* each licensee shall notify the department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (e.g., fires, explosions, toxic gas releases, and other such events).

b. Twenty-four-hour notification. Each licensee or registrant shall, within 24 hours of discovery of an event, report to the department each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours:

1. A total effective dose equivalent exceeding 5 rem (0.05 Sv);
2. A lens dose equivalent exceeding 15 rem (0.15 Sv);
3. A shallow dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv);

(2) The release of radioactive material inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) In addition to the requirements of paragraphs 37.13(2)*"a,"* and *"b,"* each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

- Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
- Involves a quantity of material greater than five times the lowest annual limit on intake specified in 10 CFR Part 20, Appendix B, for the material;
- Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

- The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
- The equipment is required to be available and operable when it is disabled or fails to function;
- No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

- The quantity of material involved is greater than five times the lowest annual limit on intake specified in 10 CFR Part 20, Appendix B, for the material;
- The damage affects the integrity of the licensed material or its container.

37.13(3) *Reports; notifications and reporting requirements of a reportable radiation incident.*

a. The licensee or registrant shall report any radiation incident involving the administration of ionizing radiation resulted from any of the following to the department, except when the event is the result of intervention by a patient or human research subject.

(1) Therapeutic radiation machines:

1. That involve the wrong patient, wrong treatment modality, or wrong treatment site.

2. For which the weekly administered dose differs from the weekly prescribed dose by more than 30 percent.

3. For which the total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

4. For which the dose differs by 50 percent or greater for any single fraction of a multi-fraction treatment.

5. Any equipment failure, personnel error, accident, mishap or other unusual occurrence that causes or is likely to cause significant physical harm to the patient.

(2) Diagnostic radiation machine:

1. Results in an unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rads).

2. Results in an unintended dose greater than five times the facility's established protocol for a procedure and exceeds any of the following:

- 0.5 Gy (50 rads) to an organ.
- 0.05 Gy (5 rads) total effective dose.

3. Involves the wrong patient or wrong site for the entire diagnostic examination (procedure/service) and exceeds any of the following:

- 0.5 Gy (50 rads) to an organ.
- 0.05 Gy (5 rads) total effective dose for the procedure.

4. Any wrong patient or wrong site imaged, regardless of dose received, shall be reported, documented, and addressed internally in accordance with the facility's established procedures.

(3) CT event investigation and reporting:

1. The cumulative CTDIvol over the course of an individual study at a particular anatomical location exceeds 60 rem (600 mGy) for a pediatric CT procedure or 150 rem (1500 mGy) for an adult CT procedure.

2. Any ionizing radiation exposure from a CT procedure results in unanticipated hair loss, erythema, or functional damage to an organ or physiological system.

3. For each event, the registrant shall conduct a root cause analysis in consultation with a qualified expert, the interpreting physician, and the operator who performed the CT procedure. The registrant shall make appropriate modifications consistent with the corrective action plan to prevent future events.

4. Involves any equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds 0.05 Gy (5 rads) total effective dose.

b. This rule applies to radiation incidents occurring during medical diagnostic and interventional X-ray procedures, as well as any other radiation machine-related incident that meets established reporting

criteria. This rule also encompasses any additional incident deemed reportable by the department based on potential or actual deviation from intended use, dose, or safety standards.

c. Any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will likely result, in unintended permanent functional damage to an organ or a physiological system, as determined by a physician, shall be reported.

d. The licensee or registrant shall notify the department by telephone no later than the next calendar day after discovery of the reportable radiation incident or medical event or sooner if required under the provisions set forth in this chapter where a more stringent reporting time frame has been established.

e. The licensee or registrant shall notify both the referring physician and the individual who is the subject of the reportable radiation incident or medical event no later than 24 hours after its discovery of the event.

(1) If the referring physician personally notifies the licensee or registrant that they will inform the individual, or determines, based on medical judgment, that informing the individual would be harmful, the licensee or registrant is not required to notify the individual directly.

(2) The licensee or registrant shall consult with the referring physician prior to notifying the individual.

(3) If the referring physician or individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter.

(4) Notification cannot delay any appropriate medical care for the individual, including necessary remedial treatment, resulting from the reportable radiation incident or medical event.

(5) If the individual is a minor or is unable to receive notification directly, notification may be made to a responsible relative or legal guardian.

(6) If notification is provided verbally, the licensee or registrant shall inform the individual, responsible relative, or legal guardian that a written description of the reportable radiation incident or medical event can be obtained from the licensee or registrant. The licensee or registrant shall provide such written description if requested.

37.13(4) *Report by telephone or electronic media.* Licensees or registrants shall make the notification of the incident report required by subrule 37.13(2) to the department by telephone or electronic media.

a. Licensees or registrants making initial reports to the department shall to the extent that the information is available at the time of notification include:

(1) The caller's name and call-back telephone number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

b. Each licensee or registrant who makes a notification of incident report required by subrule 37.13(2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all the necessary information. These written reports must be sent to the department at Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319. The reports must include the following:

(1) The licensee or registrant name and license or registration number;

(2) Name of the prescribing physician, if applicable;

(3) A description of the event, including:

1. The probable cause;

2. The manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(4) The exact location of the event;

(5) Date and time of the event;

(6) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(7) Corrective actions taken or planned to prevent recurrence and the results of any evaluations or assessments;

(8) The extent of exposure of individuals to radiation or to radioactive materials, without identification of individuals by name, and the effect, if any, on the individual(s) who received the administration or exposure;

(9) Certification that the licensee or registrant notified the individual or the individual's responsible relative or legal guardian and the referring physician in compliance with the requirements of this chapter and if not, the reason why not.

37.13(5) *Names of individuals in detachable portion.* The licensee or registrant shall prepare each written report to be submitted to the department pursuant to subrule 37.13(2) so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

37.13(6) *Rights or duties.* Aside from the notification requirement, nothing in this rule affects any rights or duties of licensees, registrants, and physicians in relation to each other; to individuals affected by the reportable radiation incident or medical event; or to that individual's responsible relatives or legal guardians.

37.13(7) *Doses from planned special exposures.* The provisions of subrule 37.13(2) do not apply to doses that result from planned special exposures provided such doses are within the limits for planned special exposures and are reported pursuant to subrule 37.13(8).

37.13(8) *Reports of planned special exposures.* The licensee or registrant shall submit a written report to the department within 30 days following any planned special exposure conducted in accordance with subrule 37.12(7) informing the department that a planned special exposure was conducted and indicating the date of the planned special exposure and the information required by subrule 37.12(7).

37.13(9) *Notifications and reports to individuals.*

a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in subrule 37.14(3).

b. When a licensee or registrant is required pursuant to subrule 37.13(8) to report to the department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to the department to the individual. Such notice shall be transmitted at a time not later than the transmittal to the department and shall comply with the provisions of subrule 37.14(3).

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.14(136C) Notices, instructions, and reports to workers.

37.14(1) *Posting of notices to workers.*

a. Each licensee or registrant shall post current copies of the following documents:

(1) This chapter;

(2) The license, certificate of registration, conditions, or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to activities under the license or registration;

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 641—Chapter 38 and any response from the licensee or registrant.

b. If posting of a document specified in subrule 37.14(1) is not practical, the licensee or registrant may post a notice that describes the document and states where it may be examined.

c. Department form "Notice to Employees" shall be posted by each licensee or registrant.

d. Department documents posted pursuant to subrule 37.14(1) shall be posted within two working days after receipt of the documents from the department; the licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

e. Documents, notices, or forms posted pursuant to subrule 37.14(1) shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

37.14(2) *Instructions to workers.*

a. All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv):

(1) Shall be kept informed of the storage, transfer, or use of sources of radiation;

(2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition that may constitute, lead to, or cause a violation of Iowa Code chapter 136C, these rules, and licenses or unnecessary exposure to radiation or radioactive material;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material;

(6) Shall be advised as to the radiation exposure reports that workers shall be furnished pursuant to subrule 37.13(2).

NOTE: The instruction in subparagraphs 37.14(2)*"a"*(2) through *"a"*(6) shall be conducted at least annually.

(7) Shall be commensurate with potential radiological health protection problems present in the workplace.

b. In determining those individuals subject to the requirements of subrule 37.14(2), consideration must be given to assigning activities during normal and abnormal situations involving exposure to sources of radiation that can reasonably be expected to occur during the life of the facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.

37.14(3) *Notifications and reports to individuals.*

a. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in rule 641—37.14(136C). The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions as shown in records maintained by the licensee or registrant pursuant to subrule 37.12(8). Each notification and report shall:

(1) Be in writing;

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(3) Include the individual's exposure information;

(4) Contain the following statement: "This report is furnished to you under the provisions of IAC 641 37.14. You should preserve this report for further reference."

b. Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of subrule 37.12(8). The licensee or registrant shall provide to each individual monitored under subrule 37.11(14) an annual report of the dose received in that monitoring year if any of the following apply:

(1) The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue,

(2) The individual requests the individual's annual dose report.

c. Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall:

(1) Include the dose record for each year the worker was required to be monitored pursuant to subrule 37.11(14);

(2) Be furnished within 30 days from the date of the request or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later;

(3) Cover the period of time that the worker's activities involved exposure to sources of radiation and include the dates and locations of work under the license or registration in which the worker participated during this period.

d. When a licensee or registrant is required to report to the department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the individual's exposure data included in the report to the department. Such reports shall be transmitted at a time not later than the transmittal to the department.

e. At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

641—37.15(136C) Inspections.

37.15(1) *Presence of representatives of licensees or registrants and workers during inspection.*

a. Each licensee or registrant shall afford to the department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

b. During an inspection, department inspectors may consult privately with workers as specified in subrule 37.15(2). The licensee or registrant may accompany department inspectors during other phases of an inspection.

c. If, at the time of inspection, an individual has been authorized by the workers to represent them during department inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

d. Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in subrule 37.14(2).

e. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspectors.

f. With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany department inspectors during the inspection of physical working conditions.

g. Notwithstanding the other provisions of subrule 37.15(1), department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by a department of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

37.15(2) *Consultation with workers during inspections.*

a. Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

b. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition that the worker has reason to believe may have contributed to or caused any violation of Iowa Code chapter 136C, these rules, or license condition or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of subrule 37.15(3).

c. The provisions of paragraph 37.15(2)*"b"* cannot be interpreted as authorization to disregard instructions pursuant to rule 641—37.14(136C).

37.15(3) *Requests by workers for inspections.*

a. Any worker or representative of workers believing that a violation of Iowa Code chapter 136C, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant no later than at the time of inspection, except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein cannot appear in such copy or on any record published, released, or made available by the department, except for good cause shown.

b. If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in subrule 37.15(4), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Informal reviews pursuant to subrule 37.15(4) need not be limited to matters referred to in the complaint.

c. No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this chapter.

37.15(4) *Inspections not warranted—informal review.*

a. If the department determines, with respect to a complaint under this rule, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department will notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the attorney general's office. Such department will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the attorney general's office. Such department will provide the complainant with a copy of such statement by certified mail.

b. Upon the request of the complainant, the attorney general's office may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the attorney general's office shall affirm, modify, or reverse the determination of the department and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

c. If the department determines that an inspection is not warranted because the requirements of subrule 37.15(4) have not been met, the complainant will be notified in writing of such determination. Such determination will be without prejudice to the filing of a new complaint meeting the requirements of subrule 37.15(4).

37.15(5) *Employee protection.*

a. Discrimination by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in 641—Chapters 38 through 44 and in general are related to the administration or enforcement of requirements imposed under 641—Chapters 38 through 44.

(1) The protected activities include but are not limited to:

1. Providing the department or the individual's employer information about alleged violations of either of the statutes named in this rule or possible violations of requirements imposed under either of those statutes;

2. Refusing to engage in any practice made unlawful under either of the statutes named in this rule or under these requirements if the employee has identified the alleged illegality to the employer;

3. Requesting that the department institute action against the individual's employer for the administration or enforcement of these requirements;

4. Testifying in any department proceeding, or before Congress, or at any federal or state proceeding regarding any provision (or proposed provision) of federal statutes or these rules;

5. Assisting or participating in, or about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee's assistance or participation.

(3) This rule has no application to any employee alleging discrimination prohibited by this rule who, acting without direction from the individual's employer (or the employer's agent), deliberately causes a violation of any requirement of 641—Chapters 38 through 44.

b. Any employee who believes that the employee has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph 37.15(5)*"a"* may seek a remedy for the discharge or discrimination through an administrative proceeding in the U.S. Department of Labor. The administration proceeding must be initiated within 180 days after an alleged violation occurs. The employee may file for the administrative proceeding by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

c. A violation of subrule 37.15(5) by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant may be grounds for:

(1) Denial, revocation, or suspension of the license or registration;

(2) Imposition of a civil penalty on the licensee, registrant, or applicant;

(3) Other enforcement action.

d. Actions taken by an employer or others that adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render the employee immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

e. No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to 641—Chapters 37 through 44, may contain any provision that would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in subrule 37.15(5), including but not limited to providing information to the department or to the individual's employer on potential violations or other matters within the department's regulatory responsibilities.

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]

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

Appendix A
ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

The provisions of 10 CFR Part 20, Appendix B are hereby adopted by reference, as incorporated in 641—Chapter 39. Compliance with these federal standards shall be deemed in compliance with the corresponding state requirements.

Appendix B
QUANTITIES OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

The provisions of 10 CFR Part 20, Appendix C are hereby adopted by reference, as incorporated in 641—Chapter 39. Compliance with these federal standards shall be deemed in compliance with the corresponding state requirements.

[Filed ARC 1479C (Notice ARC 1414C, IAB 4/2/14), IAB 6/11/14, effective 7/16/14]
[Filed ARC 3746C (Notice ARC 3578C, IAB 1/17/18), IAB 4/11/18, effective 5/16/18]
[Filed ARC 5059C (Notice ARC 4856C, IAB 1/15/20), IAB 6/17/20, effective 7/22/20]
[Filed ARC 9617C (Notice ARC 9491C, IAB 8/20/25), IAB 10/15/25, effective 12/1/25]
[Filed ARC 0387D (Amended Notice ARC 0223D, IAB 4/29/26; Notice ARC 9772C, IAB 11/26/25), IAB 6/24/26, effective 7/29/26]

CHAPTER 38
PERMITS TO OPERATE IONIZING RADIATION PRODUCING MACHINES OR ADMINISTER RADIOACTIVE MATERIALS FOR MEDICAL IMAGING

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—38.1(136C) Definitions.

"ARRT" means the American Registry of Radiologic Technologists.

"Attenuation correction" means the use of X-rays from a CT scan to construct an attenuation map of density differences throughout the body that can then be used to correct for the absorption of the photons emitted from Fludeoxyglucose (^{18}F) decay during a PET/CT scan.

"Authorized user" means an Iowa-licensed physician identified on a specific radioactive materials license or a license of broad scope pursuant to 641—Chapter 39.

"Category" defines specific duties allowed in the limited radiologic technologist permit classification.

"Classification" means a specific class of permit that allows the permit holder to perform the duties specified for that permit class.

"Continuing education activity" means a learning activity that is recognized as continuing education by the ARRT or NMTCB.

"Diagnostic computed tomography" means the use of computed tomography to create cross-sectional images of the human body to be used for diagnosis.

"Expiration date" means 11:59 p.m. on the stated date.

"Formal education" means a course of classroom and clinical instruction that meets the training standards set by the department.

"NMTCB" means Nuclear Medicine Technology Certification Board.

"Nuclear medicine diagnostic computed tomography endorsement" means a qualification that allows a nuclear medicine technologist to perform diagnostic computed tomography of the human body as ordered by an individual authorized by Iowa law to order radiography.

"Nuclear medicine procedure" means any procedure utilizing radiopharmaceuticals for diagnosis or treatment of disease in human beings and any duties performed by the technologist during sealed source procedures and includes but is not limited to:

1. Administration of any radiopharmaceutical to human beings for diagnostic purposes.
2. Administration of radioactive material to human beings for therapeutic purposes.
3. Use of radioactive material for diagnostic purposes involving transmission or excitation.
4. Quality control and quality assurance.

"Nuclear medicine technologist" means an individual who performs nuclear medicine procedures while under the supervision of an authorized user. The classifications are as follows:

1. "General nuclear medicine technologist" performs any nuclear medicine procedures and may perform computed tomography for attenuation correction during PET/CT or SPECT/CT only.
2. "Limited nuclear medicine technologist" performs nuclear medicine procedures only as approved by the department at the time the initial permit was issued.

"Permit" means the document issued to an individual by the department when the individual has met the requirements of this chapter. This document authorizes the individual to perform the duties allowed for the classification of permit issued.

"Radiation therapist" means an individual who performs radiation therapy under the supervision of a radiation oncologist licensed in Iowa.

"Radiation therapy" means the science and art of performing simulation radiography or applying ionizing radiation emitted from X-ray machines, particle accelerators, or radioactive materials in the form of sealed sources to human beings for therapeutic purposes.

"Radiography" means a technique for generating and recording an X-ray pattern for the purpose of providing the user with an image(s) during or after termination of the exposure.

"Radiologic technologist" means an individual, excluding X-ray equipment operators, who performs radiography of the human body as ordered by an individual authorized by Iowa law to order radiography. The classifications are as follows:

1. "General radiologic technologist" performs radiography and computed tomography of any part of the human body.
2. "Limited radiologic technologist" performs radiography for the chest, spine, extremities, shoulder or pediatrics, excluding computed tomography and fluoroscopy.
3. "Limited in-hospital radiologic technologist" performs radiography of any part of the human body as approved by the department at the time the initial permit was issued.

"Radiologist assistant" means an advanced-level radiologic technologist who has completed the necessary requirements in order to perform procedures as outlined in ARRT guidance while under supervision of a radiologist.

"Student" means an individual enrolled in and participating in formal education.

"Therapeutic" means a medical treatment using radiation for therapy purposes.

"X-ray equipment operator" means an individual performing radiography of the human body using dedicated equipment as ordered by an individual authorized by Iowa law to order radiography. These individuals do not qualify for a permit in any other classification. The classifications are as follows:

1. "Podiatric X-ray equipment operator" performs radiography of only the foot and ankle using dedicated podiatric equipment. Studies using computed tomography, fluoroscopy, or nondedicated equipment are prohibited.
2. "Bone densitometry equipment operator" performs bone densitometry using only dual energy X-ray absorptiometry equipment. Studies using computed tomography, fluoroscopy, or nondedicated equipment are prohibited.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.2(136C) Exemptions.

38.2(1) The following are exempt from obtaining a permit for the operation of radiation machines only as required by this chapter in accordance with Iowa Code chapter 136C.

a. A licensed physician.
b. A licensed physician assistant.
c. A licensed chiropractor.
d. A licensed dentist.
e. A licensed dental hygienist.
f. A licensed podiatrist.
g. An individual certified by the dental board in dental radiography.
h. A student as a part of the student's formal education.

38.2(2) The department may, upon application or upon its own initiative, grant such exemptions from the requirements of this chapter as it determines are authorized by law and will not result in undue hazard to public health and safety. Application for exemptions should be made in accordance with 441—Chapter 6.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.3(136C) Permit application and renewal. An individual cannot operate ionizing radiation producing machines or administer radioactive materials for diagnostic or therapeutic purposes unless the individual possesses a current Iowa permit in the individual's classification of practice.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.4(136C) Permit to practice—general radiologic technologist, nuclear medicine technologist, radiation therapist.

38.4(1) An individual applying for an initial permit shall:

a. Be at least 18 years of age.
b. Submit the appropriate completed application.
c. Submit a nonrefundable $100 application fee.

d. Submit proof of a passing score on the ARRT general radiography examination, the NMTCB nuclear medicine examination, or the ARRT radiation therapist examination.

38.4(2) An individual renewing a current permit shall:

a. Renew annually by submitting a renewal application and a nonrefundable $75 renewal fee.

b. Report 24.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

38.4(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable $100 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of applying for an initial license.

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 24.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.5(136C) Permit to practice as a general nuclear medicine technologist with computed tomography endorsement. An individual applying for a nuclear medicine diagnostic computed tomography endorsement shall:

38.5(1) Maintain an active permit to practice as a general nuclear medicine technologist. Endorsements shall not be held without an active permit.

38.5(2) Submit proof of a passing score on the ARRT or NMTCB computed tomography examination.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.6(136C) Permit to practice as a radiologist assistant.

38.6(1) An individual applying for an initial permit shall:

a. Submit the appropriate completed application.

b. Submit a nonrefundable $100 application fee.

c. Submit proof of completion of formal education for a radiologist assistant.

d. Submit proof of one year of experience as a general radiologic technologist.

e. Submit proof of a passing score on the ARRT radiologist assistant examination or another examination that is recognized by the department.

38.6(2) An individual renewing a current permit shall:

a. Renew annually by submitting a renewal application and a nonrefundable $75 renewal fee.

b. Report 50.0 hours of continuing education obtained within the biennium indicated on the individual's permit. Radiologist assistant permit holders must obtain at least one-half of the required continuing education in subject areas specific to radiography. The remainder may be earned as physician credit hours.

38.6(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable $100 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of applying for an initial permit.

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 50.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.7(136C) Permit to practice as a limited radiologic technologist with categories of chest, spine, extremities, shoulder, pediatric. An individual with a limited radiologic technologist permit can perform radiography only within the scope of the category(ies) in which the permit is issued. Limited radiologic technologists may use portable/mobile radiography equipment. The facility must maintain proof

of the completion of training on specific portable/mobile equipment as part of the facility's radiation protection program.

38.7(1) The scope of each category is defined as follows:

a. "Chest" allows the permit holder to perform radiography of the lung fields, including the cardiac shadow, as taught in the limited radiography formal education standards. Chest radiograph techniques cannot be manipulated for the evaluation of the shoulder, clavicle, scapula, ribs, thoracic spine and sternum. Limited radiologic technologists who have completed the appropriate formal education after January 1, 2009, may perform lateral decubitus chest views.

b. "Extremities" allows the permit holder to perform radiography for body parts from:

(1) The distal phalanges of the foot to the head of the femur, including its articulation with the pelvic girdle. True hip radiographs are prohibited.

(2) The distal phalanges of the hand to the head of the humerus. These projections may include the acromioclavicular or glenoid-humeral areas. The radiograph shall not include any of the views in the shoulder category unless the individual holds a limited radiologic technologist permit that includes the shoulder category.

c. "Spine" allows the permit holder to perform radiography of the spine in the approved areas only. Approved areas and limitations are described as:

(1) Cervical vertebrae.

(2) Thoracic (dorsal) vertebrae.

(3) Lumbar vertebrae to include the articulations with the sacrum and coccyx and the sacral articulation with the pelvic girdle. True pelvis radiographs or other projections performed with the image receptor positioned perpendicular to the long axis of the torso are prohibited under this category.

(4) All projections shall be performed as taught in the limited radiologic technologist formal education standards.

d. "Shoulder" allows the permit holder to perform radiography of the shoulder in the approved projections only. Approved projections and limitations are described as:

(1) AP internal and external rotation.

(2) AP neutral.

(3) Transthoracic lateral views.

(4) Scapular "Y" lateral.

(5) The image cannot include the proximal end of the clavicle on any AP projection. All other shoulder views are prohibited. The permit holder must hold a limited radiologic technologist permit with a category of either chest or extremity in order to be granted the shoulder category.

e. "Pediatric" allows the permit holder to perform radiography of either chest or extremities or both as defined in this chapter for patients aged 36 months and under. The permit holder must hold a limited radiologic technologist permit with the minimum categories of chest or extremities or both in order to qualify for pediatric radiography. This designation allows permit holders to perform pediatric radiography within the permit classifications listed on their permit only. All other projections on pediatric patients by limited radiologic technologists are prohibited.

38.7(2) An individual applying for an initial permit shall:

a. Be at least 18 years of age.

b. Submit the appropriate completed application.

c. Submit a nonrefundable $100 application fee.

d. Submit proof of completion of formal education in all limited diagnostic radiography categories for which the individual is applying. In order to apply for the shoulder category, the individual needs to also apply for the chest or extremity category. In order to apply for the pediatric category, the individual must also apply for the chest or extremity category. Each individual making application to attend a formal education course provided by the department to fulfill these requirements must submit an application and nonrefundable fee of $200 to the department each time the individual attends a course.

e. Submit proof of completion of testing as applicable for each permit category for which the individual is applying on the limited radiologic technologist permit. No examination is required for the categories of shoulder or pediatric.

(1) The following are passing scores:

1. A score of at least 70 percent on the ARRT limited scope of practice in radiography examination core section and at least 70 percent on each category;

2. A score of at least 70 percent on the American Chiropractic Registry of Radiologic Technologists limited radiography examination; or

3. A score of at least 70 percent on a department-approved examination.

(2) Three failed attempts on the examination will require the individual to repeat the formal education or complete a department-approved review program.

(3) Each individual making application to take an examination as a limited radiologic technologist in must submit an application to the department each time the individual takes the examination. The individual must also submit the examination fee directly to the ARRT each time the individual takes the examination.

f. Submit proof of completion of formal education and examination in the category to be added and a nonrefundable $40 amendment fee to add chest, extremity, or spine category to an existing limited radiologic technologist permit. A score of at least 70 percent on each category is required.

g. Submit proof of completion of formal education and a nonrefundable $40 amendment fee to add shoulder or pediatric category to an existing limited radiologic technologist permit. No examination is required.

38.7(3) An individual renewing a current permit shall:

a. Renew annually by submitting a renewal application and a nonrefundable $75 renewal fee.

b. Report 12.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

38.7(4) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable $100 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all the requirements of obtaining an initial permit.

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 12.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.8(136C) Permit to practice as an X-ray equipment operator in podiatric radiography or bone densitometry (dual energy X-ray absorptiometry or DEXA). After January 1, 2015, all individuals performing only bone densitometry or other examinations using DEXA machines must hold a bone densitometry permit.

38.8(1) An individual applying for an initial permit shall:

a. Be at least 18 years of age.

b. Submit the completed application.

c. Submit a nonrefundable $40 application fee.

d. Submit proof of completion of formal education that meets the department minimum training standards. Each individual applying to attend an X-ray equipment operator formal education course provided by the department must submit an application and nonrefundable fee of $150 to the department each time the individual attends the course.

e. Submit proof of at least a 70 percent score on a department-approved examination.

(1) Three failed attempts on the examination will cause the individual to repeat the formal education or complete a department-approved review program.

(2) Each individual applying to take an examination as an X-ray equipment operator must submit an application and nonrefundable fee of $100 to the department each time the individual takes the examination.

38.8(2) An individual renewing a current permit shall:

a. Renew annually by submitting a renewal application and a nonrefundable $40 renewal fee.

b. Report four hours of continuing education obtained within the biennium indicated on the individual's permit.

38.8(3) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and nonrefundable $100 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of applying for an initial permit.

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, four hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.9(136C) Closed classification or category permits.

38.9(1) The following classifications or categories are closed to new applicants. Permits in the following classifications or categories that are expired for more than six months are not eligible to be reinstated, and individuals shall maintain current permits as outlined below:

a. Limited nuclear medicine technologist shall:

(1) Perform nuclear medicine procedures for which the individual is qualified and has been authorized by the department.

(2) Renew annually by submitting a renewal application and a nonrefundable $75 renewal fee.

(3) Report 12.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

b. Limited radiologic technologist paranasal sinus shall:

(1) Perform diagnostic radiography procedures, excluding CT and fluoroscopy, specific to paranasal sinus.

(2) Renew annually by submitting a renewal application and a nonrefundable $75 renewal fee.

(3) Report six hours of continuing education obtained within the biennium indicated on the individual's permit.

38.9(2) An individual renewing a permit expired less than six months shall submit the following:

a. Application to reinstate and nonrefundable $150 application fee.

b. Any continuing education hours due at time of renewal.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.10(136C) Combining permits for an individual qualifying for permits in more than one classification.

38.10(1) An individual applying for an initial permit in more than one classification at the same time shall combine classifications on one permit by:

a. Indicating each classification on the appropriate completed application;

b. Submitting the required documentation for each classification as outlined in each classification section; and

c. Submitting a nonrefundable $150 application fee.

38.10(2) Permit holders can add a classification to an existing permit by:

a. Completing the appropriate application;

b. Submitting the required documentation as outlined in the rule specific to the classification to be added; and

c. Submitting a nonrefundable $40 fee.

38.10(3) An individual renewing a combined classification permit must submit the appropriately completed renewal application and submit a nonrefundable $110 renewal fee.

38.10(4) An individual shall submit a total of 24.0 hours of continuing education obtained within the biennium indicated on the individual's permit. If the permit includes the radiologist assistant classification, then the individual must submit a total of 50.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

38.10(5) An individual reinstating an expired permit shall submit the following:

a. Application to reinstate and a nonrefundable $150 application fee. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of submitting an initial application.

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 24.0 hours of continuing education obtained within the previous 24 months must be submitted. If the permit includes the radiologist assistant classification, then the individual must submit a total of 50.0 hours of continuing education obtained within the biennium indicated on the individual's permit.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.11(136C) Submission of proof of completion of continuing education by permit holder to meet continuing education requirements to renew or reinstate a permit.

38.11(1) A permit holder who has a current ARRT or NMTCB registration that has been renewed within 60 days prior to the submission of the permit renewal application required by these rules shall be credited the number of hours recognized by the ARRT or NMTCB registration or must submit proof of completion of continuing education activities recognized by ARRT or NMTCB.

a. Acceptable proof of completion is documentation signed and dated by the continuing education provider that includes the participant's name, title of the activity, approval number for the activity, dates of attendance, number of contact hours for the activity, name of the approving organization, and signature of the sponsor or instructor or authorized representative of the sponsor or instructor.

b. Continuing education activities cannot be repeated for credit in the same biennium but may be repeated across different biennia.

38.11(2) Podiatric X-ray equipment operator permit holders may submit activities as described in this chapter or may submit activities sponsored by the American Podiatric Medical Association or the Iowa Podiatric Medical Society.

a. Acceptable proof of completion must be documentation signed and dated by the continuing education provider that includes the participant's name, title of the activity, approval number for the activity, dates of attendance, and number of contact hours for the activity; the name of the approving organization; and the signature of the sponsor or instructor or authorized representative of the sponsor or instructor.

b. Continuing education activities that are lecture presentations cannot be repeated for credit in the same biennium.

c. All continuing education activities that are not lecture presentations cannot be repeated for credit in the same or any subsequent biennium.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.12(136C) Requirements for formal education. Formal education has to meet the following minimum requirements:

38.12(1) General radiologic technology formal education must be recognized by the ARRT to allow students to qualify for the general radiography examination.

38.12(2) Nuclear medicine technology formal education must be recognized by the ARRT or NMTCB to allow students to qualify for the nuclear medicine technology examination.

38.12(3) Radiation therapy formal education must be recognized by the ARRT to allow students to qualify for the radiation therapy examination.

38.12(4) Radiologist assistant formal education must provide training to allow students to qualify for a department-approved radiologist assistant examination.

38.12(5) Limited radiologic technologist formal education must meet the minimum standards specified in this chapter.

38.12(6) X-ray equipment operator formal education must meet the minimum standards as outlined in this chapter.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.13(136C) Standards for formal education for limited radiologic technologists.

38.13(1) The formal education may be a single offering that meets all standards of all categories, or it may be offered individually specific to the category the provider wishes to offer.

38.13(2) The following are the minimum standards:

a. A principal instructor shall:

(1) Be an Iowa-licensed chiropractor teaching spine and extremities categories only;

(2) Be an Iowa-permitted general radiologic technologist and have at least two years of current experience in radiography; or

(3) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

b. A clinical instructor shall:

(1) Be an Iowa-licensed chiropractor teaching spine and extremities categories only;

(2) Be an Iowa-permitted general radiologic technologist and have at least two years of current experience in radiography;

(3) Be an Iowa-permitted limited radiologic technologist in the category of instruction and have at least two years of current experience in radiography; or

(4) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

c. Clinical instructors shall be supervised by the principal instructor.

d. A principal instructor may also act as clinical instructor, if applicable.

e. Classroom and clinical standards are listed below:

Category	Classroom Hours	Clinical Practice Projections	Clinical Competency Projections
Core: completed by all trainees	60		
Chest	20	30 PA or LAT	5 PA, 5 LAT
Upper extremity	20	30 (any projections)	10 (only 2 of any projection allowed)
Lower extremity	20	30 (any projections)	10 (only 2 of any projection allowed)
Shoulder	20	20 (any projections)	6 (only 2 of any projection allowed)
Spine	20	30 (any projections)	10 (only 2 of any projection allowed)
Pediatric: add on to chest	8 of initial pediatrics	20 (any projections)	2 PA, 2 LAT
Pediatric: add on to upper extremity	8 of initial pediatrics	20 (any projections)	10 (only 2 of any projection allowed)
Pediatric: add on to lower extremity	8 of initial pediatrics	20 (any projections)	10 (only 2 of any projection allowed)

(1) All competency testing for limited radiography shall be directly supervised by the principal or clinical instructor, can only begin after the classroom hours in a category have been completed, and cannot begin until after the clinical site has been approved by the department using the Initial Clinical Site Form.

(2) Clinical instructors shall directly supervise all students before a student's competency for a specific projection is documented and indirectly supervise after the student's competency for a specific projection is documented.

(3) Current permit holders completing formal education to add a category do not need to repeat the core curriculum.

38.13(3) Department approval is required before implementing any formal education or making any changes to a formal education offering.

38.13(4) Administrative items for all formal education. The department reserves the right to audit or evaluate any aspect of the formal education or student progress.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.14(136C) Standards for formal education for X-ray equipment operators in podiatric radiography.

38.14(1) The following are the minimum standards:

a. A principal instructor shall:

(1) Be an Iowa-licensed podiatrist;

(2) Be an Iowa-permitted general radiologic technologist and have at least two years of current experience in radiography; or

(3) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

b. A clinical instructor shall:

(1) Be an Iowa-licensed podiatrist; or

(2) Be an Iowa-permitted limited radiologic technologist in the category of extremities and have at least two years of current experience in radiography;

(3) Be an Iowa-permitted X-ray equipment operator in podiatry and have at least two years of current experience in radiography;

(4) Be an Iowa-permitted general radiologic technologist and have at last two years of current experience in radiography; or

(5) Hold a current ARRT registration and have at least two years of current experience in radiography if the clinical site is located outside of Iowa.

c. Clinical instructors shall be supervised by the principal instructor.

d. A principal instructor may also act as clinical instructor, if applicable.

e. The following are classroom and clinical standards:

(1) A minimum of eight hours of classroom instruction to include radiation safety, equipment operation, patient care, and anatomy.

(2) Clinical instruction to include positioning and a minimum of 20 projections excluding the competency projections.

(3) Clinical competency projections to include ten projections with only two of any single projection allowed to count toward the competency projections.

(4) All competency testing to be directly supervised by the principal or clinical instructor.

(5) Clinical instructors to directly supervise all students before a student's competency for the specific projection is documented and indirectly supervise after the student's competency for the specific projection is documented.

38.14(2) Department approval is required before implementing any formal education or making any changes to a formal education offering.

38.14(3) Administrative items for all formal education:

a. The department reserves the right to audit or evaluate any aspect of the formal education or student progress.

b. The department may at any time request further documentation.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.15(136C) Standards for formal education for X-ray equipment operators in bone densitometry.

38.15(1) The following are the minimum standards:

a. A principal instructor shall have at least two years of current experience in radiography and bone densitometry and:

(1) Be an Iowa-permitted general radiologic technologist; or

(2) Hold a current ARRT registration if the clinical site is located outside of Iowa.

b. A clinical instructor shall have at least two years of current experience in radiography and bone densitometry and shall:

(1) Be an Iowa-permitted limited radiologic technologist;

(2) Be an Iowa-permitted X-ray equipment operator in bone densitometry;

(3) Be an Iowa-permitted general radiologic technologist; or

(4) Hold a current ARRT registration if the clinical site is located outside of Iowa.

c. Clinical instructors shall be supervised by the principal instructor.

d. A principal instructor shall also act as clinical instructor, if applicable.

e. The following are classroom and clinical standards:

(1) A minimum of eight hours of classroom instruction to include radiation safety, equipment operation, quality control, patient care, and anatomy.

(2) Clinical instruction to include positioning and a minimum of ten projections excluding the competency projections.

(3) Clinical competency projections to include five projections.

(4) All competency testing to be directly supervised by the principal or clinical instructor.

(5) Clinical instructors to directly supervise all students before a student's competency for the specific projection is documented and indirectly supervise after the student's competency for the specific projection is documented.

38.15(2) Department approval is required before implementing any formal education or making any changes to a formal education offering.

38.15(3) Administrative items for all formal education:

a. The department reserves the right to audit or evaluate any aspect of the formal education or student progress.

b. The department may at any time request further documentation.

38.15(4) Application to reinstate and nonrefundable $150 application fee.

a. If the permit is expired six months or more, all previous exemptions from this chapter are no longer valid and the individual is subject to all requirements of subrule 38.5(1).

b. Any continuing education hours due at time of renewal. If the permit is expired more than one year past the expiration date, 50.0 hours of continuing education obtained within the previous 24 months must be submitted.

c. Proof that all stipulations of any order(s) of disciplinary or enforcement action have been satisfied.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.16(136C) Administrative items and grounds for disciplinary action.

38.16(1) A nonrefundable $40 fee will be assessed for each check returned for any reason. All fees for returned checks plus original fees must be paid by certified bank check or money order.

38.16(2) A permit is valid from the date of issuance until the expiration date unless otherwise revoked or suspended.

38.16(3) The department may at any time request further documentation to ensure compliance with these rules.

38.16(4) The permit holder shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

38.16(5) The permit holder must maintain proof of continuing education for at least three years.

38.16(6) Continuing education obtained to satisfy disciplinary or enforcement action or as part of a corrective action plan cannot be reported to meet continuing education requirements.

38.16(7) All permit holders are subject to a department audit at any time.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.17(136C) Rules of conduct, self-reporting requirements, and enforcement actions for all permit holders or applicants.

38.17(1) *Rules of conduct.* These are mandatory standards of minimally acceptable professional conduct intended to promote the protection, safety, and comfort of patients. Any individual who fails to meet or allows any other individual to fail to meet the following standards may be subject to enforcement actions as outlined in this chapter. The following are grounds for disciplinary action:

a. Failing to perform with reasonable skill and safety all procedures accepted under this chapter's educational guidelines and allowed under the individual's permit.

b. Operating as a permitted individual without meeting the applicable requirements of this chapter. This includes performing procedures not allowed under the individual's current permit.

c. Failing to report immediately to the department any individual who may be operating as a permit holder and who does not meet the requirements of this chapter.

d. Engaging in any practice that results in unnecessary danger to a patient's life, health, or safety. This includes delegating or accepting the delegation of any function when the delegation or acceptance could cause unnecessary danger.

e. Engaging in any action that the department determines may jeopardize the health and safety of the public, other staff, or the permit holder. These actions can include but are not limited to:

(1) A misdemeanor or felony that may impair or limit the individual's ability to perform the duties authorized by the individual's permit.

(2) Any disciplinary action brought against the individual in connection with a certificate or license issued from a certifying or licensing entity.

(3) Being found guilty of incompetence or negligence during the individual's performance as a permit holder.

f. Failing to conform to applicable state and federal statutes and rules. This includes any action that might place a facility in noncompliance with Iowa statutes and rules.

g. Practicing when there is an actual or potential inability to perform with reasonable skill and safety due to illness; due to use of alcohol, drugs, chemicals, or any other material; or as the result of any mental or physical condition.

h. Engaging in any unethical conduct or conduct likely to deceive, defraud, or harm the public or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient.

i. Revealing privileged communication from or relating to former or current patients, except as permitted by law.

j. Improperly managing patient records, including failing to maintain adequate records; failing to furnish records; or making, causing, or allowing anyone to make a false, deceptive, or misleading entry into a patient record.

k. Providing false or misleading information that is directly related to the care of a former or current patient.

l. Interpreting or rendering a diagnosis for a physician based on a diagnostic image or prescribing medications or therapies.

m. Failing to immediately report to a supervisor information concerning an error made in connection with imaging, treating, or caring for a patient. This includes any departure from the normal standard of care and any behavior that is negligent.

n. Employing fraud or deceit to obtain, attempt to obtain or renew a permit under this chapter or in connection with a certification or license issued from a certifying or licensing entity. This includes altering documents, failing to provide complete and accurate responses or information, indicating falsely in writing that a permit is valid when that is not the case, or any form of examination subversion.

o. Failing to provide truthful, accurate, unaltered, or nondeceptive information related to continuing education activities to the department or a recordkeeper.

p. Assisting others to provide false, inaccurate, altered, or deceptive information related to continuing education to this department or a recordkeeper. This includes sharing answers, providing or using false certificates of participation, or verifying continuing education hours that have not been earned.

q. Failing to pay all fees or costs to meet the requirements of this chapter. Penalties for working without a current permit will be considered on a case-by-case basis.

r. Failing to respond to an audit request or failing to provide proper documentation.

s. Submitting false information to a facility that might place the facility in noncompliance with any federal or state statutes or laws.

t. Engaging in any conduct that subverts or attempts to subvert a department investigation.

u. Failing to comply with a subpoena issued by the department or failure to cooperate with an investigation by the department.

v. Failing to comply with the terms of a department order or the terms of a settlement agreement or consent order.

w. Engaging in sexual harassment of a patient, student, or supervisee. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal and physical conduct of a sexual nature.

x. Violating a statute of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, including but not limited to a crime involving dishonesty, fraud, theft, embezzlement, controlled substances, substance abuse, assault, sexual abuse, sexual misconduct, or homicide. A copy of the record of conviction or plea of guilty is conclusive evidence of the violation.

y. Having a permit, license, or certification related to the classification of the permit issued to the individual suspended or revoked or having other disciplinary action taken by a licensing or certifying authority of this state or another state, territory, or country. A copy of the record or order of suspension, revocation, or disciplinary action is conclusive or prima facie evidence.

z. Failing to respond within 30 days of receipt of communication from the department.

38.17(2) *Self-reporting.* Each permit holder shall:

a. Submit a report to the department within five days of the final disposition of all criminal proceedings, convictions, or military court-martials involving alcohol or illegal drug use while operating as a permit holder; sex-related infractions; or patient-related infractions in any state, territory, or country.

b. Submit a written report to the department within five days of the initial charge and within five days of the final disposition of any disciplinary action brought against the individual in connection with a certificate or license issued from a certifying or licensing entity, or any disciplinary action brought against the individual by an employer or patient.

c. Report potential ethics violations (including state licensing issues and criminal charges and convictions) within 30 days of the occurrence or during the permit holder's annual renewal process, whichever comes first.

38.17(3) *Enforcement actions.* Enforcement actions may include but are not limited to denial, probation, suspension or revocation of a permit, directed corrective action, and civil penalty.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

641—38.18(136C) Procedures for demand for information, notice of proposed action, and orders for penalties, suspensions, revocations, and civil penalties for all individuals under this chapter. These actions may be imposed on any permit holder who violates any rule in this chapter.

38.18(1) *Demand for information.*

a. The department may issue a demand for information for the purpose of determining whether any further action will be taken. The demand will state the alleged violations and allow the individual 20 days from the date of the letter to file a written answer with the department.

b. The individual must file a written answer to the department. The answer shall specifically admit or deny each allegation or charge made in the demand for information and provide fact and law on which the answer relies; set forth reasons why the demand should not have been issued; and if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer, the department may institute the next level of proceeding or consider the matter closed. If no answer is filed, the department will institute the notice of proposed action.

38.18(2) *Procedures for enforcement actions.*

a. Notice of proposed action.

(1) In response to an alleged violation of any provision of the Iowa Code, these rules, or any order issued by the department, the department may issue a written notice of proposed action. The notice of proposed action will concisely state the alleged violation(s), the action the department is proposing, the time period in which a written response must be received, and the process for requesting a hearing.

(2) A written response has to state any facts, explanations, or arguments denying the violations or demonstrate any extenuating circumstances, error in the notice, or other reason why the proposed action should not be imposed. Responses may also request remission or mitigation of any penalty.

(3) If a request for a hearing is received within the allotted time period, the proposed action is to be suspended pending the outcome of the hearing. Prior to or at the hearing, the department may rescind the notice of proposed action upon satisfaction that the reason for the proposed action has been resolved.

(4) If no answer is filed, the department will institute the order.

b. Order. An order may be issued upon response to the notice of proposed action or if no answer to the notice has been filed. The order may institute a proceeding to impose a penalty or suspend, revoke, or place on probation the individual's permit or issue a civil penalty. An order will concisely state the violation(s), the action the department has imposed, the effective date of the order, the time period for written response to be received by the department, and the process for requesting a hearing. If there has been consent in writing to the notice of proposed action, no written response to the order is necessary.

(1) If a request for a hearing is received within the allotted time period, the proposed action of the order is suspended pending the outcome of the hearing. Prior to or at the hearing, the department may rescind the order upon satisfaction that the reason for the proposed action has been resolved.

(2) If no answer is filed, the department will institute the order. A consent to the order constitutes a waiver to a hearing, findings of fact and conclusions of law, and of all right to seek department and judicial review or to contest the validity of the order in any form as to those matters that have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to has the same force and effect as an order made after hearing by a presiding officer or the department and is effective as provided in the order. Failure to comply with an order either consented to or validated by a hearing officer will result in further enforcement action.

c. Civil penalty. Before instituting any proceeding to impose a civil penalty, the department will serve written notice of violation upon the individual charged. This notice will be included in the notice of proposed action or order issued. The notice of proposed action or order specifies the amount of each proposed penalty for each alleged violation. The notice or order will state that the amount charged may be paid as specified or protested in its entirety or in part. Upon final action of a civil penalty, payment must be made within the specified time stated in the order or the department may refer the matter to the attorney general for collection.

d. Settlement and compromise. At any time after the issuance of a notice or order designating the time and place of hearing in response to an order, the department and the regulated individual may enter into a stipulation for a settlement or compromise of the notice or order. The stipulation of compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the chief administrative law judge. The presiding officer or chief administrative law judge may order such adjudication of the issued notice or order as deemed to be in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.

[**ARC 0288D**, IAB 5/13/26, effective 7/1/26]

These rules are intended to implement Iowa Code sections 136C.3, 136C.4, 136C.5, 136C.10, and 136C.14.

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◊ Two or more ARCs

1 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.

CHAPTER 39
REGISTRATION AND SAFETY REQUIREMENTS FOR RADIOACTIVE MATERIALS

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—39.1(136C) General provisions. This rule establishes the requirements for licensees or registrants regarding the possession, use, storage, and transfer of radioactive materials in Iowa as an agreement state. The provisions of this chapter are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 37, 38, 40, and 42.
[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.2(136C) Definitions. The definitions contained in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70, 71, and 150 as amended to August 1, 2025, and adopted by reference, apply to the provisions of this chapter. The definitions provided in 641—Chapters 37, 38, 40, and 42 may also apply. Additionally, the definitions set forth below are specific to this chapter.

"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 to August 1, 2025 (73 Stat. 689). The state of Iowa is an agreement state as of January 1, 1986.

"ANSI" means the American National Standards Institute.

"Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure independent of existing architectural structures, except the floor upon which it may be placed. The cabinet X-ray system is intended to:

1. Contain at least that portion of a material being irradiated;
2. Provide radiation attenuation; and
3. Exclude personnel from its interior during generation of radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

"Certifiable cabinet X-ray system" means an existing uncertified X-ray system that has been modified to meet certification requirements specified in 21 CFR 1020.40.

"Certified cabinet X-ray system" means an X-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

"Certifying entity" means an independent certifying organization meeting the requirements of Appendix A in 10 CFR Part 34 or an agreement state meeting the requirements in Appendix A, Parts II and III, of 10 CFR Part 34.

"Collimator" means a small radiation shield of lead or other heavy metal that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Commission" or *"NRC"* means the Nuclear Regulatory Commission or its duly authorized representatives.

"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; describes where each diagnostic clinical procedure has been approved by the authorized user; and includes the radiopharmaceutical, dosage, and route of administration.

"Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded-room radiography.

"Field station" means a facility where registered radiation machines may be stored or used and from which equipment is dispatched.

"GED" means general educational development.

"Iowa HHS" means the Iowa department of health and human services. For purposes of this chapter, this definition applies unless otherwise specified. For any CFR provisions incorporated by reference in this chapter that use the term "department," the definition provided in 10 CFR 50.2 applies.

"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.

"Minimal threat" means that during the operations of electronic devices capable of generating or emitting fields of radiation:

1. No deliberate exposure of an individual occurs;
2. The radiation is not emitted in an open beam configuration; and
3. No known physical injury to an individual has occurred.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

"Radiation safety officer" means an individual named by the registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of subparagraph 39.10(2)*"g"*(5).

"Radiographer" means any individual who has successfully completed the training, testing, and documentation requirements of subparagraph 39.10(2)*"g"*(2), who performs or personally supervises industrial radiographic operations, and who is responsible to the registrant for ensuring compliance with the requirement of these rules and all license and certificate of registration conditions.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographer's assistant" means any individual who has successfully completed the training, testing, and documentation requirements of subparagraph 39.10(2)*"g"*(1) and who uses sources of radiation and related handling tools or radiation survey instruments under the direct supervision of a radiographer trainer.

"Radiographer trainer" or *"instructor"* means any individual who instructs and supervises radiographer's assistants during on-the-job training and who meets the requirements of subparagraph 39.10(2)*"g"*(3).

"Radiographic personnel" means any radiographer or radiographer's assistant.

"RAM" means radioactive materials.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located, including but not limited to houses, apartments, condominiums, and garages.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—subrule 37.11(11).

"Temporary job site" means any location where radiographic operations are conducted and may be stored other than the location(s) listed in a certificate of registration.

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.3(136C) General regulatory requirements for incorporating CFR by reference.

39.3(1) Congress authorized the NRC in Section 274b of the Atomic Energy Act to enter into agreements that allow states to assume, and the NRC to discontinue, regulatory authority over byproduct, source, and small quantities of special nuclear material. The state can then regulate byproduct, source, and small quantities of special nuclear materials that are covered in the agreement, using its own legislation, regulations, or other legally binding provisions.

39.3(2) The Commission will enter into an agreement if the Commission finds the state program adequate to protect public health and safety and compatible with the NRC's regulatory program. The NRC ensures that an agreement state program remains adequate and compatible through periodic review and assessment under the Integrated Materials Performance Evaluation Program (IMPEP) as amended to August 1, 2025. The state of Iowa is an agreement state as of January 1, 1986.

39.3(3) As an agreement state, the requirements of 10 CFR Parts 19, 20, 30, 32, 33, 34, 35, 36, 37, 39, 40, 70, and 71 as amended to August 1, 2025, are hereby adopted by reference, as specified in the corresponding subrules of this chapter, unless specifically exempted. Where Iowa HHS forms are required, as specified in this chapter, such forms shall be submitted to Iowa HHS. A copy of 10 CFR is available at no charge from the NRC website.

39.3(4) All Iowa RAM facilities and personnel shall comply with the applicable provisions of this chapter; the related portions of 641—Chapters 37, 38, 40 and 42; and the referenced 10 CFR parts. All CFR references in this chapter are as amended to August 1, 2025. Where differences exist, compliance with the most stringent applicable standard, whether CFR regulations or Iowa Administrative Code, shall apply.
[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.4(136C) Notices, instructions and reports to workers: inspection and investigations.

39.4(1) In addition to the rules of this chapter, RAM facilities as defined in rule 641—37.2(136C) shall comply with the requirements of 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspection and Investigations," except where specific exemptions apply.

39.4(2) The provisions of 10 CFR Part 19 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 19.1, 19.2(a)(2) through (4), 19.2(b), 19.4, 19.5, 19.8, 19.11(b)(e), 19.14(a), 19.17, 19.18, 19.20, 19.30, 19.32, and 19.40.

b. Where the word "NRC" appears in 10 CFR 19.3, 19.11(f), and 19.14, substitute the words "Iowa HHS."

c. Where the word "Commission" appears in 10 CFR 19.3 (definition of "worker"), 19.11(g), 19.12, 19.13, 19.14, 19.15, and 19.16, substitute the words "Iowa HHS."

d. Where the words "Nuclear Regulatory Commission" appear in 10 CFR 19.13(a), substitute the words "Iowa HHS."

e. Where the words "Administrator of the appropriate Commission Regional Office" appear in 10 CFR 19.16(a), substitute the words "Iowa HHS."

f. Where the words "Regional Office Administrator" appear in 10 CFR 19.16(a) and (b), substitute the words "Iowa HHS."

g. Where the sentence "Regulated activities means any activity carried on that is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or any title of the Energy Reorganization Act of 1972, as amended" appears in 10 CFR 19.3, substitute the sentence "Regulated activities means any activity carried on which is under the jurisdiction of the Iowa HHS under Iowa Code chapter 136C."

h. Where the sentence "Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an applicant for or holder of a standard design approval under subpart E of part 52 of this chapter or a standard design certification under subpart B of part 52 of this chapter" appears in 10 CFR 19.3, substitute the sentence "Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of Iowa HHS under Iowa Code chapter 136C."

i. In 10 CFR 19.11(a), the phrase "(except for a holder of an early site permit under subpart A of part 52 of this chapter, or a holder of a manufacturing license under subpart F of part 52 of this chapter)" is deleted and does not apply.

j. Where the sentence "Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to subpart B of part 2 of this chapter, and any response from the licensee" appears in 10 CFR Part 19.11(a)(4), substitute the sentence "Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued by Iowa HHS, and any response from the licensee."

k. Where the words "the Act" appear in 10 CFR 19.16, substitute the words "Iowa Code chapter 136C."

l. Where the sentence "All persons who receive, possess, use, or transfer material licensed by the NRC under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility under parts 50 or 52 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) under part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter" appears in 10 CFR Part 19.2(a)(1), substitute the sentence "All persons who receive, possess, use, or transfer material licensed by Iowa HHS under the regulations in parts 30 through 36, 39, 40, or 70 of this chapter."

m. The Iowa form "Notice to Employees and Notice to Employees – Spanish" shall be posted in place of NRC Form 3 as specified in 10 CFR Part 19.

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.5(136C) Standards for protection against radiation. In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 20, "Standards for Protections Against Radiation," unless specific exemptions apply.

39.5(1) The provisions of 10 CFR Part 20 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR Part 20.1006, 20.1007, 20.1008, 20.1009, 20.1401(b), 20.1406(b), 20.1905(g), 20.2004(b)(1), 20.2201(a)(2)(i) and (b)(2)(i), 20.2202(d)(1), 20.2203(d), 20.2401, 20.2402, and Appendix D to Part 20.

b. Where the word "Commission" appears in 10 CFR 20.1002, 20.1003, 20.1204(c)(2), 20.1301(f), 20.1302(c), 20.1403(d) and (d)(1), 20.1404(a) and (a)(4), 20.1405, 20.1601(c), 20.1704, 20.1705, 20.1901(a), 20.2002, 20.2004(a)(3), 20.2102(b), 20.2103(b), 20.2104(f), 20.2105(b), 20.2106(f), 20.2107(b), 20.2108(b), 20.2201(e), 20.2202(c), 20.2204, 20.2205, 20.2301, 20.2302, and Appendix A to Part 20 (footnote c), substitute the words "Iowa HHS."

c. Where the words "under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended" appear in 10 CFR Part 20.1001(a), substitute the words "under Iowa Code chapter 136C."

d. Where the words "Nuclear Regulatory Commission" appear in 10 CFR 20.1001(a), substitute the words "Iowa HHS."

e. Where the words "NRC Headquarters Operations Center by telephone at the numbers specified in appendix A to part 73 of this chapter" appear in 10 CFR 20.1906(d), substitute the words "Iowa HHS."

f. Where the words "Administrator of the appropriate NRC Regional Office listed in appendix D to part 20" appear in 10 CFR 20.2204, substitute the words "Iowa HHS."

g. Where the sentences "The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, and 72 of this chapter, and release of part of a facility or site for unrestricted use in accordance with § 50.83 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. For high-level and low-level waste disposal facilities (10 CFR parts 60, 61, and 63), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to appendix A to 10 CFR part 40 or the uranium solution extraction facilities" appear in 10 CFR Part 20.1401(a), substitute with the sentences "The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 61, and 70 of this chapter, as well as other facilities subject to Iowa HHS's jurisdiction under Iowa Code chapter 136C. For high-level and low-level waste disposal facilities (10 CFR Part 61), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to appendix A to 10 CFR part 40 or the uranium solution extraction facilities."

h. The following are excluded from adoption by reference of 10 CFR Part 20:

(1) 10 CFR 20.1401(c): the phrase "or after part of a facility or site has been released for unrestricted use in accordance with § 50.83 of this chapter and in accordance with the criteria in this subpart";

(2) 10 CFR 20.1403(d) and 20.1404(a)(4): references to "50.82(a) and (b)" and "72.54";

(3) 10 CFR 20.1501(b): references to "50.75(g)" and "72.30(d)";

(4) 10 CFR 20.2106(d): the phrase "These records are protected by most State privacy laws and, when transferred to the NRC, are protected by the Privacy Act of 1974, Public Law 93-579, 5 U.S.C. 552a, and the Commission's regulations in 10 CFR part 9."

i. Reports required in 10 CFR 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, and 20.2207 shall be submitted to Iowa HHS.

39.5(2) The following conditions apply to 10 CFR Part 20, Appendix G:

a. Where the words "Commission or Agreement State license" appear in 10 CFR Part 20 Appendix G Section I, substitute the words "Iowa HHS, U.S. Nuclear Regulatory Commission, or Agreement State license."

b. Where the word "Commission" appears in 10 CFR Part 20, Appendix G, Section II and Section III.D.2, substitute the words "Iowa HHS."

c. Where the words "Administrator of the nearest Commission Regional Office listed in appendix D of this part" appear in 10 CFR Part 20 Appendix G, Section III.B.8, Section III.C.11, and Section III.D.3, substitute the words "Iowa HHS."

d. Where the words "nearest Commission Regional Office listed in appendix D of this part" appear in 10 CFR Part 20 Appendix G Section III.E.2, substitute the words "Iowa HHS."

e. Where the words "appropriate NRC Regional Office" appear in 10 CFR Part 20 Appendix G Section III.E.2, substitute the words "Iowa HHS."

f. Where the sentence "Licensees are not required by NRC to comply with the manifesting requirements of this part when they ship" appears in 10 CFR Part 20 Appendix G Section I, substitute the sentence "Licensees are not required by Iowa HHS to comply with the manifesting requirements of this part when they ship."

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.6(136C) Rules of general applicability to licensing of byproduct material. In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," unless specific exemptions apply. Information and records, including applications and supporting documents submitted to the department, may be made available for public inspection in accordance with Iowa Code chapter 22, Examination of Public Records (Open Records). However, the department may withhold any information and record, in whole or in part, from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned. Information related to the possession, use, or storage of radioactive materials shall not be made available for public inspection due to associated security risks.

39.6(1) *Adoption by reference—conditions.* The provisions of 10 CFR Part 30 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 30.3(b), (c), (d), 30.4 (definition of commencement of construction – paragraph 2), 30.4 (definition of "construction" – paragraph 9ii), 30.8, 30.11(c), 30.19, 30.21(c), 30.32(f), 30.33(a)(5), 30.34(d), (e)(1), (e)(3), (k), 30.41(b)(6), 30.55, 30.63, 30.64.

b. Where the word "NRC" appears in 10 CFR 30.10(a)(2), 30.35(a)(2),(b)(2),(h), 30.36(d)(4), (e)(2), (f), 30.50(a),(b), Appendix A, Appendix C, Appendix D, and Appendix E, substitute the words "Iowa HHS."

c. Where the word "Commission" appears in 10 CFR 30.5, 30.7(a), 30.7(a)(1)(i) and (iii) through (iv); 30.7(c) and (e)(2); 30.9; 30.10(a)(1); 30.10(c)(1); 30.31; 30.32; 30.34(a), (b)(1), (c), (e), and (f); 30.35(f)(2)(i) through (iii) and (g); 30.36(a) through (c), (f), (g)(1), (g)(2), (g)(5), and (k); 30.39 (where the word is the title); 30.41(b)(5), (7), and (c); 30.51(b) and (c)(1) through (2); 30.52(a) through (b); 30.53; 30.61(b); 30.62; and Appendices A, C, D, and E, substitute the words "Iowa HHS."

d. Where the words "General Counsel" appear in 10 CFR 30.5, substitute the words "Iowa HHS."

e. Where the words "NRC Regional Office specified in § 30.6" appear in 10 CFR 30.34(f), 30.51(d) through (f), substitute the words "Iowa HHS."

f. Where the words "NRC Regional Administrator" appear in 10 CFR 30.34(h)(1), substitute the words "Iowa HHS."

g. Where the words "appropriate NRC Regional Office" appear in 10 CFR 30.51(d) and (f), substitute the words "Iowa HHS."

h. For the purpose of this chapter, where 10 CFR Part 30.32 requires "NRC Form 313," licensees shall use "Iowa HHS Form 313."

i. For the purpose of this chapter, where 10 CFR Part 30.36(j)(1) requires "NRC Form 314," licensees shall use "Iowa HHS Form 314."

j. The Iowa HHS form "Notice to Employees and Notice to Employees – Spanish" shall be posted in place of NRC Form 3 as specified in 10 CFR 30.7(e).

k. In 10 CFR 30.3(a), the phrase "as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section" is deleted and does not apply.

l. In 10 CFR 30.7(e)(3), the phrase "writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, via email to *Forms.Resource@nrc.gov*, or by" is deleted and does not apply.

m. Where the words "Administrator of the appropriate Regional Office" appears in 10 CFR 30.9(b), substitute the words "Iowa HHS."

n. Where the sentence "Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material" appears in 10 CFR 30.33(b), substitute the sentence "Upon a determination that an application meets the requirements of Iowa Code chapter 136C and the regulations of Iowa HHS, Iowa HHS will issue a specific license authorizing the possession and use of byproduct material."

o. Where the words "NRC operations center" appear in 10 CFR 30.32(i)(3)(viii), substitute the words "Iowa HHS."

p. Where the words "NRC Headquarters Operations Center at the numbers specified in appendix A to part 73 of this chapter" appear in 10 CFR 30.50(c)(1) and the words "NRC using an appropriate method listed in § 30.6(a)" appear in 10 CFR 30.50(c)(2), substitute the words "Iowa HHS."

q. In 10 CFR 30.50(c)(2), the phrase "and a copy must be sent to the appropriate NRC Regional office listed in appendix D to part 20 of this chapter" is deleted and does not apply.

r. Where the words "Commission under § 32.210 of this chapter, with an Agreement State" appear in 10 CFR 30.32(g), substitute in the words "Iowa HHS, the U.S. Nuclear Regulatory Commission under § 10 CFR 32.210 of this chapter, or with an Agreement State."

s. Where the words "Director, Office of Nuclear Material Safety and Safeguards" appear in 10 CFR 30.35(h)(3), substitute the word "Iowa HHS."

t. In 10 CFR 30.36(d), the phrase "consistent with the administrative directions" is deleted and does not apply.

u. Where the words "Atomic Energy Commission, the Commission, or an Agreement State" appear in 10 CFR 30.41(b)(5), substitute the words "Iowa HHS, the U.S. Nuclear Regulatory Commission, or with an Agreement State."

v. Where the words "Commission or an Agreement State" and "Commission or with an Agreement State" appear in 10 CFR 30.41(c), substitute the words "Iowa HHS, the U.S. Nuclear Regulatory Commission, or an Agreement State."

w. Where the words "Commission or the licensing department of an Agreement State" appears in 10 CFR 30.41(d)(4) and (d)(5), substitute the words "Iowa HHS, the U.S. Nuclear Regulatory Commission, or the licensing department of an Agreement State,"

x. Where the words "section 81 of the Act" appear in 10 CFR 30.13, 30.14, 30.15, 30.18, 30.19, 30.20, 30.21, and 30.22, substitute the words "Iowa Code chapter 136C."

y. Where the word "Act" appears in 10 CFR 30.32(d), 30.33(a)(1), 30.34(a), 30.34(b)(1), 30.34(e)(4), and 30.41(b)(2) and (b)(3), substitute the words "Iowa Code chapter 136C."

z. Where the words "section 183b.- d., inclusive, of the Act" appear in 10 CFR 30.34(d), substitute the words "Iowa Code chapter 136C."

aa. Where 10 CFR Part 30 references fees listed in 10 CFR parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

39.6(2) *Reciprocity—out-of-state radiation machines.*

a. Whenever any radiation machine is to be brought into the state for temporary use, the person proposing to bring such machine into the state shall:

(1) Use Iowa HHS Form 241;

(2) Submit the form to Iowa HHS at least three working days before such machine is to be used; and

(3) Submit the appropriate fee as specified in 641—subrule 37.9(4).

b. The form shall contain complete and accurate information and shall include all of the following:

(1) The type of radiation machine;

(2) The nature, duration, and scope of use;

(3) The exact location(s) where the radiation machine is to be used; and

(4) States in which the machine is registered.

c. If, for a specific case, the three-working-day period would impose an undue hardship on the person, upon application to the department, approval to proceed sooner may be granted.

d. Persons seeking to bring an out of state radiation machine into the state shall:

(1) Comply with all applicable rules of the department;

(2) Supply the department with information as the department may reasonably request; and

(3) Not operate within the state on a temporary basis in excess of 180 calendar days in a 365-day period. The 365-day period starts on the day the department receives the appropriate fee, as specified in 641—subrule 37.9(4), and ends at the conclusion of those 365 days. It is the registrant's responsibility to ensure the 180-day limit is not exceeded and to ensure that the reciprocal recognition is renewed 30 days prior to the expiration of the 365-day reciprocity period.

39.6(3) *Reciprocal recognition of licenses.*

a. Licenses of byproduct, source, and special nuclear material in quantities not sufficient to form a critical mass.

(1) Subject to the provisions set forth in this chapter, any person who holds a specific license from the Commission or an agreement state, and having jurisdiction in where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized in the licensing document issued by the department having jurisdiction within Iowa.

1. This general license shall be for a period not in excess of 180 days in a 365-day period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 37.9(4) is received by the department and ends exactly 365 days later.

2. Licensees are responsible for ensuring they do not exceed the 180-day limit within the 365-day period and must apply for renewal 30 days prior to the expiration date of the 365-day reciprocal recognition period.

3. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain a full Iowa radioactive materials license.

(2) The licensing document issued by the department having jurisdiction, as referenced in subparagraph 39.6(3)*"a"*(1), cannot limit the activity authorized by the document to specified installations or locations.

(3) The out-of-state licensee shall notify the department in writing at least three working days prior to engaging in activities in the state.

1. The initial notification shall include all of the following:

A. The location of use;

B. The period of time for use;

C. The type of proposed possession and use within the state; and

D. A copy of the pertinent licensing document.

2. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed with use sooner.

3. The department may waive the requirement for filing additional written notifications during the remainder of the 365-day reciprocity period following the receipt of the initial notification from a person wishing to engage in activities under the general license granted by subparagraph 39.6(3)*"a"*(1).

(4) The out-of-state licensee shall comply with all applicable rules of the department and with all the terms and conditions of the licensing document, with the exception of any terms and conditions that may be inconsistent with the applicable rules of this chapter.

(5) The out-of-state licensee shall supply other information upon the request of the department.

(6) The out-of-state licensee cannot transfer or dispose of radioactive material possessed or used under the general license granted by subrule 39.6(3), except by transfer to a person specifically licensed by the department, another agreement state, or the Commission to receive such material.

(7) Notwithstanding the provisions of this chapter, any person who holds a specific license issued by the Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 641—subrule 37.8(3) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that all of the following requirements are met:

1. Such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device, under regulations of the authority that licensed manufacture of the device, bear a statement that "Removal of this label is prohibited";

4. The holder of the specific license shall furnish a copy of the general license contained in rule 641—37.8(136C), or in equivalent regulations of the department having jurisdiction over the manufacture and distribution of the device, to each general licensee to whom the holder transfers such device to or on whose premises the holder installs such device.

(8) The department may withdraw, limit, or qualify its acceptance of any specific license, equivalent licensing document issued by the Commission or an agreement state, or any product distributed pursuant to such licensing document upon determining that such action is necessary in order to prevent undue hazard to public health and safety or to property.

(9) Enforcement and revocation of industrial radiographer ID cards.

1. Any industrial radiographer who violates these rules shall be subject to formal enforcement action. The department may require the radiographer to appear at a formal hearing to show cause why the ID card should not be suspended or revoked.

2. When the department issues an order directing an industrial radiographer to cease and desist from the use of radioactive material, or suspending or revoking an ID card, the radiographer shall immediately surrender the ID card to the department. The ID card shall not be reissued until the order has been modified or rescinded or the period of suspension has expired.

3. An inspector of the department is authorized, with prior approval of the department, to confiscate an industrial radiographer's ID card during an inspection or investigation if the inspector determines that the radiographer's activities constitute a severity level of I, II, or III, as specified in rule 641—37.10(136C). Upon confiscation, the department shall transmit the ID card(s) to the issuing entity and notify the U.S. Nuclear Regulatory Commission and all applicable agreement states.

b. Licenses of naturally occurring or accelerator-produced radioactive material.

(1) Any person who holds a specific license from the Commission or an agreement state, and issued by the department for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized in the licensing document issued by the department having jurisdiction within Iowa.

1. This general license shall be for a period not in excess of 180 days in a 365-day period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 37.9(4), is received by the department and ends exactly 365 days later.

2. Licensees are responsible for ensuring they do not exceed the 180-day limit within the 365-day period and must apply for renewal 30 days prior to the expiration date of the 365-day reciprocal recognition period.

3. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where

records pertaining to licensed activities are maintained and where material can be stored. This office must have at least one full-time employee and a telephone.

(2) The licensing document issued by the department having jurisdiction, as referenced in subparagraph 39.6(3)*"a"*(1), cannot limit the activity authorized by the document to specified installations or locations.

(3) The out-of-state licensee shall notify the department in writing at least three days prior to engaging in activities in the state.

1. The notification shall include all of the following:

A. The location of use;

B. The period of time for use;

C. The type of proposed possession and use within the state;

D. A copy of the pertinent licensing document.

2. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed with use sooner.

3. The department may waive the requirement for filing additional written notifications during the remainder of the 365-day reciprocity period following the receipt of the initial notification from a person wishing to engage in activities under the general license granted by subparagraph 39.6(3)*"b"*(1).

(4) The out-of-state licensee shall comply with all applicable rules of the department and with all the terms and conditions of the licensing document, with the exception of any terms and conditions that may be inconsistent with the applicable rules of this chapter.

(5) The out-of-state licensee shall supply other information upon the request of the department.

(6) The out-of-state licensee cannot transfer or dispose of radioactive material possessed or used under the general license granted by paragraph 39.6(3)*"b,"* except by transfer to a person who meets either of the following criteria:

1. The person is specifically licensed by the department, another agreement state, or the Commission to receive such material; or

2. The person is exempt from the requirements for a license for such material under Appendix E of this chapter.

(7) Notwithstanding the provisions of this chapter, any person who holds a specific license issued by the Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 10 CFR 31.5 within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate, or service such a device in this state provided that all of the following requirements are met:

1. Such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device, under regulations of the authority that licensed manufacture of the device, bear a statement that "Removal of this label is prohibited";

4. The holder of the specific license shall furnish a copy of the general license contained in subparagraph 39.6(3)*"b"*(1), or in equivalent regulations of the department having jurisdiction over the manufacture and distribution of the device, to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device.

(8) The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or to property.

(9) The department may revoke or suspend an out-of-state radiographer's ID card issued by the Commission, a licensing state, or another agreement state in accordance with the provisions of 10 CFR 30.61.

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.7(136C) General domestic licenses for byproduct material.

39.7(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," unless specific exemptions apply.

39.7(2) The provisions of 10 CFR Part 31 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 31.4, 31.22, and 31.23.

b. Where the word "NRC" appears in 10 CFR 31.5(c)(8)(iii), (c)(13)(ii), and (c)(13)(iv) and in 31.12(a)(5), (c)(1), (c)(2), (c)(4), and (c)(5), substitute the words "Iowa HHS."

c. Where the words "Nuclear Regulatory Commission" appear in 10 CFR 31.5(c)(11), substitute the words "Iowa HHS."

d. Where the word "Commission" appears in 10 CFR 31.5(c)(5)(first and third mention), (c)(13)(ii) (both mentions), (c)(13)(iii), and (c)(13)(iv); 10 CFR 31.8(c)(2) (second mention), 31.11(b)(1), and (d)(2) (second mention); and 10 CFR 31.21, substitute the words "Iowa HHS."

e. Where the words "Office of Nuclear Material Safety and Safeguards" appear in 10 CFR 31.5(c)(5), 31.5(c)(14), and 31.12(c)(1), substitute the words "Iowa HHS at 321 E. 12th Street, Des Moines, Iowa 50319."

f. For the purpose of this chapter, where 10 CFR Part 31.11(b)(1) requires "NRC Form 483," licensees shall use "Iowa HHS Form 483."

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641—39.8(136C) Specific domestic licenses to manufacture or transfer certain items containing byproduct material.

39.8(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," unless specific exemptions apply.

39.8(2) The provisions of 10 CFR Part 32 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 32.1(c)(1), 32.2, 32.8, 32.11, 32.12, 32.13, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, 32.30, 32.31, 32.32, 32.74(c), 32.211, 32.301, and 32.303.

b. Where the word "NRC" appears in 10 CFR 32.51a(a)(5) and (b)(1) and 32.210(a) and (d)(all mentions), substitute the words "Iowa HHS."

c. Where the words "Agreement State" appear in 10 CFR 32.51(c), 32.51a(b), 32.51a(b)(1), 32.55(d), 32.56(b), 32.59, and 32.62(e), substitute the words "U.S. NRC or an Agreement State."

d. Where the words "to the NRC and to any appropriate Agreement State" appear in 10 CFR 32.51(c), 32.51a(b), 32.51a(b)(1), 32.55(d), 32.56(b), 32.59, and 32.62(e), substitute the words "to Iowa HHS, the NRC and to any appropriate Agreement State."

e. Where the words "U.S. NRC or an Agreement State" appear in 10 CFR 32.54(b)(2)(iv), substitute the words "HHS, NRC, or an Agreement State."

f. Where the words "Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, by an appropriate method listed in § 30.6(a) of this chapter" appear in 10 CFR 32.52(a) and 32.56(a), substitute the words "Iowa HHS."

g. Where the words "NRC's Office of Nuclear Material Safety and Safeguards, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter" appear in 10 CFR 32.210(b), substitute the words "Iowa HHS."

h. Where the words "US Nuclear Regulatory Commission" appear in 10 CFR 32.74(a)(3), substitute the words "Iowa HHS."

i. Where the words "Commission or an Agreement State" appear in 10 CFR 32.72(b)(5)(i) and (b)(5)(ii), substitute the words "Iowa HHS, Commission, or an Agreement State."

j. Where the word "Commission" appears in 10 CFR 32.3, 32.6(c)(1) and (e), 32.51(a)(3) and (b), 32.51a(c), 32.53(b)(6) and (d), 32.54(a) and (b) and (b)(2)(v), 32.57(b)(7) and (d), 32.61(b)(8) and (e), 32.72(b)(5), 32.74(b)(2), 32.210(e) and (h)(all mentions), substitute the words "Iowa HHS."

k. For the purpose of this chapter, where 10 CFR 32.11 requires "NRC Form 313," licensees shall use "Iowa HHS Form 313."

l. For the purpose of this chapter, where 10 CFR 32.52(a) requires "NRC Form 653," licensees shall use "Iowa HHS Form 653."

m. Where 10 CFR Part 30 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

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641—39.9(136C) Specific domestic licenses of broad scope for byproduct material.

39.9(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," unless specific exemptions apply.

39.9(2) The provisions of 10 CFR Part 33 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 33.8, 33.21, and 33.23.

b. Where the word "Commission" appears in 10 CFR 33.16 and 33.17(a)(3), substitute the words "Iowa HHS."

c. For the purpose of this chapter, where 10 CFR 33.8 and 33.12 require "NRC Form 313," licensees shall use "Iowa HHS Form 313."

d. Where 10 CFR Part 30 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

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641—39.10(136C) Licenses for industrial radiography and radiation safety requirements for industrial radiographic operations. In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," unless specific exemptions apply.

39.10(1) *Adoption by reference—conditions.* The provisions of 10 CFR Part 34 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 34.5, 34.8, 34.11, 34.41(b), 34.41(c), and 34.121.

b. Where the word "NRC" appears in 10 CFR 34.42(c)(1), 34.42(d), 34.43(b)(1)(both mentions) and (c)(1)(both mentions), and 34.89(b)(2), substitute the words "Iowa HHS."

c. Where the words "NRC or an Agreement State" appear in 10 CFR 34.27(a), substitute the words "Iowa HHS, NRC, or an Agreement State."

d. Where the words "Director, Office of Nuclear Material Safety and Safeguards by appropriate methods listed in 30.6(a) of this chapter" appear in 10 CFR 34.27(d) and 34.43(a)(1), substitute the words "Iowa HHS."

e. In 10 CFR 34.27(d), the sentence "A copy of the report must be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter "Standards for Protection Against Radiation"" is deleted and does not apply.

f. Where the word "Commission" appears in 10 CFR 34.3, 34.20(a)(2), 34.27(d), 34.41(b), 34.42(b), 34.43(a)(2) and (e) and (e)(3), 34.61(both mentions), 34.81, 34.83(c) and (d), 34.111, and Appendix A, substitute the words "Iowa HHS."

g. Where the words "Commission or an Agreement State" appear in 10 CFR 34.27(b) and (c)(both mentions) and (e) and 34.41(c), substitute the words "Iowa HHS, NRC, or an Agreement State."

h. Where the words "NRC's office of Nuclear Material Safety and Safeguards" and "NRC regional office" appear in 10 CFR 34.101, substitute the words "Iowa Health and Human Services – Bureau of Radiological Health, 321 E 12th Street, Des Moines, Iowa 50319."

i. Where the words "When operating under reciprocity pursuant to 150.20 of this chapter, a copy of the Agreement State license authorizing the use of licensed materials" appears in 10 CFR 34.89(b)(12), substitute the words "When operating under reciprocity pursuant to 150.20 of this chapter, a copy of the NRC or Agreement State license authorizing the use of licensed materials."

j. For the purpose of this chapter, where 10 CFR 34.8 and 34.11 require "NRC Form 313," licensees shall use "Iowa HHS Form 313."

k. Where 10 CFR Part 30 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

39.10(2) *General requirements for use of radiation machines in industrial radiography.* The requirements of this subrule are in addition to, and not in substitution for, other applicable requirements of 10 CFR 34, 641—Chapter 37, and this chapter. These rules apply to all licensees or registrants who use radiation for industrial or nonhuman purposes.

a. Exemptions.

(1) Uses of certified and certifiable cabinet X-ray systems designed to exclude individuals are exempt from the requirements of this chapter, except for the requirements of subparagraphs 39.10(2)*"e"*(2) and *"f"*(3).

(2) Radiation machines determined by the agency to constitute a minimal threat to human health and safety in accordance with 641—subrule 37.3(1) are exempt from the rules in this chapter, except for the requirements of this subrule.

b. Receipt, transfer, and disposal of sources of radiation. Each registrant shall maintain records showing the receipt, transfer, and disposal of machine-produced sources of radiation.

(1) These records shall include all of the following:

1. The date;
2. The name of the individual making the record; and
3. The make, model, and serial number of each source of radiation and device, as appropriate.

(2) Records shall be maintained for three years after they are made.

c. Radiation survey instruments.

(1) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make physical radiation surveys as required by this chapter and 641—subrule 37.11(13). Instrumentation required by this subrule shall have a range such that two millirems (0.02 millisievert) per hour through one rem (0.01 sievert) per hour can be measured.

(2) Notwithstanding the requirements of 641—paragraph 37.11(13)*"c,"* each radiation survey instrument shall be calibrated:

1. At energies appropriate for use and at intervals not to exceed six months and after each instrument servicing;
2. Such that accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked;
3. At 2 points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at 2 points of at least 1 decade for logarithmic scale instruments; and at 3 points between 2 and 1,000 mrem per hour for digital instruments; and
4. By a person licensed or registered by the agency, another agreement state, or the Commission to perform such service.

(3) Records of these calibrations shall be maintained for three years after the calibration date for inspection by the agency.

(4) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

d. Utilization logs.

(1) Each registrant shall maintain current logs of the use of each source of radiation. The logs shall include all of the following:

1. A unique identification, which includes the make, model and serial number of each source of radiation;

2. The identity of the radiographer using the source of radiation;

3. The date(s) each source of radiation is energized or used and the number of exposures made.

(2) Utilization logs must be kept on clear, legible records containing all the information required by this chapter. Copies of utilization logs shall be maintained for agency inspection for three years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

e. Inspection and maintenance.

(1) Each registrant shall perform visual and operability checks on survey meters, radiation machines and associated equipment before use on each day that the components are to be used to ensure that the components are in good working condition and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means.

(2) Each registrant shall have written procedures and conduct a program at intervals not to exceed three months, or prior to the first use thereafter, of inspection and maintenance of radiation machines, survey instruments, and associated equipment to ensure proper functioning of components important to safety.

1. All appropriate parts shall be maintained in accordance with manufacturer's specifications.

2. Replacement components shall meet design specifications.

3. This program shall cover, as a minimum, the items in Appendix F of this chapter.

(3) If equipment defects or issues are found, the equipment must be removed from service until repaired.

(4) A record of equipment defects or issues and of any maintenance performed under the requirements of this chapter must be retained for three years after the record is made. The record must include all of the following:

1. The date of check or inspection;

2. The name of the inspector;

3. The specific equipment involved;

4. Any problems found; and

5. What repair or maintenance was performed, if any.

f. Permanent radiographic installations. Permanent radiographic installations having high radiation area entrance controls of the type described in 641—subparagraphs 37.11(15)*"a"*(2) and *"a"*(3) shall also meet all of the following requirements:

(1) Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation.

1. The visible signal shall be activated by radiation.

2. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

(2) The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use.

1. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed.

2. Records of these tests shall be maintained for inspection by the agency for three years from the date of the event.

g. Training and testing for radiographic personnel.

(1) Radiographer's assistant requirements. No registrant shall permit any individual to act as a radiographer's assistant, as defined in this chapter, until it has been documented on the appropriate agency form or equivalent that such individual has received copies of, and has demonstrated an understanding of, the following:

1. The subjects outlined in Appendix A;

2. The rules contained in this chapter and the applicable sections of 641—Chapter 37.

3. The appropriate conditions of certificate(s) of registration;

4. The registrant's operating and emergency procedures;

5. A developed competence to use, under the personal supervision of the radiographer, the registrant's radiation machine and radiation survey instruments that the assistant will use;

(2) Radiographer requirements. No registrant shall permit any individual to act as a radiographer until it has been documented to the agency that such individual has:

1. Completed the requirements of subparagraph 39.10(2)*"g"*(4);

2. Completed on-the-job training as a radiographic trainee supervised by one or more radiographic trainers. The on-the-job training shall be documented on the appropriate agency form or equivalent and shall include a minimum of one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Active participation does not include safety meetings or classroom training;

3. Demonstrated competence in the use of radiation machines and radiation survey instruments that may be employed in industrial radiographic assignments by successful completion of a practical examination covering this material;

4. Completed, within the last five years, an appropriate examination and possesses a current ID card.

(3) Radiographer trainer. No individual shall act as a radiographer trainer unless such individual:

1. Has met the requirements of subparagraph 39.10(2)*"g"*(1) and numbered paragraph 39.10(2)*"g"* (2)"2";

2. Has one year of documented experience as an industrial radiographer and possesses a current ID card issued at least one year prior to acting as a trainer; and

3. Is named on the certificate of registration issued by the agency and under which an individual is acting as a radiographer trainer.

(4) Radiation safety officer (RSO). The RSO, as defined in rule 641—37.2(136C), shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the registrant's program.

1. An RSO shall be designated for every certificate of registration issued by the agency.

2. The RSO's qualifications shall include the following:

A. Possession of a high school diploma or a certificate of high school equivalency based on the GED tests;

B. Completion of the training and testing requirements of subparagraphs 39.10(2)*"g"*(1), *"g"*(3), and *"g"*(4).

C. Formal training in the establishment and maintenance of a radiation protection program.

D. The agency will consider alternatives when the RSO has either appropriate training or experience, or both, in the field of ionizing radiation and, in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

3. The specific duties of the RSO include but are not limited to the following:

A. To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

B. To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

C. To ensure that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

D. To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by rule 641—37.11(136C);

E. To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

F. To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules, and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

G. To have a thorough knowledge of management policies and administrative procedures of the registrant;

H. To assume control and have the authority to institute corrective actions, including shutdown of operations when necessary in emergency situations or unsafe conditions;

I. To maintain records as required by these rules (Appendix C contains more information);

J. To ensure the proper storing, labeling, transport, and use of sources of radiation;

K. To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with the requirements of this chapter;

L. To ensure that personnel are complying with these rules, the conditions of the registration, and the operating and emergency procedures of the registrant; and

M. To ensure that annual refresher safety training has been provided for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(5) Training and testing records. Each registrant shall maintain, for agency inspection, training and testing records that demonstrate that the applicable requirements of subparagraphs 39.10(2)*"g"*(1) and *"g"*(2) are met.

1. Records of training for all industrial radiographic personnel must include all of the following:

A. Personnel certification documents and verification of certification status;

B. Copies of written tests;

C. Dates of oral and practical examinations; and

D. The names of individuals conducting and receiving the oral and practical examinations.

2. Records of annual refresher training and semiannual inspection of job performance for all industrial radiographic personnel must include all of the following:

A. The topics discussed during the refresher safety training;

B. The dates the annual refresher safety training was conducted; and

C. The names of the instructors and attendees.

3. For inspections of job performance, the records must also include a list showing the items checked and any noncompliance observed by the RSO.

4. Records shall be maintained until disposal is authorized by the agency. The agency cannot release records for disposal unless the records have been maintained at least three years.

(6) Reciprocity.

1. Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that all of the following conditions are met:

A. The individual holds a valid certification in the appropriate category and class issued by a certifying entity as defined in this chapter;

B. The requirements and procedures of the certifying entity issuing the certification require the same or comparable certification standards as those required by subparagraphs 39.10(2)*"g"*(1) through *"g"*(5); and

C. The individual submits a legible copy of the certification to the agency prior to entry into Iowa.

2. Enforcement actions with the agency, another agreement state, or the Commission or any sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

3. Certified radiographers who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted or, prior to the expiration of such certification, shall meet the requirements of subparagraph 39.10(2)*"g"*(2).

h. Internal audits.

(1) The RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that these rules and the registrant's operating and emergency procedures are followed. The inspection program must:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

2. Provide that, if a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last audit, the radiographer or radiographer's assistant must demonstrate understanding of the subjects contained in Appendix A of this chapter by a practical examination before the individual can participate in a radiographic operation.

(2) When a single individual serves as both radiographer and RSO and performs all radiography operations, an inspection program is not required. Alternatives shall be submitted and approved by the department in these situations.

(3) Records of audits shall be maintained by the licensee or registrant for agency inspection for three years from the date of the audit.

i. Personnel monitoring control.

(1) The personnel monitoring program shall meet the applicable requirements of rule 641—37.11(136C).

(2) Records of pocket dosimeter readings of personnel exposures and yearly operability checks required in 10 CFR 34.47(c) shall be maintained for three years by the licensee or registrant for agency inspection.

1. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained for three years after they are recorded.

2. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges, OSLs, or TLDs, shall be maintained until the agency terminates the license.

(3) Reports received from the film badge, OSL device or TLD processor shall be kept for inspection by the agency until the agency terminates the license.

j. Access control. During each industrial radiographic operation, a radiographer or radiographer's assistant shall maintain continuous, direct visual surveillance of the operation to protect against unauthorized entry into a restricted area, radiation area, or high radiation area, except at permanent radiographic installations where all entryways are locked to protect against unauthorized or accidental entry and the requirements of paragraph 39.10(2)*"f"* are met.

k. Posting.

(1) Notwithstanding any provisions in 641—subrule 37.11(21), areas in which radiography is being performed shall be conspicuously posted as required by 641—paragraphs 37.11(20)*"a"* and *"b."*

(2) Whenever practicable, ropes or barriers shall be used in addition to appropriate signs to designate areas in accordance with 641—subrule 37.11(20) and to help prevent unauthorized entry.

(3) Notwithstanding the requirements of subparagraph 39.10(2)*"k"*(1), a restricted area may be established in accordance with 641—subrule 37.11(20) and may be posted in accordance with 641—paragraphs 37.11(20)*"a"* and *"b,"* i.e., both signs may be posted at the same location at the boundary of the restricted area.

l. Temporary job site requirements. Each registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for inspection by the department:

(1) Appropriate certificate of registration or equivalent document;

(2) The appropriate operating and emergency procedures;

(3) The applicable agency rules; and

(4) Survey records required pursuant to subparagraph 39.10(3)*"e"*(4) for the period of operation at the site.

m. Notifications.

(1) The agency shall be notified of thefts or losses of sources of radiation, overexposures, and excessive levels in accordance with 641—subrule 37.13(1) and 10 CFR 20.2203.

(2) Each registrant shall submit a written report within 30 days to the department whenever one of the following events occurs:

1. An indicator on a radiation-producing machine fails to show that radiation is being produced; and

2. An exposure switch fails to terminate production of radiation when turned to the off position.

(3) The licensee or registrant shall include the following information in each report submitted in accordance with 10 CFR 34.101 and 641—subrule 37.13(4):

1. The licensee or registrant name and license or registration number;

2. The name of the prescribing physician, if applicable;

3. A description of the event, including:

A. The probable cause;

B. The manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

4. The exact location of the event;

5. The date and time of the event;

6. The isotopes, quantities, and chemical and physical form of the licensed material involved;

7. Corrective actions taken or planned to prevent recurrence and the results of any evaluations or assessments;

8. The extent of exposure of individuals to radiation or to radioactive materials, without identification of individuals by name, and the effect, if any, on the individual(s) who received the administration or exposure; and

9. Certification that the licensee or registrant notified the individual or the individual's responsible relative or legal guardian and the referring physician in compliance with the requirements of this chapter and, if not, why not.

n. Copies of operating and emergency procedures. Each registrant shall maintain a copy of current operating and emergency procedures until the agency terminates the license. Superseded material must be retained for three years.

39.10(3) *Radiation safety requirements for the use of radiation machines in industrial radiography.* The requirements of this subrule are in addition to, and not in substitution for, other applicable requirements of 10 CFR 34, 641—Chapter 37, and this chapter. These rules apply to all licensees or registrants who use radiation for industrial or nonhuman purposes.

a. Locking of sources of radiation. The control panel of each radiation machine shall be equipped with a locking device that will prevent the unauthorized use of an X-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times, except when under the direct visual surveillance of a radiographer.

b. Permanent storage precautions. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

c. Requirements for radiation machines used in industrial radiographic operations.

(1) Equipment used in industrial radiographic operations involving radiation machines manufactured after January 1, 1992, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537-1976.

(2) The registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on all vehicles used to transport radiation machines for temporary job site use.

d. Operating and emergency procedures.

(1) The registrant's operating and emergency procedures shall include instructions in, at a minimum, the following:

1. Operation and safety instruction on the radiation machine(s) to be used;

2. Methods and occasions for conducting radiation surveys;

3. Methods for controlling access to radiographic areas;

4. Methods and occasions for locking and securing sources of radiation;

5. Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;

6. Minimizing exposure of individuals in the event of an accident;

7. The procedure for notifying proper personnel in the event of an accident;

8. Maintenance of records; and

9. Inspection and maintenance of radiation machines.

(2) Each registrant shall provide, as a minimum, two radiographic personnel when radiation machines are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, or bunker). If one of the personnel is a radiographer's assistant, the other shall be a radiographer trainer authorized by the certificate of registration.

(3) No individual other than a radiographer or a radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

e. Radiation surveys and survey records.

(1) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in paragraph 39.10(2)*"c,"* is available and used at each site where radiographic exposures are made.

(2) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is off.

(3) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with paragraph 39.10(2)*"c,"* based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that paragraph 39.10(2)*"c"* requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subparagraph 37.11(11)*"a"*(1).

(4) Records shall be kept of the surveys required by subparagraphs 39.10(3)*"e"*(1) and *"e"*(2). Such records shall be maintained for inspection by the agency for three years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

f. Special requirements and exemptions for enclosed radiography.

(1) Systems for enclosed radiography, including shielded-room radiography and cabinet radiography, designed to allow admittance of individuals shall:

1. Comply with all applicable requirements of this chapter and 641—subparagraph 37.11(11)*"a"*(1). If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this chapter and 21 CFR 1020.40.

2. Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subparagraph 37.11(11)*"a"*(1). Records of these evaluations shall be maintained for inspection by the agency for a period of three years after the evaluation.

(2) Certified and certifiable cabinet X-ray systems are exempt from the requirements of this chapter, except for the following:

1. Operating personnel must be provided with individual monitoring devices in accordance with the appropriate provisions of 641—subrule 37.11(14);

2. No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of, and instruction in, the operating procedures for the unit and has demonstrated competence in its use. Records that demonstrate compliance with this subparagraph shall be maintained for inspection by the agency until disposition is authorized by the agency.

3. Tests for proper operation of interlocks used to control entry to the high radiation area or alarm systems, where applicable, shall be conducted and recorded every three months. Records of these tests shall be maintained for agency inspection until disposal is authorized by the agency.

4. The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with 641—subparagraph 37.11(11)*"a"*(1).

A. If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40.

B. Records of these evaluations shall be maintained for inspection by the agency for a period of three years after the evaluation.

(3) Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the agency pursuant to 641—subrule 37.3(1).

g. Registration for industrial radiographic operations.

(1) No person shall receive, possess, use, transfer, own, or acquire an analytical X-ray device, except as authorized by a registration issued in accordance with rule 641—37.8(136C).

(2) Each industrial radiography device shall be registered in accordance with the requirements of 641—subrule 37.8(2).

(3) In addition to the registration requirements of 641—subrule 37.8(2), an application for a certificate of registration shall include all of the following information:

1. A schedule or description of the program for training radiographic personnel that specifies:

A. Initial training,

B. Periodic training,

C. On-the-job training, and

D. Methods to be used by the registrant to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, registration requirements, and the operating and emergency procedures of the applicant.

2. Written operating and emergency procedures, including all items listed in Appendix B.

3. A description of the internal inspection system or other management control to ensure that radiographic personnel follow registration provisions, rules of the agency, and the applicant's operating and emergency procedures.

4. A list of permanent radiographic installations and descriptions of permanent storage and use locations.

5. A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.

(4) A certificate of registration will be issued if the requirements of rule 641—37.8(136C) and this subrule are met.

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641—39.11(136C) Medical use of byproduct material.

39.11(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 35, "Medical Use of Byproduct Material," unless specific exemptions apply.

39.11(2) The provisions of 10 CFR Part 35 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 35.8, 35.10, 35.11(c)(1), 35.11(c)(2), 35.13(a)(1), 35.13(a)(2), 35.13(b)(5), 35.4001, and 35.4002.

b. Where the word "NRC" appears in 10 CFR 35.6(c), 35.13(b)(4)(i), 35.57(c), 35.3045(g), 35.3047(f)(1), and 35.3204(a), substitute the words "Iowa HHS."

c. Where the words "NRC Operations Center" appear in 10 CFR 35.3045(c), 35.3047(c), and 35.3204(a), substitute the words "Iowa HHS."

d. Where the words "The commercial telephone number of the NRC Operations Center is (301) 816–5100" appear in the footnote of 10 CFR 35.3045, substitute the words "The 24-hour emergency phone number of Iowa HHS is 515-725-4160."

e. Where the words "appropriate NRC Regional Office listed in § 30.6 of this chapter" appear in 10 CFR 35.3045(d), 35.3047(d), 35.3067, and 35.3204(b), substitute the words "Iowa HHS."

f. In 10 CFR 35.3067, the phrase "with a copy to the Director, Office of Nuclear Material Safety and Safeguards" is deleted and does not apply.

g. Where the word "Commission" appears in 10 CFR 35.5, 35.12(d)(4), 35.14(a) and (b), 35.18, 35.19, 35.24, 35.26, and 35.1000, substitute the words "Iowa HHS."

h. Where the words "Commission or an Agreement State" appears in 10 CFR 35.2, 35.11, 35.13, 35.14, 35.50, 35.51, 35.55, 35.57, 35.67, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.433, 35.490, 35.590, 35.605, 35.655, and 35.690, substitute the words "Iowa HHS, NRC, or an Agreement State."

i. For the purpose of this chapter, where 10 CFR 35.8 requires "NRC Form 313, including NRC Form 313A" licensees shall use "Iowa HHS Form 313, including Iowa HHS Form 313A."

j. For the purpose of this chapter, where 10 CFR 35.12(b)(1), 35.12(c)(1)(i), 35.12(c)(1)(ii), and 35.18(a)(1) require "NRC Form 313," licensees shall use "Iowa HHS Form 313A."

k. Where 10 CFR Part 35 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

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641—39.12(136C) Licenses and radiation safety requirements for irradiators.

39.12(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," unless specific exemptions apply.

39.12(2) The provisions of 10 CFR Part 36 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 36.2, paragraph (2) of the definition of commencement of construction, along with 10 CFR 36.5, 36.8, 36.91, and 36.93.

b. Where the sentence "The application and one copy must be sent to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter" appears in 10 CFR 36.11, substitute the phrase "Application must be sent to Iowa HHS."

c. Where the word "NRC" appears in 10 CFR 36.15, 36.51(a)(1) and (a)(2), and 36.83(a)(both mentions), substitute the words "Iowa HHS."

d. Where the words "Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954 (Act), as amended, and rules, regulations, and orders issued under the Act" appear in 10 CFR 36.15, substitute the words "Any activities undertaken prior to the issuance are entirely at the risk of the applicant and have no bearing on the issuance of a license by Iowa HHS."

e. Where the words "NRC or an Agreement State" appear in 10 CFR 36.59(c), substitute the words "Iowa HHS, NRC, or an Agreement State."

f. Where the word "Commission" appears in 10 CFR 36.13, 36.13(b)(4) and (f), 36.17(a) and (b), 36.19(a)(both mentions) and (b)(both mentions), 36.53(c), 36.69(a) and (b), and 36.81(a) and (d) and (e), substitute the words "Iowa HHS."

g. Where the words "Commission or an Agreement State" appear in 10 CFR 36.13(g) and 10 CFR 36.59(a)(both mentions), substitute the words "Iowa HHS, NRC, or an Agreement State."

h. For the purpose of this chapter, where 10 CFR 36.8(c)(1) and 36.11 requires "NRC Form 313," licensees shall use "Iowa HHS Form 313."

i. Where 10 CFR Part 36 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

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641—39.13(136C) Physical protection of category 1 and category 2 quantities of radioactive material.

39.13(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," unless specific exemptions apply.

39.13(2) The provisions of 10 CFR Part 37 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 37.7, 37.9, 37.11(b), 37.13, 37.107, and 37.109.

b. Where the word "NRC" appears in 10 CFR 37.31(d), 37.43(c)(3)(iii), 37.57(a), 37.57(c), 37.77 (except "the NRC's Web site" in 37.77(a)(1)), substitute the words "Iowa HHS."

c. Where the word "Commission" appears in 10 CFR 37.5 (definition of "person"), 37.11(a), 37.43(a)(3), 37.43(c)(1)(ii), 37.101, 37.103, and 37.105, substitute the words "Iowa HHS."

d. Where the words "Commission or an Agreement State" appear in 10 CFR 37.71 and 10 CFR 37.77(f), substitute the words "Iowa HHS, NRC, or an Agreement State."

e. Where the words "Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Source Management and Protection Branch" appear in 10 CFR 37.23(b)(2), substitute the words "Iowa HHS."

f. Where the words "NRC regional office" appear in 10 CFR 37.41(a)(3) and 37.81, substitute the words "Iowa HHS."

g. Where the words "appropriate NRC regional office listed in § 30.6(a)(2) of this chapter" appear in 10 CFR 37.45(b), substitute the words "Iowa HHS."

h. Where the words "NRC's Operational Center (301-816-5100)" appear in 10 CFR 37.57(a), 37.57(b), and 37.81, substitute the words "Bureau of Radiological Health and Human Services (515-725-4160)."

i. Where the words "NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to 301-816-5151" appear in 10 CFR 37.77(a)(1), substitute the words "Iowa HHS."

j. Where the words "NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001" appear in 10 CFR 37.77(c)(1), 37.77(c)(2), and 37.77(d), substitute the words "Iowa HHS."

k. Where the words "NRC by an appropriate method listed in 10 CFR § 37.7" appear in 10 CFR 37.81(g), substitute the words "Iowa HHS."

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641—39.14(136C) Licenses and radiation safety requirements for well logging.

39.14(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging," unless specific exemptions apply.

39.14(2) The provisions of 10 CFR Part 39 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 39.5, 39.8, 39.91, 39.101, and 39.103.

b. Where the words "NRC or an Agreement State" appear in 10 CFR 39.35(d), substitute the words "Iowa HHS, NRC, or an Agreement State."

c. Where the words "Commission or an Agreement State" appear in 10 CFR 39.35(b) and 10 CFR 39.43(d) and (e), substitute the words "Iowa HHS, NRC, or an Agreement State."

d. Where the word "Commission" appears in 10 CFR 39.2, 39.13, 39.15, 39.17, 39.33, 39.35(a), 39.37, 39.39, 39.45, 39.65, 35.67, 39.77 and 39.91, substitute the words "Iowa HHS."

e. Where the word "NRC" appears in 10 CFR 39.61, 39.73 and 39.77, substitute the words "Iowa HHS."

f. Where the words "NRC Regional Office listed in appendix D of part 20 of this chapter" appear in 10 CFR 39.11 and 10 CFR 39.35, substitute the words "Iowa HHS."

g. Where the words "NRC Regional Office" appear in 10 CFR 39.61, 39.73 and 39.77, substitute the words "Iowa HHS."

h. Where the words "Commission under 10 CFR § 32.210 of this chapter or with an Agreement State" appear in 10 CFR 39.41(f), substitute the words "Iowa HHS, NRC, or an Agreement State."

i. Where the words "Commission pursuant to 10 CFR § 39.13(c) or by an Agreement State" appear in 10 CFR 39.43(c) and 10 CFR 39.51, substitute the words "Iowa HHS, NRC, or an Agreement State."

j. For the purpose of this chapter, where 10 CFR Part 39.11 requires "NRC Form 313," licensees shall use "Iowa HHS Form 313."

k. Where 10 CFR Part 39 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.15(136C) Domestic licensing of source material.

39.15(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 40 unless specific exemptions apply.

39.15(2) The provisions of 10 CFR Part 40 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 40.2a; 40.4(definitions of "commencement of construction," "construction," "foreign obligations," "reconciliation," and residual radioactive material"); 40.5; 40.6; 40.7; 40.8; 40.10(b); 40.20(b) and (c); 40.12(b); 40.13(c)(5)(iv); 40.23; 40.27; 40.28; 40.31(c), (e), (f), (g), (j), (k), (l), and (m); 40.32(d), (e), and (g); 40.33; 40.38; 40.41(d), (e)(1), (e)(3), (g), and (h); 40.51(b)(6); 40.52; 40.53; 40.56; 40.64; 40.66; 40.67; 40.71; 40.81; 40.82, Appendix A (criteria 11 and 12).

b. Where the word "NRC" appears in 10 CFR 40.2, 40.7(e)(1) and (e)(2), 40.7(f)(both mentions), 40.10(a)(2)(both mentions), 40.22(b)(1) and (4), 40.22(c), 40.36(b)(2)(both mentions), 40.36(g), 40.42(c)(2) and (d)(both mentions) and (d)(4), 40.60(a) and (b), and Appendix A (criteria 4 and 6), substitute the words "Iowa HHS."

c. Where the words "U.S. NRC or an Agreement State" appear in 10 CFR 40.35(b), substitute the words "Iowa HHS, NRC, or an Agreement State."

d. Where the words "Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in 10 CFR § 40.5, with a copy to the appropriate NRC Regional Administrator" appear in 10 CFR 40.25(c)(1), substitute the words "Iowa HHS."

e. Where the words "NRC Headquarters Operations Center at the numbers specified in appendix A of this chapter" appear in 10 CFR 40.60(c)(1), substitute the words "Iowa HHS."

f. Where the words "NRC Document Controls Desk by an appropriate method listed in § 40.5, with a copy to the appropriate NRC regional office listed in appendix D to part 20 of this chapter" appear in 10 CFR 40.60(c)(2), substitute the words "Iowa HHS."

g. Where the words "appropriate NRC regional office" appear in 10 CFR 40.61(d) and (f), and Appendix A (criterion 8), substitute the words "Iowa HHS."

h. Where the words "Director, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 40.5, with a copy to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter" appear in 10 CFR 40.65(a)(1), substitute the words "Iowa HHS."

i. Where the words "appropriate NRC Regional Administrator" appear in 10 CFR 40.41(f)(1), substitute the words "Iowa HHS."

j. Where the word "Commission" appears in 10 CFR 40.1(a), 40.3, 40.9(a) and (b)(all mentions), 40.10(a)(1) and (c)(1), 40.11(all mentions), 40.13(i), 40.14(a), 40.20(a), 40.22(a)(1)(both mentions) and (e), 40.26(b)(both mentions), 40.26(c)(2) 40.31(a) and (b)(both mentions) and (c) and (d) and (f) and (g) and (g)(1), 40.34(b) and (c), 40.35(e) and (f)(all mentions), 40.36(e)(1) and (e)(2)(i)(both mentions) and (e)(2)(ii) and (e)(2)(iii) and (f), 40.41(a) and (c), 40.42(a) and (b)(all mentions) and (c) and (e)(2) and (f)(all mentions) and (g)(1) and (g)(2)(both mentions) and (g)(5) and (i)(both mentions) and (i)(5) and (k), 40.45, 40.46(a), 40.51(b)(2) and (b)(7) and (d)(4) and (d)(5), 40.54(b), 40.55(d)(3) and (e), 40.61(a)(2) and (a)(3) and (c)(1) and (c)(2)(all mentions), 40.62(a) and (b), 40.63(both mentions), 40.65 (a)(1)(all mentions), and Appendix A, substitute the words "Iowa HHS."

k. Where the words "Director, Office of Nuclear Material Safety and Safeguards, with a copy to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D of part 20 of this chapter" appear in 10 CFR 40.25(c)(2) and (d)(4), substitute the words "Iowa HHS."

l. Where the words "appropriate NRC regional office as indicated in appendix D to part 20 of this chapter, or the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555" appear in 10 CFR 40.26(c)(2), substitute the words "Iowa HHS."

m. Where the words "Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555" appear in 10 CFR 40.55(d)(1), substitute the words "Iowa HHS."

n. Where the words "Commission or an Agreement State" appear in 10 CFR 40.51(b)(5) and (c)(both mentions), substitute the words "Iowa HHS, NRC, or an Agreement State."

o. Where the words "Act", "Atomic Energy Act of 1954, as amended (68 Stat. 919)", "section 62 of the Act", and "section 182 of the Act" appear in 10 CFR 40.12, 40.13, 40.31(d), 40.32(a), 40.41(a), (b), and (e)(4), 40.46, and 40.51(b)(2), (b)(3), substitute the words "Iowa Code chapter 136C."

p. Where the words "Administrator of the appropriate Regional Office" appear in 10 CFR 40.9(b), substitute the words "Iowa HHS."

q. Where the words "Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in 40.5" appear in 10 CFR 40.22(b)(4) and (c), and where the words "Director, Office of Nuclear Materials Safety and Safeguards, by an appropriate method listed in 40.5" appear in 10 CFR 40.35(e)(1) and (f), substitute the words "Iowa HHS."

r. Where the words "Director, Office of Nuclear Material Safety and Safeguards" appear in 10 CFR 40.36(g)(3), substitute the words "Iowa HHS."

s. Where the words "Agreement State agency" and "Agreement State" appear in 10 CFR 40.55, substitute the words "Agreement State or the NRC."

t. Where the words "appropriate NRC regional office as indicated in appendix D to 10 CFR part 20 of this chapter, or the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001" appear in Appendix A (criterion 8A), substitute the words "Iowa HHS."

u. For the purpose of this chapter, where 10 CFR 40.42 requires "NRC Form 314," licensees shall use "Iowa HHS Form 314."

v. For the purpose of this chapter, where 10 CFR 40.25 and 10 CFR 40.35 requires "NRC Form 244," licensees shall use "Iowa HHS Form 244."

w. Where 10 CFR Part 40 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.16(136C) Domestic licensing of special nuclear material.

39.16(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," unless specific exemptions apply.

39.16(2) The provisions of 10 CFR Part 70 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 70.1(c), (d), and (e), Construction Paragraph 9ii; 70.4; 70.5; 70.6; 70.7; 70.8; 70.10(b); 70.13; 70.14; 70.17(c) and (d); 70.20a; 70.20b; 70.21 (a)(1), (a)(2), (a)(3), (b), (c), (d), and (e), (f), (g), (h); 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m), and (n); 70.23(a)(1), (a)(6), (a)(7), (a)(8), (a)(9), (a)(10), (a)(11), (a)(12), and (b); 70.23a; 70.24; 70.25(a)(1); 70.31(c), (d), and (e); 70.32 (a)(1), (a)(4), (a)(5), (a)(6), (a)(7), (b)(1), (b)(3), (b)(4), (c), (d), (e), (f), (g), (h), (i), (j), and (k); 70.34; 70.37; 70.40; 70.42(b)(6); 70.44; 70.50(c)(2)(iv) and (d); 70.52; 70.55(c); 70.59; 70.60; 70.61; 70.62; 70.64; 70.65; 70.66; 70.72; 70.73; 70.74; 70.76; 70.81; 70.82; 70.91; 70.92, and Appendix A.

b. Where the word "NRC" appears in 10 CFR 70.2, 70.10(a)(2)(both mentions), 70.25(b)(2)(both mentions) and (h), 70.38(c)(2) and (d)(both mentions) and (d)(4), and 70.50(a) and (b), substitute the words "Iowa HHS."

c. Where the words "NRC Headquarters Operations Center at the number specified in appendix A to part 73 of this chapter" appear in 10 CFR 70.50(c)(1), substitute the words "Iowa HHS."

d. Where the words "appropriate NRC Regional Administrator" appear in 10 CFR 70.32(a)(9)(i), substitute the words "Iowa HHS."

e. Where the words "appropriate NRC Regional Office" appear in 10 CFR 70.51(a), substitute the words "Iowa HHS."

f. Where the word "Commission" appears in 10 CFR 70.1(a), 70.3, 70.9(a)(both mentions) and (b)(both mentions), 70.10(a)(1) and (c)(1), 70.17(a), 70.18, 70.22(a)(8) and (d)(both mentions), 70.23(a) and (a)(5), 70.25(f)(1) and (f)(2)(i)(both mentions) and (f)(2)(ii) and (f)(2)(iii) and (g), 70.31(a)(both mentions), 70.32(a)(8) and (b), 70.33, 70.35, 70.36(a), 70.38(a) and (b)(all mentions) and (c) and (e)(2) and (f)(all mentions) and (g)(1) and (g)(2)(both mentions) and (g)(5) and (i)(5) and (k), 70.39(a)(4), 70.42(b)(7), 70.51(c)(1) and (c)(2)(all mentions), 70.55(a) and (b) and (c)(1) and (c)(2), 70.56(both mentions), substitute the words "Iowa HHS."

g. Where the words "Commission or an Agreement State" and "Commission or with an Agreement State" appear in 70.42(c)(both mentions), substitute the words "Iowa HHS, NRC or an Agreement State."

h. Where the words "Commission or the licensing agency of an Agreement State" appear in 10 CFR 70.42(d)(4) and (d)(5), substitute the words "Iowa HHS, the U.S. Regulatory Commission, or the licensing agency of an Agreement State."

i. For the purpose of this chapter, where 10 CFR Part 70.38(j)(1) requires "NRC Form 314," licensees shall use "Iowa HHS Form 314."

j. Where the words "the Atomic Energy Act of 1954, as amended (68 Stat. 919) and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242)" appear in 10 CFR 70.1(b), substitute the words "Iowa Code chapter 136C."

k. Where the word "Act" appears in 10 CFR 70.21(b), 70.32(a)(3), and 70.36(a), substitute the words "Iowa Code chapter 136C."

l. Where the words "Administrator of the appropriate Regional Office" appear in 10 CFR 70.9(b), substitute the words "Iowa HHS."

m. Where the words "Any person in a non-agreement State who holds a specific license issued by the Commission or the Atomic Energy Commission" appear in 10 CFR 70.19(a)(1), substitute the words "Any person who holds a specific license issued by Iowa HHS."

n. Where the words "Any Government agency, as defined in 10 CFR § 70.4 of this chapter, which holds a specific license issued under this chapter" appear in 10 CFR 70.19(a)(2), substitute the words "Any person who holds a specific license issued by the NRC."

o. Where the words "Director, Office of Nuclear Material Safety and Safeguards" appear in 10 CFR 70.25(h)(3), substitute the words "Iowa HHS."

p. In 10 CFR 70.25(a), "(a)(1) and" is deleted and does not apply.

q. In 10 CFR 70.38(d), the phrase "consistent with the administrative directions in 10 CFR § 70.5" is deleted and does not apply.

r. In 10 CFR 70.50(c)(1), the phrase "and by § 70.74 and appendix A of this part, if applicable" is deleted and does not apply.

s. Where 10 CFR Part 70 references fees listed in 10 CFR Parts 170 and 171, licensees shall comply with the fee requirements specified in rule 641—37.9(136C).

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.17(136C) Packaging and transportation of radioactive material.

39.17(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," unless specific exemptions apply.

39.17(2) The provisions of 10 CFR Part 71 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 71.1, 71.2, 71.6, 71.9, 71.11, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85(a) through (c), 71.91(b), 71.99, 71.100, 71.101(c)(2) and (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125.

b. Where the word "NRC" appears in 10 CFR 71.0(a) and (c) and (d)(both mentions) and (g), 71.5(a), 71.8(b)(2)(both mentions), 71.10, 71.93(c), 71.95(a)(1) and (a)(2) and (c), 71.101(f), and 71.106(a) (all mentions) and (a)(1) and (b)(all mentions) and (b)(1), substitute the words "Iowa HHS."

c. Where the word "Commission" appears in 10 CFR 71.0(c), 71.3, 71.4, 71.7(a)(both mentions) and (b)(all mentions), 71.8(b)(1) and (d)(1), 71.10, 71.11, 71.12, 71.17(a) and (b), 71.21(a) and (b), 71.22(a) and (b), 71.23(a) and (b), 71.91(c), and 71.101(c) and (c)(2) and (f)(all mentions), substitute the words "Iowa HHS."

d. Where the words "the Director, Office of Nuclear Materials Safety and Safeguards, US Nuclear Regulatory Commission, Washington, DC 20555-0001" appear in 10 CFR 71.5(b), substitute the words "Iowa HHS."

e. Where the words "Notification must be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information" appear in 10 CFR 71.7(b), substitute the words "Notification must be provided to Iowa HHS within 2 working days of identifying the information."

f. Where the words "the Director, Office of Nuclear Materials Safety and Safeguards, US Nuclear Regulatory Commission, Washington, DC 20555-0001" appear in 10 CFR 71.5(b), substitute the words "Iowa HHS."

g. Where the section "*Approval of program.* (1) Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Using an appropriate method listed in § 71.1(a), each licensee shall file a description of

its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards," appears in 10 CFR 71.101(c), substitute with "*Approval of program.* (1) Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Iowa HHS's approval of its quality assurance program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, with Iowa HHS."

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

641—39.18(136C) Reciprocal recognition of licenses.

39.18(1) In addition to the rules of this chapter, RAM facilities shall comply with the requirements of 10 CFR Part 150, "Packaging and Transportation of Radioactive Material," unless specific exemptions apply.

39.18(2) The provisions of 10 CFR Part 150 are hereby adopted by reference and are subject to the following conditions:

a. Not adopted by reference are 10 CFR 150.3 definition of "foreign obligations," 150.4, 150.5, 150.7, 150.8, 150.10, 150.14, 150.15, 150.15a, 150.16, 150.17, 150.17a, 150.19, 150.21, 150.30, and 150.33.

b. Where the words "Recognition of Agreement State licenses" appear in the title of 10 CFR Part 150.20, substitute the words "Recognition of U.S. Nuclear Regulatory Commission or Agreement State licenses."

c. Where the sentence "Provided that the provisions of paragraph (b) of this section have been met, any person who holds a specific license from an Agreement State, where the licensee maintains an office for directing the licensed activity and retaining radiation safety records, is granted a general license to conduct the same activity in" appears in 10 CFR 150.20(a)(1), substitute the sentence "Provided that the provisions of paragraph (b) of this section have been met, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State, where the licensee maintains an office for directing the licensed activity and retaining radiation safety records, is granted a general license to conduct the same activity in Iowa."

d. Where the words "specific Agreement State license" appear in 10 CFR 150.20(a)(2), substitute the words "specific U.S. Nuclear Regulatory Commission or Agreement State license."

e. Where 10 CFR 150.20(b) states "Notwithstanding any provision to the contrary in any specific license issued by an Agreement State to a person engaging in activities in a non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters under the general licenses provided in this section, the general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7(a) through (f), 30.9, 30.10, 30.34, 30.41, and 30.51 through 30.63 of this chapter; §§ 40.7(a) through (f), 40.9, 40.10, 40.41, 40.51, 40.61 through 40.63, 40.71, and 40.81 of this chapter; §§ 70.7(a) through (f), 70.9, 70.10, 70.32, 70.42, 70.52, 70.55, 70.56, 70.60 through 70.62 of this chapter; §§ 74.11, 74.15, and 74.19 of this chapter; and to the provisions of 10 CFR parts 19, 20 and 71 and subparts C through H of part 34, §§ 39.15 and 39.31 through 39.77 of this chapter. In addition, any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in this section," substitute with the sentences "Notwithstanding any provision to the contrary in any specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State to a person engaging in activities in Iowa under the general licenses provided in this section, the general licenses provided in this section are subject to all the provisions of Iowa Code chapter 136C, now or hereafter in effect, and to all applicable rules, regulations, and orders of Iowa HHS including the provisions of 10 CFR §§ 30.9, 10 CFR 30.10, 10 CFR 30.34, 10 CFR 30.41, and 10 CFR 30.51 through 10 CFR 30.62 of this chapter; 10 CFR §§ 40.9, 10 CFR 40.10(a), 10 CFR 40.41, 10 CFR 40.51, 10 CFR 40.61 through 10 CFR 40.63 of this chapter; 10 CFR §§ 70.9, 10 CFR 70.10(a), 10 CFR 70.32, 10 CFR 70.42, 10 CFR 70.55, 10 CFR 70.56 of this chapter; 10 CFR §§ 74.11, 10 CFR 74.15, and 10 CFR 74.19 of this chapter; and to the provisions of 10

CFR parts 19, 20 and 71 and subparts C through F of part 34, 10 CFR §§ 39.15 and 10 CFR 39.31 through 39.77 of this chapter. In addition, any person engaging in activities in Iowa under the general licenses provided in this section."

f. Where the words "file a submittal containing an NRC Form 241, 'Report of Proposed Activities in Non-Agreement States' a copy of its Agreement State specific license, and the appropriate fee as prescribed in § 170.31 of this chapter with the Regional Administrator of the U.S. Nuclear Regulatory Commission Regional Office listed on the NRC Form 241 and in appendix D to part 20 of this chapter for the Region in which the Agreement State that issued the license is located" appear in 10 CFR 150.20(b)(1), substitute the words "file a copy of its U.S. Nuclear Regulatory Commission or Agreement State specific license, with Iowa HHS."

g. For the purpose of this chapter, where 10 CFR 150.20(b)(1)(i), (b)(1)(iii), and (b)(2) require "NRC Form 241," licensees shall use "Iowa HHS Form 241."

h. Where the word "Region" appears in 10 CFR 150.20(b)(1)(i) and (b)(1)(ii), substitute the words "Iowa HHS."

i. Where the words "Regional Administrator" appear in 10 CFR 150.20(b)(1) and (b)(2), substitute the words "Iowa HHS."

j. Where the words "a copy of the Agreement State license, and the fee payment" appear in 10 CFR 150.20(b)(iii), substitute the words "a copy of the U.S. Nuclear Regulatory Commission or Agreement State license."

k. Where the sentence "Shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer to a person who is specifically licensed by the Commission to receive this material." appears in 10 CFR 150.20(b)(3), substitute the sentence "Shall not, in Iowa, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer to a person who is specifically licensed by Iowa HHS to receive this material."

l. Where the sentence "Shall not, under the general license concerning activities in non-Agreement States or in areas of exclusive Federal jurisdiction within Agreement States, possess or use radioactive materials, or engage in the activities authorized in paragraph (a) of this section, for more than 180 days in any calendar year, except that the general license in paragraph (a) of this section concerning activities in offshore waters authorizes that person to possess or use radioactive materials, or engage in the activities authorized, for an unlimited period of time" appears in 10 CFR 150.20(b)(4), substitute the sentence "Shall not, under the general license concerning activities in Iowa, possess or use radioactive materials, or engage in the activities authorized in paragraph (a) of this section, for more than 180 days in any calendar year."

m. Where the words "specific license issued by an Agreement State" appear in 10 CFR 150.20(b)(5), substitute the words "specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State."

[**ARC 0179D**, IAB 4/1/26, effective 7/1/26]

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

CHAPTER 39—APPENDIX A

SUBJECTS FOR INSTRUCTION OF RADIOGRAPHER'S ASSISTANTS

Training provided to qualify individuals as radiographer's assistants in compliance with paragraph 39.10(2)*"g"* shall be presented on a formal basis. The training shall include the following subjects:

I. Fundamentals of radiation safety
- A. Characteristics of radiation
- B. Units of radiation dose and quantity of radioactivity
- C. Significance of radiation dose
  1. Radiation protection standards
  2. Biological effects of radiation
  3. Case histories of radiography accidents
- D. Levels of radiation from sources of radiation
- E. Methods of controlling radiation dose
  1. Working time
  2. Working distances
  3. Shielding

II. Radiation detection instrumentation to be used
- A. Use of radiation survey instruments
  1. Operation
  2. Calibration
  3. Limitations
- B. Survey techniques
- C. Use of personnel monitoring equipment
  1. Film badges
  2. Thermoluminescent dosimeters (TLDs)
  3. Pocket dosimeters
  4. OSL devices

III. The requirements of pertinent federal and state regulations

IV. The registrant's written operating and emergency procedures

V. Radiographic equipment to be used for operation and control of X-ray equipment

CHAPTER 39—APPENDIX B

OPERATING AND EMERGENCY PROCEDURES

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

A. Handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in 641—Chapter 37;

B. Methods and occasions for conducting radiation surveys, including lock-out survey requirements;

C. Methods for controlling access to industrial radiography areas;

D. Methods and occasions for locking and securing sources or radiation;

E. Personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off-scale;

F. Methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation (including applicable U.S. Department of Transportation requirements);

G. Methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;

H. Procedures for notifying proper personnel in the event of an accident;

I. Specific posting requirements;

J. Maintenance of records (Appendix C); and

K. Inspection and maintenance of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines.

CHAPTER 39—APPENDIX C

TIME REQUIREMENTS FOR RECORDKEEPING

Specific Section	Name of Record	Time Interval Required for Recordkeeping
39.10(2)*"b"*	Receipt, transfer and disposal.	3 years.
39.10(2)*"c"*(2)	Survey instrument calibrations.	3 years.
39.10(2)*"g"*(4)"3"(K)	Quarterly inventory.	3 years.
39.10(2)*"d"*	Utilization logs.	3 years.
39.10(2)*"e"*	Quarterly inspection and maintenance.	3 years.
39.10(2)*"j"*	High radiation area control devices or alarm systems.	Until disposal is authorized by the department.
39.10(2)*"g"*	Training and testing records.	3 years.
39.10(2)*"i"*	Pocket dosimeter readings.	3 years.
	Pocket dosimeter calibrations.	3 years.
	Film badge, OSL device, or TLD reports.	Until the agency terminates the license.
	Alarming ratemeter calibrations.	3 years.
	Alarming ratemeter functions.	3 years.
	Estimates of overexposures.	Until the agency terminates the license.
39.10(2)	Current operating and emergency procedures.	Until the license is terminated.
	Superseded material.	3 years after change.
39.10(2)*"h"*	Internal audit program.	3 years.
39.10(2)*"h"*	Radiographer audits.	3 years.
39.10(3)*"e"*	Radiation surveys.	2 years or until disposal is authorized by the agency if a survey was used to determine an individual's exposure.
39.10(2)*"l"*	Records at temporary job sites.	During temporary job site operations.
39.10(3)*"f"*	Annual evaluation of enclosed X-ray systems.	2 years.
10 CFR 34.67	Leak tests.	3 years or until the source in storage is removed.
39.10(3)*"f"*	Evaluation of certified cabinet X-ray systems.	2 years.

CHAPTER 39—APPENDIX D

EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152(9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

1/ Values are given in Column I only for those materials normally used as gases.

2/ μCi/g for solids.

NOTE 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

NOTE 2: For purposes of rule 641—39.6(136C) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1."

EXAMPLE: $\frac{\text{Concentration of Radionuclide A in Product}}{\text{+ Exempt concentration of Radionuclide A}}$

$\frac{\text{Concentration of Radionuclide B in Product}}{\leq 1 \text{ Exempt concentration of Radionuclide B}}$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 (2×10^{-4} μCi/ml multiplied by 37 is equivalent to 74×10^{-4} MBq/l)

CHAPTER 39—APPENDIX E
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100

Radioactive Material	Microcuries
Europium-152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100

Radioactive Material	Microcuries
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10

Radioactive Material	Microcuries
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10

Radioactive Material	Microcuries
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

NOTE 1: For purposes of rule 641—39.6(136C) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

$$\frac{\text{Amt. of Radionuclide A possessed}}{1000 \times \text{Appendix B quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{1000 \times \text{Appendix B quantity for Radionuclide B}} \mu\ 1$$

NOTE 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

CHAPTER 39—APPENDIX F

GENERAL REQUIREMENTS FOR INSPECTION OF INDUSTRIAL RADIOGRAPHIC EQUIPMENT

I. Panoramic devices (devices in which the sealed source is physically removed from the shielded container during exposure) shall be inspected for:

A. Radiographic exposure unit:

1. Abnormal surface radiation levels anywhere on camera, collimator, or guide tube;
2. Condition of safety plugs;
3. Proper operation of locking mechanism;
4. Condition of pigtail connector;
5. Condition of carrying device (straps, handle, etc.);
6. Proper labeling.

B. Source tube:

1. Rust, dirt, or sludge buildup inside the source tube;
2. Condition of source tube connector;
3. Condition of source stop;
4. Kinks or damage that could prevent proper operation;
5. Presence of radioactive contamination.

C. Control cables and drive mechanism:

1. Proper drive mechanism with camera, as appropriate;
2. Changes in general operating characteristics;
3. Condition of connector on drive cable;
4. Drive cable flexibility, wear, and rust;
5. Excessive wear or damage to crank assembly parts;
6. Damage to drive cable conduit that could prevent the cable from moving easily;
7. Connection of the control cable connector with the pigtail connector for proper mating;
8. Proper operation of source position indicator, if applicable;
9. Presence of radioactive contamination.

II. Directional beam devices shall be inspected for:

A. Abnormal surface radiation;
B. Changes in the general operating characteristics of the unit;
C. Proper operation of shutter mechanism;
D. Chafing or binding of shutter mechanism;
E. Damage to the device that might impair its operation;
F. Proper operation of locking mechanism;
G. Proper drive mechanism with camera, as appropriate;
H. Condition of carrying device (strap, handle, etc.);
I. Proper labeling.

III. X-ray equipment shall be inspected for:

A. Change in the general operating characteristics of the unit;
B. Wear of electrical cables and connectors;
C. Proper labeling of console;
D. Proper console with machine, as appropriate;
E. Proper operation of locking mechanism;

F. Timer run-down cutoff;

G. Damage to tube head housing that might result in excessive radiation levels.

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CHAPTER 40
REGISTRATION AND SAFETY REQUIREMENTS FOR RADIATION EMITTING MACHINES IN THE HEALING ARTS—MEDICINE, PODIATRY, DENTAL, CHIROPRACTIC, AND VETERINARY MEDICINE

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—40.1(136C) General provisions. This rule establishes the requirements of a registrant for the use of diagnostic X-ray equipment and imaging systems. Such equipment shall be used only by, or under the supervision of, an individual who is authorized to operate the equipment and is licensed in accordance with state statutes to practice in the healing arts, including medicine, podiatry, dentistry, chiropractic, or veterinary medicine.

40.1(1) The provisions of this chapter are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 37 through 42.

40.1(2) All references to any Code of Federal Regulations (CFR) in this chapter are those as amended to August 1, 2025.

[**ARC 0180D**, IAB 4/1/26, effective 7/1/26]

641—40.2(136C) Definitions. The definitions provided in 641—Chapter 37 may also apply to the provisions of this chapter. Additionally, the following definitions set forth below are specific to this chapter.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

"Attenuation block" means a block or stack having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic exposure control" or *"AEC"* (see also "phototimer") means a device that automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (includes devices such as phototimers and ion chambers).

"C-arm fluoroscope" means a fluoroscopic X-ray system in which the image receptor and the X-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

"Computed radiography" or *"CR"* (see also "DR") means a digital X-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.

"Computed tomography dose index" or *"CTDI"* means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{nT}\int_{-7T}^{+7T} D(z)\,dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

D(z)= Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that:

1. The dose profile is centered around z = 0; and
2. For a multiple tomogram system, the scan increment between adjacent scans is nT.

"Cone beam computed tomography" or *"CBCT"* is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays and a cone-shaped (instead of fan-shaped) X-ray beam that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

"CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system, including but not limited to nominal tomographic section thickness, filtration, and the technique factors as defined in this chapter.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers that hold and enclose these components within a computed tomography system.

"Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Digital radiography" or *"DR"* means an X-ray imaging method (or radiography) that produces a digital rather than analog image. "DR" includes both computed radiography (CR) and direct digital radiography (DDR).

"Direct digital radiography" or *"DDR"* (see also "CR" and "DR") means an X-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an X-ray image. Some DDR systems use a scintillator to convert X-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert X-rays directly to charge, which is stored on the thin-film transistor.

"Dose area product," "DAP," "kerma-area product," or *"KAP"* means the product of the air kerma and the area of the irradiated field and are typically expressed in Gy-cm^2, so do not change with distance from the X-ray tube.

"Dose profile" means the dose as a function of position along a line.

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Field emission equipment" means equipment that uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Fluoroscopically guided interventional," "FGI" or *"special procedures"* means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, that uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site; to monitor the procedure; and to control and document therapy. These procedures could result in extended fluoroscopy examination times and higher doses than typical imaging procedures.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device; electrical interlocks, if any; and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot (actual)" means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Focal spot size" means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

"Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under subrule 40.4(10), or
2. An individual licensed as a physician in Iowa.

"Image intensifier" means a device, installed in its housing, that instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

"Image receptor" means any device, such as a fluorescent screen, radiographic film, X-ray image intensifier tube, solid-state detector, or gaseous detector that transforms incident X-ray photons either into a visible image or into another form that can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, "image receptor" means the preselected portion of the device.

"Last-image hold (LIH) radiograph" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

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

"mA" means milliampere.

"mAs" means milliampere second.

"Multiple tomogram system" means a computed tomography X-ray system that obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

"Peak tube potential," "Kilovolts peak" or *"kVp"* means the maximum value of the potential difference across the X-ray tube during an exposure.

"Phototimer" (see also "automatic exposure control") means a method for controlling radiation exposures to image receptors by the amount of radiation that reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit that controls the duration of time the tube is activated.

"Position indicating device" or *"PID"* means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Protective apron" means an apron made of radiation-absorbing materials used to reduce radiation exposure.

"Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure.

"Radiation detector" means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

"Radiography" means a technique for generating and recording an X-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

"Recording" means producing a retrievable form of an image resulting from X-ray photons.

"Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

"Sensitivity profile" means the relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

"Source" means the focal spot of the X-ray tube.

"Source-image receptor distance" or *"SID"* means the distance from the source to the center of the input surface of the image receptor.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
2. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;
3. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either:
   A. Tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or
   B. The product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;
4. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
5. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

"Tomogram" means the depiction of the X-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

"X-ray control" or *"control panel"* means a device that controls input power to the X-ray high-voltage generator and the X-ray tube, including equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices that control the technique factors of an X-ray exposure.

"X-ray equipment" or *"equipment"* means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

1. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
2. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried but used with a tripod or other stabilization mechanism so the operator is not holding the equipment during exposure.
3. "Stationary X-ray equipment" means X-ray equipment that is installed in a fixed location.
4. "Handheld X-ray equipment" means X-ray equipment designed by the manufacturer to be handheld by the operator during the exposure. X-ray equipment designed without a back-scatter shield is prohibited.

"X-ray exposure control" means a device, a switch, a button, or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-

limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes but is not limited to any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

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641—40.3(136C) General regulatory requirements.

40.3(1) The registrant shall be responsible for directing the operation of the X-ray system(s) under the registrant's administrative control and shall ensure that the requirements of these regulations are met in the operation of the X-ray system(s).

40.3(2) In addition to the rules of this chapter, registrants shall also comply with the requirements of the rules in 641—Chapter 37, including but not limited to:

a. Requirements for registration in rule 641—37.8(136C);

b. Fees in rule 641—37.9(136C);

c. Administrative enforcement actions in rule 641—37.10(136C);

d. Standards for protection against radiation in rule 641—37.11(136C);

e. Record requirements in rule 641—37.12(136C);

f. Notifications and reporting requirements of a reportable radiation incident in 641—subrule 37.13(3);

g. Notices, instructions, and reports to workers in rule 641—37.14(136C).

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641—40.4(136C) Administrative controls.

40.4(1) *Registrant.* The registrant shall be responsible for:

a. Maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control for ensuring that the requirements of these rules are met in the operation of the X-ray system(s).

b. Ensuring the X-ray equipment is maintained and tested by a registered service provider, and qualified expert when applicable, through an equipment performance evaluation based on manufacturer recommendations or according to the following minimum tests and schedule, whichever is more frequent. Veterinary systems are exempt from the equipment performance evaluation requirements of paragraph 40.4(2)*"b."*

40.4(2) *Equipment performance evaluation (EPE).*

a. EPE following installation or modifications. For X-ray, fluoroscopic, and CT systems, an EPE shall be performed under the following conditions:

(1) Within 30 days after initial installation of new machines;

(2) Within 30 days after reinstallation of a machine; or

(3) Within 30 days after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, and power supply.

b. EPE frequency. For X-ray, fluoroscopic, and CT systems, excluding veterinary, an EPE shall be performed at the frequency and by the appropriately trained service provider or qualified expert as required in the following table:

Type of Machine	**Frequency**	**Performed By**
CT	Annually	Qualified expert
Fluoroscopy	Annually	Qualified expert
Dental (intraoral and panoramic/cephalometric)	4 years	Service provider
CBCT	2 years	Qualified expert
All other X-ray equipment (medical/chiropractic/podiatric)	2 years	Service provider

c. Records of EPE results. Records of the test results shall:

(1) Include measurements and numerical readings;

(2) Indicate a pass or fail for each test; and

(3) Be reviewed and signed by a registered service provider or qualified expert.

d. Correction of EPE results. Any items not meeting the specifications of the EPE shall be corrected or repaired.

(1) The correction or repair shall begin within 30 days following the EPE and shall be performed according to a plan designated by the registrant.

(2) Correction or repair shall be completed no longer than 90 days from discovery unless authorized by the department.

(3) The registrant shall maintain records of corrections or repairs in accordance with this chapter.

(4) These records must be retained and made available to the department upon request.

40.4(3) *EPEs for service and installation.* All EPEs for service and installation shall be performed by a person registered as a radiation machines service provider or qualified expert under 641—subrules 37.8(3) and 37.8(4).

40.4(4) *Compliance prior to operation.* The registrant or the registrant's agent shall ensure that the requirements of these rules are met prior to the operation of the X-ray system(s).

40.4(5) *Compliance or prior approval by department.* An X-ray system that does not meet the provisions of these rules cannot be operated for diagnostic purposes without prior approval by the department. To ensure compliance, the following provisions must be met:

a. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.

b. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

c. The registrant cannot operate an X-ray machine for diagnostic or therapeutic purposes when the X-ray machine:

(1) Does not meet the provisions of this chapter; or

(2) Is malfunctioning and threatens the health or safety of the patient, operator, or general public.

40.4(6) *Operator competency and training.* Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

a. Operators shall meet the requirements of 641—Chapter 38, as applicable, and shall make the permit available at the individual's place of employment.

b. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

c. Operators of diagnostic X-ray systems for clinical purposes should receive training specific to the equipment, procedures, and examination protocols specific to the facility's operations.

40.4(7) *Protocol—no operational anatomic programming.* For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include the following:

a. Patient's body part and anatomical size (adult and pediatric, if appropriate);

b. Technique factors;

c. Type of image receptor used;

d. Source to image receptor distance used (except for dental intraoral radiography); and

e. Type of grid, if any.

40.4(8) *Written safety procedures.* Written safety procedures, as outlined in 641—Chapter 37, shall be established and provided to each individual operating X-ray equipment. The procedures shall include:

a. Patient holding requirements and any restrictions on operating technique necessary for the safe operation of the specific X-ray system.

b. Procedures with which the operator shall be able to demonstrate familiarity, including:

(1) Except for patients who cannot be moved out of the room, only staff and ancillary personnel required for the medical procedure or training shall be present in the room during the radiographic exposure.

(2) Other than the patient being examined, all individuals shall be positioned so that no part of the body is struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

(3) The X-ray operator, other staff, ancillary personnel, and any other persons required for the medical procedure, with the exception of handheld dental operators, shall be protected from scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent. This requirement does not apply to the use of dental handheld X-ray units, provided the device's backscatter shield is in place and used as intended by the manufacturer and as specified in subrule 40.7(5).

(4) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be positioned so the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

40.4(9) *Protective apparel.* A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with X-ray operations.

a. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with lead equivalent.

b. Registrants shall maintain a patient shielding policy consistent with ALARA principles. The use of shielding shall be determined in accordance with the radiation machine facility's established policy in alignment with national guidance. The policy should include procedures for addressing patient requests for shielding.

40.4(10) *Exposure to the useful beam.*

a. Individuals cannot be exposed to the useful beam unless:

(1) The radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner (ARNP) pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and

(2) Such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed.

b. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by subrule 40.4(14).

40.4(11) *Auxiliary support.* When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

a. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by subrule 40.4(8), shall list individual projections where holding devices cannot be utilized;

b. Written safety procedures, as required by subrule 40.4(8), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

c. A human holder shall be instructed in personal radiation safety and protected as required by subrule 40.4(8);

d. No individual shall be used routinely to hold image receptors or patients; and

e. Each facility shall have lead aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

40.4(12) *Procedures and auxiliary equipment.* Facilities shall use procedures and auxiliary equipment that reduce radiation exposure to patients and staff, as much as reasonably possible, while still obtaining the necessary diagnostic information.

a. Radiation exposure to the patient shall be limited to the minimum exposure required to produce images of good diagnostic quality.

b. Portable or mobile X-ray equipment shall be used only for examinations, excluding intraoral dental imaging, where it is impractical to transfer the patient(s) to a stationary X-ray installation.

c. Handheld mobile X-ray equipment may be used for routine intraoral dental imaging in place of stationary equipment, provided the device's backscatter shield is in place and used as intended by the manufacturer as specified in subrule 40.7(5).

d. X-ray systems subject to 641—Chapter 40 shall not be used in procedures where the source to human patient distance is less than 30 centimeters.

e. If grids are used between the patient and the image receptor to decrease scatter and improve contrast, the grid shall:

(1) Be positioned properly, including the tube side facing the correct direction, and the grid centered to the central ray; and

(2) For focused type grids, be at the proper focal distance for the SIDs being used.

40.4(13) *Personnel monitoring devices.* All individuals who are associated with the operation of an X-ray system are subject to the requirements of rule 641—37.11(136C) for standards for protection against radiation. In addition:

a. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, the device(s) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57 as amended to August 1, 2025.

b. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

40.4(14) *Healing arts screening program.* The registrant shall not initiate a healing arts screening program in which an individual is exposed to the useful beam without an order as specified in subrule 40.4(10) without prior written approval from the department.

a. An application for approval shall be submitted to the department in accordance with requirements specified in Appendix A of this chapter.

b. The department cannot approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened.

c. If any information submitted to the department becomes invalid or outdated, the applicant shall notify the department in writing within five calendar days.

40.4(15) *Maintenance of records.*

a. The registrant shall maintain all of the following records for each X-ray system until the X-ray system is removed from the facility, or as otherwise specified, and shall make such records available for inspection by the department:

(1) Model and serial numbers of all major components, and user's manuals for those components, including software;

(2) Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the X-ray system(s);

(3) A copy of all correspondence with the department regarding each X-ray system;

(4) Medical and imaging records as specified in 641—subrule 37.12(2);

(5) Personnel and dosimetry records as specified in 641—subrule 37.12(8);

b. X-ray utilization records shall be kept until the facility is inspected by this department or until all images listed on the utilization record log have been purged as specified in 641—subrule 37.12(2).

40.4(16) *X-ray utilization records.* Each facility, excluding veterinary, shall maintain a written or electronic utilization log that shall be made available to the department, upon request, for a date range specified by the department. The utilization record shall include but is not limited to all of the following:

a. The patient's name;

b. The type of examination(s);

c. The date the examinations were performed;

d. Dose information, when available from the imaging equipment or associated software.

40.4(17) *Quality assurance (QA).* The registrant shall establish and maintain a QA program, including but not limited to the following:

a. Maintain personnel qualifications as specified in 641—Chapter 38.

b. Establish and maintain written QA and quality control (QC) procedures, which shall be reviewed annually.

c. Conduct image evaluations at established intervals to identify operator training needs or imaging system deficiencies.

d. Retain QA/QC records of evaluations and reviews as specified in subrule 40.4(15).

40.4(18) *Shielding plan review.* Unless otherwise specified by the department, registrants shall ensure the following conditions related to shielding for X-ray machines are met:

a. Prior to construction of all new installations, modifications of existing installations, or installation of equipment into existing facilities where the X-ray machine is fixed in one location or otherwise routinely used in a specific location, the floor plans and equipment arrangements shall be submitted to the department for review and verification that national standards have been met. Required submission details are outlined in Appendix B of this chapter.

b. The department may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

c. The approval of such plans cannot preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 37.

40.4(19) *Design requirements for an operator's booth.*

a. Space requirements.

(1) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(2) The operator's booth may be any geometric configuration with no dimension of less than two feet (0.61 m).

(3) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(4) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

b. Structural requirements.

(1) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high.

(2) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock that will prevent an exposure when the door or panel is not closed.

(3) Shielding shall be provided to meet the requirements of this chapter.

c. Radiation exposure control panel. The radiation exposure control for the system shall be fixed within the booth and shall:

(1) Be at least 40 inches (1.0 m) from any point subject to direct scatter, leakage, or primary beam radiation.

(2) Allow the operator to use the majority of the available viewing windows or mirrors.

d. Viewing system requirements. Each booth shall have at least one viewing device that will:

(1) Be placed so that the operator can view the patient during any exposure.

(2) Be placed so that the operator can have full view of any occupant in the room and be able to view any entry into the room.

e. Warning devices. If any door that allows access to the room cannot be seen from the booth, there shall be an "X-ray on" warning sign outside that door that will be lighted anytime the rotor of the X-ray tube is activated.

f. Alternative to warning devices. A door as specified in paragraph 40.4(19)*"e"* must have an interlock controlling the exposure that will prevent the exposure if the door is not closed.

g. Additional requirements when the viewing system is a window. When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least one square foot (0.09 m^2);

(2) Regardless of size or shape, at least one square foot (0.09 m^2) of window area shall be centered no less than two feet (0.6 m) from the open edge of the booth and no less than five feet (1.5 m) from the floor;

(3) The window shall have the same lead equivalence as that required in the booth's wall on which it is mounted.

h. Additional requirements when the viewing system is by mirrors. The mirrors shall be located to meet the general requirements as specified in paragraph 40.4(19)*"d."*

i. Additional requirements when the viewing system is electronic. The camera shall be located as to accomplish the general requirements as specified in paragraph 40.4(19)*"d."*

j. Alternate viewing system as backup. An alternate viewing system shall be provided as a backup to the primary electronic system.

40.4(20) *Federal performance standards for equipment.* All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 through 1020.40 that were in effect at the time the unit was manufactured. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

40.4(21) *Modification of certified diagnostic X-ray components and systems.* Diagnostic X-ray components and systems certified in accordance with 21 CFR Part 1020 cannot be modified such that the component or system fails to comply with any applicable provision of this chapter.

a. The owner of a diagnostic X-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this chapter.

b. The owner who causes such modification need not submit the reports required by this rule, provided the owner records the date and the details of the modification in the system records and maintains this information and provided the modification of the X-ray system does not result in a failure to comply with this chapter.

40.4(22) *X-ray film processing.* A registrant using analog image receptors (e.g., radiographic film) shall maintain equipment suitable for handling and processing radiographic film in accordance with manufacturer recommendations and appropriate nationally recognized standards for image processing and maintaining image quality. Facilities shall establish and follow an image quality control program in accordance with the recommendations of a qualified expert, the system manufacturer, or a nationally recognized organization.

40.4(23) *X-ray digital image processing facilities using CR or DDR.* When exposure indicators are available, the facility shall establish and document an acceptable range for the exposure values for examinations routinely performed at the facility.

a. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented.

b. Facilities shall establish and follow an image quality control program in accord with the recommendations of a qualified expert, the system manufacturer, or a nationally recognized organization.

c. CR facilities shall perform erasure of all CR cassettes at least on a weekly basis.

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641—40.5(136C) General requirements for all diagnostic X-ray systems. In addition to the applicable requirements of this chapter, all diagnostic X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.30 and 1020.31.

40.5(1) *Warning label.* Diagnostic registrants shall comply with the warning label requirements of 21 CFR 1020.30(j).

40.5(2) *Leakage radiation from the diagnostic source assembly.* Diagnostic registrants shall comply with the leakage radiation from the diagnostic source assembly requirements of 21 CFR 1020.30(k).

40.5(3) *Radiation from components other than the diagnostic source assembly.* Diagnostic registrants shall comply with the radiation from components other than the diagnostic source assembly requirements of 21 CFR 1020.30(l).

40.5(4) *Beam quality.* Diagnostic registrants shall comply with the beam quality requirements of 21 CFR 1020.30(m).

40.5(5) *Battery charge indicator.* Diagnostic registrants shall comply with battery charge indicator requirements of 21 CFR 1020.30(o).

40.5(6) *Multiple tubes.* Diagnostic registrants shall comply with multiple tube requirements of 21 CFR 1020.31(k).

40.5(7) *Technique indicators.* Diagnostic registrants shall comply with technique indicator requirements of 21 CFR 1020.31(a).

40.5(8) *Beam-on indicators.* Diagnostic registrants shall comply with beam-on indicator requirements of 21 CFR 1020.31(j).

40.5(9) *Maintaining compliance.* Diagnostic registrants shall comply with the performance standards for ionizing radiation emitting product requirements of 21 CFR 1020.

40.5(10) *Systems designed for mammography.* All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1998 as amended to August 1, 2025, and the provisions of 641—Chapter 41.

40.5(11) *Invasive breast localization X-ray machines.* All systems designed for invasive breast localization X-ray machines shall comply with the provisions of 641—Chapter 41.

40.5(12) *Medical cabinet X-ray machine for nonhuman use.* All systems designed for tissue specimen imaging shall comply with provisions of rules 641—37.8(136C) and 641—37.9(136C).

[**ARC 0180D**, IAB 4/1/26, effective 7/1/26]

641—40.6(136C) General requirements for all fluoroscopy and interventional X-ray systems. In addition to the applicable requirements of this chapter, all fluoroscopic and interventional X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.32 to include all of the following minimum requirements.

40.6(1) *Fluoroscopic equipment.* Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy. Non-image intensified fluoroscopic equipment cannot be used.

40.6(2) *Primary protective barrier.* Fluoroscopic and interventional X-ray registrants shall comply with primary protective barrier requirements of 21 CFR 1020.32(a).

40.6(3) *Field limitation.* Fluoroscopic and interventional X-ray registrants shall comply with field limitation requirements of 21 CFR 1020.32(b).

40.6(4) *Activation of tube.* Fluoroscopic and interventional X-ray registrants shall comply with activation of tube requirements of 21 CFR 1020.32(c).

40.6(5) *Air kerma rates.* Fluoroscopic and interventional X-ray registrants shall comply with air kerma rate requirements of 21 CFR 1020.32(d).

40.6(6) *Measuring compliance of equipment parameters.* Compliance with fluoroscopy equipment parameters required in this chapter shall be conducted by a qualified expert and according to manufacturer or nationally recognized standards at intervals not to exceed 12 months.

40.6(7) *Indication of potential and current.* Fluoroscopic and interventional X-ray registrants shall comply with indication of potential and current requirements of 21 CFR 1020.32(f).

40.6(8) *Source-skin distance.* Fluoroscopic and interventional X-ray registrants shall comply with source-skin distance requirements of 21 CFR 1020.32(g).

40.6(9) *Fluoroscopic irradiation time, display, and signal.* Fluoroscopic and interventional X-ray registrants shall comply with fluoroscopic irradiation time, display, and signal requirements of 21 CFR 1020.32(h).

40.6(10) *Display of last-image-hold (LIH).* Fluoroscopic and interventional X-ray registrants shall comply with display of LIH requirements of 21 CFR 1020.32(j).

40.6(11) *Displays of values of AKR and cumulative air kerma.* Fluoroscopic and interventional X-ray registrants shall comply with displays of values of AKR and cumulative air kerma requirements of 21 CFR 1020.32(k).

40.6(12) *Protection from scatter radiation.*

a. For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

b. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met:

(1) Shielding required under paragraph 40.6(12)*"a"* shall be maintained to the degree possible under the clinical conditions;

(2) All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm;

(3) The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest);

(4) Operating and safety procedures shall reflect the above conditions, and operators shall exhibit awareness of situations requiring the use and nonuse of the protective drapes.

40.6(13) *Equipment operation.* All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

a. Overhead fluoroscopy cannot be used as a positioning tool for general purpose radiographic examinations.

b. Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall include all of the following:

(1) Patient identification;

(2) Type of examination;

(3) Date of examination;

(4) Operator's name.

c. The operation of a fluoroscopy X-ray system for clinical purposes is limited to those individuals permitted to operate radiation machines as specified in 641—Chapter 38 and persons who have received additional training provided by a qualified expert specific to:

(1) Radiation protection methods for patients and staff;

(2) Units of measurement and dose, including DAP (dose-area product) values and air kerma;

(3) Factors affecting fluoroscopic outputs;

(4) High level control options;

(5) Dose management, including dose reduction techniques, monitoring, and recording;

(6) Principles and operation of the specific fluoroscopic X-ray system(s) to be used;

(7) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically;

(8) Applicable requirements of these regulations.

d. Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.

e. Procedure planning for fluoroscopic procedures on pregnant female patients shall include feasible modifications to minimize the dose to the conceptus.

f. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

g. The registrant monitor dose during a fluoroscopic procedure.

h. The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent.

40.6(14) *Additional requirements for stationary fluoroscopic systems used for fluoroscopically guided interventional or special procedures.* Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s).

a. If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 mm of lead equivalent.

b. Protective aprons of not less than 0.25 mm of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient).

c. Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified.

d. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant woman must meet the requirements of 641—subrule 37.11(14).

40.6(15) *Supervision of fluoroscopy.* The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner, a radiologist assistant or an ARNP, pursuant to 481—subrule 621.4(5), for the purpose of localization or to obtain images for diagnostic or therapeutic purposes.

40.6(16) *Dose-area-product monitor requirements.* All fluoroscopic equipment used for interventional or special procedures shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used.

a. Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for department review the patient radiation exposure received per procedure.

b. The registrant shall maintain the records required by this subrule and shall make them available to the department upon request.

[**ARC 0180D**, IAB 4/1/26, effective 7/1/26]

641—40.7(136C) General requirements for dental intraoral, panoramic, cephalometric, and volumetric dental imaging equipment.

1. In addition to the applicable requirements of this chapter, all dental intraoral, panoramic, cephalometric, and volumetric imaging X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.31, as well as the requirements of this chapter, unless otherwise specifically authorized by the department.

2. Dental facilities using CBCT technology shall follow applicable provisions of this chapter.

40.7(1) *X-ray systems used for dental imaging.* In addition to the applicable requirements of rule 641—40.5(136C), X-ray systems used for dental imaging must meet all of the following:

a. Intraoral dental units. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than 18 cm.

(1) The X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm.

(2) Intraoral dental X-ray machines cannot be operated at less than a measured 51 kVp.

b. Extraoral, panoramic, and cephalometric units. X-ray systems designed for use with extraoral image receptors, and when used with an extraoral image receptor, shall:

(1) Be provided with means to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

(2) Be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

1. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

2. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

40.7(2) *Operators of dental X-ray systems.* Operators of dental X-ray machines must meet the requirements of rule 481—575.3(153) and be trained in the appropriate use of the radiation machines in operation at the registered dental facility.

40.7(3) *Exposure control location and operator protection.* Except for units designed to be handheld, the exposure control shall allow the operator to be:

a. Behind a protective barrier at least 6.5 feet (2 meters) tall; or

b. At least 6.5 feet (2 meters) from the tube housing assembly, outside the path of the useful beam, while making exposures.

40.7(4) *Administrative controls.* Patient and image receptor holding devices shall be used when the techniques permit.

a. Except for units designed to be handheld and allowed by these rules, the tube housing and position indicating device (PID) cannot be handheld during an exposure.

b. Dental fluoroscopy without image intensification cannot be used.

40.7(5) *Handheld intraoral equipment.* Only equipment specifically designed by the manufacturer to be held by the operator for intraoral dental X-ray exposures is allowed to be operated. In addition to the applicable requirements in this chapter, the following apply specifically to handheld devices:

a. The handheld X-ray system shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 6 inches (15.2 cm) in diameter that is positioned as close as practicable to the distal end of the position indication device.

b. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer. Records of training shall be kept at the facility until the operator is no longer an employee or until the equipment is removed from the facility.

c. The facility shall adopt and follow protocols provided by the manufacturer regarding the safe operation of the device.

d. Protective aprons of not less than 0.25 mm lead equivalent shall be available for operators to wear while operating a handheld intraoral dental radiographic unit at the discretion of the facility's policy and procedures.

e. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

f. The equipment cannot be operated in hallways, waiting rooms, or other areas where access for individuals of the general public cannot be controlled.

g. When not in use, the equipment shall be stored in a manner that would prevent inadvertent exposures or use by unauthorized individuals.

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641—40.8(136C) Computed tomography X-ray systems. In addition to the applicable requirements of this chapter, all computed tomography X-ray systems, except CT used exclusively for radiation therapy, shall meet the requirements for manufacture as specified in 21 CFR 1020.33 and the requirements set forth in this chapter at the time of installation and at all times when in use.

40.8(1) *Requirements for equipment.*

a. Conditions of operation. Computed tomography X-ray registrants shall comply with control and indication of conditions of operation as specified in 21 CFR 1020.33(f).

b. Visual indication. CT X-ray systems shall meet the requirements as specified in 21 CFR 1020.33(f)(1).

c. Timers. CT X-ray systems shall meet the requirements as specified in 21 CFR 1020.33(f)(2).

d. Tomographic plane indication and alignment. CT X-ray registrants shall comply with tomographic plane indication and alignment as specified in 21 CFR 1020.33(g).

e. Beam-on and shutter status indicators and control switches. CT X-ray registrants shall comply with beam-on and shutter status indicators as specified in 21 CFR 1020.33(h).

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed as specified in 21 CFR 1020.33(h)(1).

(2) Each emergency button or switch shall be clearly labeled as to its function.

f. Information to be provided for users. CT X-ray registrants shall comply with information to be provided for users as specified in 21 CFR 1020.33(c).

g. Conditions of operation. CT X-ray registrants shall comply with conditions of operations as specified in 21 CFR 1020.33(c)(1).

h. Dose information. CT X-ray registrants shall comply with dose information as specified in 21 CFR 1020.33(c)(2).

i. Imaging performance information. CT X-ray registrants shall comply with imaging performance information as specified in 21 CFR 1020.33(c)(3).

j. Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

(1) The total error in the indicated location of the tomographic plane or reference plane cannot exceed 5 mm as specified in 21 CFR 1020.33(g)(3).

(2) If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible as specified in 21 CFR 1020.33(h)(1).

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 mm with any mass from 0 to 100 kilograms resting on the support device as specified in 21 CFR 1020.33(i).

(4) The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position as specified in 21 CFR 1020.33(i).

(5) Measurement of actual versus indicated scan increment may be taken anywhere along this travel as specified in 21 CFR 1020.33(i).

(6) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan as specified in 21 CFR 1020.33(f)(2)(ii).

40.8(2) *Facility design requirements.* The location of a mobile and fixed CT X-ray system must be designed and constructed as follows.

a. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

b. Viewing systems.

(1) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(2) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

c. Radiation protection shielding survey. Within 30 days of first use of a mobile or fixed stationary CT X-ray system, the registrant shall complete and keep on file a radiation protection shielding survey of the room and surrounding areas consistent with the National Council on Radiation Protection and Measurements Report #147 (2004) and subrule 40.8(3).

40.8(3) *CT shielding requirements for mobile and stationary fixed CT X-ray systems.* The operator's booth and surrounding occupied areas must be designed and constructed in accordance with the National Council on Radiation Protection and Measurements Report #147 (2004) or other nationally accepted standard.

a. Protective barriers must be provided in the ceiling, floor, and walls of the CT X-ray system enclosure to ensure exposure does not exceed acceptable dose limits established in 641—subrule 37.11(7).

b. The control panel must be shielded by a protective position between the operator and the radiation source during CT X-ray system operation.

c. The registrant shall submit a revised radiation shielding plan for department review in accordance with this rule after replacement of a mobile or fixed stationary CT X-ray system or any change in the CT X-ray system room's construction or surrounding rooms construction.

d. Rooms in which a mobile CT X-ray system is used are exempt from the requirements of paragraphs 40.8(3)*"a," "b,"* and *"c."* However, the operator must be protected to ensure exposure does not exceed dose limits established in 641—Chapter 37 for dose limits to members of the public.

40.8(4) *Surveys, calibrations, and routine QC.*

a. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert within 30 days of installation.

b. Existing systems not previously surveyed shall have a survey made by, or under the direct supervision of, a qualified expert within 12 months of the effective date.

c. Such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

d. The registrant shall obtain a written survey report from the qualified expert. A copy of the report shall be retained and made available to the department upon request for the duration of use and registration of the CT X-ray system.

40.8(5) *System performance evaluation.* The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

a. The calibration of a CT X-ray system shall be performed annually as specified in paragraph 40.4(2)*"b"* by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

b. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system.

(1) The calibration of such system shall be traceable to a national standard.

(2) The dosimetry system shall have been calibrated within the preceding two years.

c. The use of a water equivalent CT phantom shall be incorporated. At a minimum, noise, CT number, and artifacts shall be evaluated.

40.8(6) *Calibration.* Calibration shall meet the following requirements:

a. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable.

b. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness, the CTDI along the two axes specified in paragraph 40.8(5)*"c"* shall be measured for the purpose of determining the CTDI, and the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

c. The CT dosimetry phantom shall be oriented so that the measurement point 1 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified.

d. The CT conditions of operation shall correspond to typical values used by the registrant, and the spot checks specified in subrule 40.8(7) shall be made as specified in 21 CFR 1020.33(c)(2)(iv).

40.8(7) *Routine QC (spot checks).* Spot check procedures shall be in writing and shall have been verified by a qualified expert.

a. The spot check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material as specified in 21 CFR 1020.33(d)(1).

b. All spot checks shall be included in the calibration required by subrules 40.8(5) and 40.8(6) and at time intervals and under system conditions specified by a qualified expert.

c. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by subrules 40.8(5) and 40.8(6).

d. The images shall be retained until a new calibration is performed and retained in two forms:

(1) Photographic copies of the images obtained from the image display device; and

(2) Images stored in digital form on a storage medium compatible with the CT X-ray system.

e. Written records of the spot checks performed shall be retained and made available to the department upon request as specified in subrule 40.4(15).

40.8(8) *CT operating procedures.* The CT X-ray system cannot be operated except by a licensed practitioner or an individual who has been specifically trained in its operation and holds a current permit to practice as a general radiologic technologist as defined under the provisions of 641—Chapter 38. The following information shall be readily available to the CT operator:

a. Instructions on performing routine QC;

b. Scanning protocols for operators;

c. A record of radiation output information, maintained by the registrant, so the radiation dose may be estimated in accordance with established protocols in accordance with the utilization log requirements of this chapter.

40.8(9) *CT systems used for radiation therapy, including PET CT, SPECT CT and CT simulation systems.*

a. PET CT and SPECT CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements of this chapter.

b. Operators must meet the requirements of 641—Chapter 38 and be specifically trained in the operation of the PET CT or SPECT CT system.

c. CT systems used exclusively for radiation therapy simulation treatment planning shall be subject to the requirements of this chapter.

40.8(10) *Remote CT scanning requirements.*

a. Operator requirements. Each person who seeks to operate CT X-ray systems in Iowa from a remote location outside of Iowa must possess a current Iowa permit to practice in accordance with 641—Chapter 38 before engaging in remote CT procedures.

b. Facility requirements. Facilities utilizing remote CT scanning shall ensure qualified operators meet the following requirements:

(1) The facility shall maintain documentation demonstrating that each remote operator of a CT system meets the qualification requirements specified in 641—Chapter 38, applicable to the location of the CT system.

(2) The facility shall verify that each operator meets the qualifications outlined in 641—Chapter 38, including operators located out of state, to ensure compliance with Iowa requirements.

c. On-site personnel. Each on-site personnel shall receive training specific to the personnel's assigned responsibilities in the operation of the remote CT system. Training shall include, at a minimum, both of the following:

(1) Patient positioning;

(2) Administration of contrast.

d. Procedures. Procedure review to ensure safe operation and compliance with state regulations will include, at a minimum, all of the following:

(1) Patient ID procedures;

(2) Protocol management procedures;

(3) Emergency procedures.

e. Radiation safety program elements for remote CT. The facility shall ensure all of the following are met. In addition, records should be maintained and made available upon request to the department.

(1) Use only remote CT systems and components that can adequately protect patient information and to establish policies and procedures for ensuring patient information is protected at the imaging facility, remote imaging locations, and locations where other members of the medical team will view or access patient information.

(2) Maintain a list of the remote operating locations and associated imaging sites. The list must contain the name of the facility, location, and a contact person.

(3) Define the roles and responsibilities and develop procedures for the remote CT technologist and the on-site personnel.

(4) Ensure the on-site personnel completes annual radiation safety training related to the personnel's CT responsibilities.

(5) Ensure the on-site personnel maintains constant surveillance of the patient throughout the CT imaging procedure and performs only one CT imaging procedure at a time.

(6) Ensure remote CT will not be performed if communications (verbal and virtual) or connectivity between the remote site and the imaging facility are not functioning properly or are otherwise unreliable.

(7) Perform checks of the communication system (verbal and visual) and the functionality and connectivity between the remote location and the imaging facility prior to initiating each CT imaging procedure.

(8) Develop procedures for responding to emergencies and situations where there may be a loss of connectivity between the remote site and the imaging facility.

(9) Ensure the remote CT technologist maintains constant surveillance via vocal and visual communications throughout a CT imaging procedure and performs only one CT imaging procedure at a time.

(10) Develop policies and procedures to ensure adequate management oversight of remote operations, including all of the following:

1. Audits to evaluate the effectiveness and safety of the remote CT operations;
2. Reportable radiation incidents;
3. Observations of work being performed at both the imaging facility and the remote location;
4. Processes to identify, track, investigate, and implement corrective actions for incidents where CT examinations are incomplete or repeated.

40.8(11) *Cone-beam CT (CBCT) X-ray systems; equipment requirements.* The CBCT X-ray system must meet the applicable requirements of this chapter.

a. The X-ray field in the plane of the image receptor may not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

b. The registrant shall document and follow QC recommendations in accordance with manufacturer recommendations or as established by a qualified expert in accordance with nationally recognized guidelines.

c. The registrant shall document and implement imaging protocols and a policy addressing deviations from established protocols.

d. The CBCT X-ray system shall only be operated by an individual who meets the requirements of 641—Chapter 38 or rule 481—575.4(153) and who has been specifically trained in the operation of the CBCT X-ray system.

e. The registrant shall maintain documentation of the established protocols, policies, and QC testing until the X-ray system is removed from the facility for inspection by the department.

f. The CBCT operator shall have instructions on all of the following:

(1) Instructions on performing routine QC;

(2) Scanning protocols for operators;

(3) CT systems, including CBCT systems, solely used in nonhuman imaging refer to rule 641—40.10(136C).

[**ARC 0180D**, IAB 4/1/26, effective 7/1/26]

641—40.9(136C) Dual-energy X-ray absorptiometry (DXA). DXA systems shall be registered in accordance with 641—subrule 37.8(2) and maintained and operated, at a minimum, in accordance with the manufacturer's specifications.

40.9(1) *Shielding.* No additional shielding for the room is required.

40.9(2) *Operator requirements.* Operators shall meet the requirements of 641—Chapter 38 and be trained in the safe and effective operation of the specific equipment used at the facility.

a. Specific operating procedures must be prepared and made available to the operator.

b. DXA imaging on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1(7), or a licensed registered nurse who is registered as a qualified ARNP.

40.9(3) *Operation of the DXA system.*

a. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and DXA system during the examination.

b. The operator shall advise the patient that the DXA examination is a type of X-ray procedure.

[**ARC 0180D**, IAB 4/1/26, effective 7/1/26]

641—40.10(136C) Veterinary medicine X-ray systems. Veterinary registrants shall be registered in accordance with 641—subrule 37.8(2) and maintained and operated, at a minimum, in accordance with the manufacturer's specifications.

40.10(1) *Equipment.* All veterinary equipment shall follow the general requirements as specified in rule 641—40.5(136C).

40.10(2) *Operator and ancillary personnel protection for veterinary systems.* All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with the provisions of this chapter.

a. All stationary, mobile, or portable X-ray systems used for veterinary work shall be provided with either a 6.5-foot (2-meter-) high protective barrier for operator protection during exposures or shall be provided with means to allow the operator to be at least 6.5 feet (2 meters) from the tube housing assembly during exposures.

b. Otherwise, in cases where animals are held, the operator and ancillary personnel shall be protected by a minimum of 0.25 mm lead equivalent from scatter radiation and 0.5 mm from the useful beam.

40.10(3) *Operating procedures.* Veterinary medicine radiographic registrants are exempt from the requirements of this chapter, except for the provisions of rules 641—40.4(136C), 641—40.5(136C), and 641—40.10(136C).

a. No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required.

b. The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures.

c. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used.

d. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and an apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

40.10(4) *Tube stands for portable X-ray systems.* Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support shall be used for portable X-ray systems so that the X-ray tube housing assembly need not be handheld during an exposure.

40.10(5) *Veterinary handheld equipment.* Handheld intraoral dental X-ray units used in veterinary practice shall meet the requirements of subrule 40.7(5).

40.10(6) *Veterinary CT systems.* CT systems, including CBCT systems, solely used in nonhuman imaging shall meet the requirements of paragraph 40.4(2)*"a"* but are otherwise exempt from the standards of paragraph 40.4(2)*"b."*

[**ARC 0180D**, IAB 4/1/26, effective 7/1/26]

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

Appendix A—Healing Arts Screening Program

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING PROGRAM

For the purposes of this program, healing arts screening refers to testing human subjects with X-ray machines to detect or evaluate health indications in individuals considered at high risk, when such tests are not specifically and individually ordered by:

a. An individual authorized under subrule 40.4(10); or

b. An individual licensed as a physician in Iowa.

Persons requesting that the department approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.

3. A detailed description of the X-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, e.g., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over the age of 45 or men over the age of 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.

5. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the registrant's applicable quality control program.

8. A copy of the technique chart for the X-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the X-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the physician who will interpret the images and a copy of the physician's license to practice in Iowa.

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention of images and other records pertaining to the X-ray examinations.

14. An indication of the frequency of screening and the duration of the entire screening program.

15. Documentation justifying the reason for the screening. The applicant must submit data that supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data that will be acceptable to the department includes but is not limited to the following:

(1) The recommendation of a nationally recognized certifying medical or government body;

(2) The recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or

(3) Medical literature from peer-reviewed journals supporting the screening.

16. The procedures for preventing pregnant women from participating in the screening or justification for allowing pregnant women to participate.

17. The dates of the screening to include beginning and ending dates.

18. A copy of the Institutional Research Board approval for a research project or information justifying the research project.

Appendix B
INFORMATION ON RADIATION SHIELDING
REQUIRED FOR PLAN REVIEWS

In order for the department to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.), and the maximum technique factors.

(f) The type of examination(s) or treatment(s) that will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

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CHAPTER 41
REGISTRATION AND SAFETY REQUIREMENTS FOR MAMMOGRAPHY AND STEREOTACTIC BREAST BIOPSY

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—41.1(136C) Registration and safety requirements for mammography and stereotactic breast biopsy. The following provisions of 21 CFR 900 as amended to August 1, 2025, for mammography are hereby adopted by reference:

41.1(1) 21 CFR 900.2 Definitions.

41.1(2) 21 CFR 900 Subpart B—Quality Standards and Certification.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.2(136C) Definitions. The definitions contained in 21 CFR 900.2, as adopted by reference, apply to the mammography provisions of this chapter. The definitions provided in 641—Chapters 37 and 40 may also apply. Additionally, the definitions set forth below are specific to this chapter.

"Annually" means within 10 to 14 months of previous occurrence.

"Authorization" means the same as defined in 641—Chapter 37.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient's benefit.

"EQUIP" means Enhancing Quality Using the Inspection Program and uses inspection questions related to the image quality regulations of MQSA to emphasize the significance of continuous clinical image quality.

"Full field digital mammography" or *"FFDM"* means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

"Iowa-approved" means recognized or accepted by the department as meeting the training and experience requirements established by MQSA and any additional criteria set forth in this chapter. This may include but is not limited to formal approval by the department based on documentation of education, training, certification, and clinical experience.

"Phantom" means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Procedure" means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

"Qualified training physician" means a physician who is qualified under the rules of this chapter to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

"Radiologic technologist" means the same as defined in 21 CFR 900.2 and also includes the definition of "general radiologic technologist" as set forth in 641—Chapter 38.

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Reinstatement" means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

"Review workstation" or *"RWS"* means soft copy display device intended for use in mammography interpretations.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Stereotactic training phantom" means a training or practice tool or medium used for stereotactically guided breast biopsy procedures.

"Stereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system that emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.3(136C) General provisions for mammography. All Iowa mammography facilities and personnel shall comply with the applicable regulations of 21 CFR 900 as adopted in rule 641—41.1(136C). In addition, compliance with the requirements of 641—Chapters 37 and 40 and the rules contained herein are required. Where differences exist, compliance with the most stringent applicable standard, whether CFR regulations or the Iowa Administrative Code, applies.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.4(136C) Mammography registration, certification, and general requirements. In addition to the rules of this chapter, mammography facilities shall comply with the requirements of 21 CFR 900.11.

41.4(1) *Registration and certificates.* Each radiation machine used to perform mammography shall be registered according to 641—subrule 37.8(2).

a. A certificate issued by the FDA or this department is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this department, facilities are required to meet the quality standards of this chapter and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for authorization by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for department-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually (within 10 to 14 months of previous occurrence) by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

41.4(2) *Inspections.* After initial mammography certification, the department will conduct an inspection of each radiation machine no later than every 14 months thereafter.

a. An application for authorization shall be submitted to the department and processed for department approval. A mammography authorization is effective for three years.

b. A phantom image taken with the authorized unit(s) will be reviewed at the time of annual inspection by the department.

41.4(3) *Review workstation (RWS) requirements.* RWS used for final interpretation of mammogram images shall meet the following criteria:

a. Have 5 megapixel resolution; or

b. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

c. The workstation shall have a quality control program substantially the same as that outlined by the mammography unit manufacturer's quality control manual, that outlined by the RWS monitor manufacturer's quality control manual, or the quality control program outlined by an FDA-approved accrediting body.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.5(136C) Mammography personnel. In addition to the rules of this chapter, mammography personnel shall comply with the requirements of 21 CFR 900.12. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities.

41.5(1) *Interpreting physicians.* All radiologists interpreting mammograms shall comply with the requirements of 21 CFR 900.12(a)(1) and meet the following qualifications before beginning to interpret mammography independently, unless the exemptions in 21 CFR 900.12(a)(1)(iii)(A) apply.

a. A current state of Iowa medical license shall be in effect whenever mammography interpretations are performed by the physician.

b. Mammography personnel who fail to meet continuing education or experience requirements may requalify once without providing proof of extenuating circumstances. The department will assess any submitted proof and make a determination after reviewing all relevant information. If requalification is denied, individuals may reapply after a 90-day waiting period following the date of expiration.

41.5(2) *Radiologic technologists.* All general radiographers performing mammographic examinations shall comply with the requirements of 21 CFR 900.12(a)(2) and meet the following requirements:

a. A current state of Iowa permit to practice as a general radiologic technologist shall be in effect whenever all mammographic examinations are performed by the radiologic technologist.

b. Mammography personnel who fail to meet continuing education or experience requirements may requalify once without providing proof of extenuating circumstances. The department will assess any submitted proof and make a determination after reviewing all relevant information. If requalification is denied, individuals may reapply after a 90-day waiting period following the date of expiration.

41.5(3) *Medical physicists.* All medical physicists providing any of the following mammography services shall comply with the requirements of 21 CFR 900.12(a)(3).

a. Health physics consultations or surveys of mammography equipment.

b. Health physics consultations or surveys of mammography reading workstations.

c. Oversight of the mammography facility's quality assurance program.

d. Additional mammography services as deemed appropriate by the department.

e. All medical physicists providing mammography surveys as outlined in this chapter must, at the time of the survey(s), be Iowa-approved as defined in this chapter.

f. Medical physicists that are Iowa-approved for mammography may perform only the mammography services outlined in this chapter.

g. Medical physicists wishing to perform services other than those outlined in this chapter must be registered with the department, under the provisions of 641—Chapter 37, as a radiation machine service provider, whether as an individual, as part of a corporation, or any other entity included in the definition of "person" in 641—Chapter 37.

h. A medical physicist cannot perform any services, including those related to mammography modalities, unless such services are specifically listed on the Iowa approval notice or radiation machine service provider notice issued by the department.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.6(136C) Retention of personnel records for mammography. Mammography facilities shall comply with the retention of personnel records requirements of 21 CFR 900.12(a)(4).

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.7(136C) Equipment and safety requirements for mammography. Mammography facilities shall comply with the equipment requirements of 21 CFR 900.12(b).

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.8(136C) Medical records and reports for mammography. Mammography facilities shall comply with the requirements for medical records and mammography reports of 21 CFR 900.12(c) and of this chapter.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.9(136C) Contents and terminology for mammography. Mammography facilities shall comply with the contents and terminology requirements of 21 CFR 900.12(c)(1) and this chapter.

41.9(1) A separate and distinct section entitled "Assessment" with the appropriate assessment term or an approved equivalent shall be included.

41.9(2) The breast density information as designated in the report pursuant to this chapter shall be included in the patient lay letter with a reference to a department-accepted site or document where the patient can obtain more information about breast density.

41.9(3) Mammography facilities shall comply with the requirements for the communication of mammography results to patients found in 21 CFR 900.12(c)(2).

41.9(4) Mammography facilities shall comply with the requirements for the communication of mammography results to health care providers found in 21 CFR 900.12(c)(3).

41.9(5) Mammography facilities shall comply with the recordkeeping requirements of 21 CFR 900.12(c)(4) and 641—subrule 37.12(2). Facilities performing mammography shall maintain mammography records for a minimum of seven years.

41.9(6) Mammography facilities shall comply with the mammographic image identification requirements of 21 CFR 900.12(c)(5).

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.10(136C) Quality assurance for mammography. Mammography facilities shall comply with the quality assurance requirements of 21 CFR 900.12(d), 21 CFR 900.12(e), 21 CFR 900.12(f) and the requirements of this chapter.

41.10(1) Mammography facilities shall comply with the general quality assurance requirements of 21 CFR 900.12(d).

a. Mammography facilities shall comply with the requirements of responsible individuals found in 21 CFR 900.12(d)(1).

b. Mammography facilities shall comply with the quality assurance records requirements of 21 CFR 900.12(d)(2).

c. Mammography facilities shall comply with the equipment quality assurance requirements of 21 CFR 900.12(e).

d. Mammography facilities shall comply with the quality control test requirements of 21 CFR 900.12(e)(1) through 21 CFR 900.12(e)(6).

e. Mammography facilities shall comply with the mobile unit requirements of 21 CFR 900.12(e)(7).

f. Mammography facilities shall comply with the use of test results requirements of 21 CFR 900.12(e)(8).

g. Mammography facilities shall comply with the survey requirements of 21 CFR 900.12(e)(9).

h. Mammography facilities shall comply with the mammography equipment evaluation requirements of 21 CFR 900.12(e)(10).

i. Mammography facilities shall comply with the facility cleanliness requirements of 21 CFR 900.12(e)(11).

j. Mammography facilities shall comply with the calibration of air kerma measuring instrument requirements of 21 CFR 900.12(e)(12).

k. Mammography facilities shall comply with the infection control requirements of 21 CFR 900.12(e)(13).

l. Mammography facilities shall comply with the mammography medical outcomes audit quality assurance requirements of 21 CFR 900.12(f).

m. Mammography facilities shall comply with the mammographic procedure and techniques for mammography of patients with breast implant requirements of 21 CFR 900.12(g).

n. Mammography facilities shall comply with the consumer compliant mechanism requirements of 21 CFR 900.12(h).

o. Mammography facilities shall comply with the clinical image quality requirements of 21 CFR 900.12(i).

p. Mammography facilities shall comply with the mammography review and patient and referring provider notification requirements of 21 CFR 900.12(j).

41.10(2) Reserved.
[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.11(136C) Revocation, suspension, reinstatement and appeals for mammography.

41.11(1) *Revocation of accreditation and revocation of accreditation body approval.* Mammography facilities shall comply with the revocation of accreditation and revocation of accreditation body approval requirements of 21 CFR 900.13.

41.11(2) *Suspension or revocation of certificates.* Mammography facilities shall comply with the suspension or revocation of certificate requirements of 21 CFR 900.14.

a. If certification is revoked, the radiation machine cannot be used for mammography until reinstated.

b. If suspension or revocation of a certificate is initiated, the administrative enforcement actions specified in rule 641—37.10(136C) shall apply.

41.11(3) *Reinstatement of mammography certification or authorization after revocation.*

a. An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions shall be submitted with the application.

b. A full certificate shall be issued only after the department has determined the radiation machine meets the requirements of these rules.

41.11(4) *Appeals.*

a. Mammography facilities shall comply with the appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification requirements of 21 CFR 900.15.

b. Mammography facilities shall comply with the appeals of denials of certification requirements of 21 CFR 900.16 and rule 641—37.10(136C).
[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.12(136C) Alternative requirements for quality standards for mammography. Mammography facilities may also comply with the alternative quality standard requirements of 21 CFR 900.12 and 21 CFR 900.18.
[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.13(136C) General provisions for stereotactic breast biopsy. All Iowa facilities and persons certified to perform stereotactic breast biopsies shall comply with the applicable requirements of this chapter and the applicable provisions in 641—Chapters 37 and 40.
[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.14(136C) Registration and application standards and requirements for stereotactic breast biopsy. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to the requirements set forth in 641—subrule 37.8(2).

41.14(1) Each facility wishing to perform stereotactically guided breast biopsies shall apply to the department for authorization by providing or verifying the following information for each machine:

a. The stereotactically guided breast biopsy equipment and facility meet the general requirements of the rules for radiation machines.

b. The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

c. The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

d. The radiation machine is operated by individuals meeting the requirements of this rule.

e. The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

f. The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

41.14(2) The department will conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.
[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.15(136C) Requirements for physicians performing stereotactic breast biopsy. Physicians shall be qualified according to the setting and their role in performing stereotactically guided breast biopsies.

41.15(1) *Requirements for stereotactic breast biopsies for radiologists in collaborative settings.*

a. Initial training and qualifications for radiologists in collaborative settings.

(1) Radiologists shall be qualified according to the rules of this chapter.

(2) Radiologists shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under the conditions laid out in this chapter and has performed at least 24 stereotactically guided breast biopsies.

(3) Radiologists shall have at least three hours of Category 1 continuing medical education (CME) or three hours of training approved by the department in stereotactically guided breast biopsy.

(4) Radiologists shall be responsible for mammographic interpretation and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

(5) Radiologists shall be responsible for the supervision of the radiologic technologist during the procedure.

b. Maintenance of continuing experience and CME requirements for radiologists performing stereotactic breast biopsy in collaborative settings.

(1) Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures shall be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.
2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
3. Stereotactic breast biopsy case review, which shall be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
4. Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image-guided technique.
5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department-approved manufacturer applications specialist before resuming unsupervised procedures.

(2) Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME or three hours of training approved by the department in stereotactic-guided breast biopsy during the 36 months immediately preceding the date of the facility's annual stereotactic breast biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician shall requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

(3) A current state of Iowa medical license shall be in effect whenever procedures are performed independently by the physician.

41.15(2) *Physician requirements for stereotactic breast biopsy in a collaborative setting (nonradiologists).*

a. Initial training and qualifications for physicians in a collaborative setting (nonradiologists):

(1) Physicians shall be licensed to practice medicine in Iowa.

(2) Physicians shall have at least three hours of Category 1 CME or three hours of training approved by the department in stereotactically guided breast biopsy.

(3) Physicians shall have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to perform stereotactic breast biopsy procedures according to the rules of this chapter and has performed at least 24 stereotactically guided breast biopsies.

(4) Physicians shall be responsible for post-biopsy management of the patient.

(5) Physicians shall be responsible for supervision of the radiologic technologist during the procedure.

b. Maintenance of continuing experience and CME requirements for physicians performing stereotactic breast biopsy in collaborative settings (nonradiologists):

(1) Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures shall be met for each calendar year, with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.

2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.

3. Stereotactic breast biopsy case review, that shall be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.

4. Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image-guided technique.

5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department-approved manufacturer applications specialist before resuming unsupervised procedures.

(2) Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME immediately preceding the date of the facility's annual stereotactic breast biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician shall requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

(3) A current state of Iowa medical license shall be in effect whenever unsupervised procedures are performed by the physician.

41.15(3) *Requirements for stereotactic breast biopsy for radiologists in an independent setting.*

a. Initial training and requirements for radiologists in an independent setting.

(1) Radiologists shall be qualified according to the rules of this chapter.

(2) Radiologists shall have at least three hours of Category 1 CME or three hours of training approved by the department in stereotactically guided breast biopsy.

(3) Radiologists shall obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

(4) Radiologists shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to the rules of this chapter, and has performed at least 24 stereotactically guided breast biopsies.

(5) Radiologists shall be responsible for mammographic interpretation.

(6) Radiologists shall be responsible for patient selection.

(7) Radiologists shall be responsible for the supervision of the radiologic technologist during the procedure.

(8) Radiologists shall be responsible for post-biopsy management of the patient, which may include referral to a surgeon for a follow-up on certain lesions.

b. Maintenance of continuing experience and CME requirements for radiologists performing stereotactic breast biopsy in an independent setting.

(1) Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures in each calendar year, with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.

2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.

3. Stereotactic breast biopsy case review, that shall be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.

4. Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image-guided technique.

5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department-approved manufacturer applications specialist before resuming unsupervised procedures.

(2) Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME immediately preceding the date of the facility's annual stereotactic breast biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection, which includes post-biopsy management of the patient. If education is not maintained, the physician shall requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

(3) A current state of Iowa medical license shall be in effect whenever unsupervised procedures are performed by the physician.

41.15(4) *Physician requirements for performing stereotactic breast biopsy in an independent setting (nonradiologist).*

a. Initial training and requirements for physicians performing stereotactic breast biopsy in an independent setting (nonradiologist).

(1) Physicians shall have evaluated at least 480 mammograms in the prior 24 months in consultation with a qualified physician.

(2) Physicians shall have at least 15 hours of Category 1 CME or 15 hours of training approved by the department in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.

(3) Physicians shall have four hours of Category 1 CME in medical radiation physics.

(4) Physicians shall have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to this chapter, and has performed at least 24 stereotactically guided breast biopsies.

(5) Physicians shall be responsible for patient selection.

(6) Physicians shall be responsible for the supervision of the radiologic technologist during the procedure.

(7) Shall be responsible for post-biopsy management of the patient.

b. Maintenance of continuing experience and CME requirements for physicians performing stereotactic breast biopsy in an independent setting.

(1) Physicians shall continue to evaluate at least 480 mammograms every 24 months in consultation with a qualified physician.

(2) Physicians shall complete a total of 12 breast biopsy procedures in each calendar year with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.

2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.

3. Stereotactic breast biopsy case review, that shall be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.

4. Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image-guided technique.

5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department-approved manufacturer applications specialist before resuming unsupervised procedures.

(3) Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME immediately preceding the date of the facility's annual stereotactic breast biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician shall requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.

(4) A current state of Iowa medical license shall be in effect whenever unsupervised procedures are performed by the physician.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.16(136C) Requirements for radiologic technologists performing stereotactic breast biopsy.

41.16(1) Radiologic technologists shall be qualified according to the rules of this chapter.

41.16(2) An Iowa permit to practice radiography as a general radiologic technologist shall be in effect whenever stereotactic procedures are performed by the radiologic technologist and shall meet the following initial requirements:

a. Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a qualified physician or technologist.

b. Three contact hours in stereotactically guided breast biopsy.

41.16(3) Maintenance of continuing experience and continuing education and experience requirements for stereotactic breast biopsy.

a. Following the first anniversary in which the requirements of this subrule were met, a total of 12 breast biopsy procedures shall be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining six must be clearly documented and can be any combination of the following:

(1) Stereotactic breast biopsy procedures.

(2) Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.

(3) Stereotactic breast biopsy case review, that shall be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.

(4) Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image-guided technique.

(5) If experience is not maintained, the radiologic technologist shall requalify by performing three stereotactically guided breast biopsies under the supervision of a qualified physician or radiologic technologist.

b. Following the third anniversary in which the requirements of this subrule were met, obtain at least three hours of continuing education in stereotactically guided breast biopsy during the 36 months immediately preceding the date of the facility's annual stereotactic breast biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection, or requalify by obtaining additional CME credits to reach three CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.17(136C) Requirements for medical physicists performing surveys of stereotactic breast biopsy systems.

41.17(1) Qualified medical physicists, as outlined in this chapter, shall have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on

stereotactically guided breast biopsy system physics survey under the guidance of a qualified medical physicist.

41.17(2) Each person engaged in providing health physics services for stereotactic breast biopsy in Iowa who meets the requirements of this chapter shall apply for Iowa approval with the department prior to providing such services in accordance with 641—subrule 37.9(2).

41.17(3) Maintenance of proficiency and continuing education requirements for medical physicists performing surveys of stereotactic breast biopsy systems. Qualified medical physicists shall meet the following requirements:

a. Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist.

b. Following the third anniversary in which the requirements of this subrule were met, have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach three CME credits in the prior 36 months.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.18(136C) Obtaining and preserving records for stereotactic breast biopsy. Records must be retained for a minimum of ten years. The facility shall make, for each procedure, a record of the services provided, including all of the following:

41.18(1) The date of the procedure;

41.18(2) The name of the patient and one additional patient identifier;

41.18(3) The names of the physicians performing the procedure;

41.18(4) The names of the radiologic technologists performing the procedure or any other department-approved documentation;

41.18(5) A description of the service provided;

41.18(6) The name of the referring physician, if any.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.19(136C) Quality assurance program for stereotactic breast biopsy. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems to ensure high-quality images with minimum patient exposure.

41.19(1) The facility shall name a supervising stereotactic breast biopsy physician who shall be responsible for all of the following:

a. Quality assurance activities including the medical audit;

b. Oversight and review of the quality control program at least annually;

c. Supervision of the radiologic technologist(s) and the medical physicist.

41.19(2) Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program.

a. The program shall include equipment performance monitoring conducted at installation and at least annually thereafter. Performance monitoring shall include the following:

(1) Evaluation of biopsy unit assembly. Any failed items shall be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

(2) Collimation.

1. X-ray field cannot extend beyond the image receptor by more than 5 mm on any side.
2. Any failures shall be corrected within 30 days of the survey.

(3) Evaluation of focal spot. Focal spot cannot degrade from initial measurement. If reduction in lp/mm is found, focal spot shall be corrected within 30 days of survey.

(4) kVp accuracy/reproducibility. kVp accuracy/reproducibility shall be accurate to within +/- 5 percent of nominal kVp setting. Failures shall be corrected before further procedures are performed.

(5) Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures shall be corrected before further procedures are performed.

(6) Automatic Exposure Control System Assessment.

(7) Digital receptor uniformity. The SNR in each corner shall be within +/- 15 percent of the SNR in the center. Failures shall be corrected within 30 days of the survey.

(8) Breast entrance exposure, average glandular dose and exposure reproducibility. Exposure shall be reproducible to within +/- 15 percent of mean exposure. Average glandular dose shall be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.2 centimeter breast. Failures shall be corrected before further procedures are performed.

(9) Image quality evaluation. Phantom image shall meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures shall be corrected before further procedures are performed.

(10) Artifact evaluation. Any significant black or white artifacts seen in the image detector field shall be corrected within 30 days of the survey.

(11) Localization simulation (gelatin phantom) test. Localization accuracy shall be within 1 mm of target, and the test shall include a portion of the test "lesion" in the sample chamber. Failures shall be corrected before further procedures are performed.

b. Analyzing the performance monitoring results to determine if there are any problems requiring correction.

c. Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

41.19(3) Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired.

41.19(4) The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

a. Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate shall be within manufacturer specifications for the intended target value. Failures shall be corrected before further procedures are performed.

b. Visual checklist (monthly). Any failed items shall be corrected within 30 days.

c. Phantom image (weekly). Phantom image shall meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures shall be corrected before further procedures are performed.

d. Compression (semiannually). The maximum auto drive compression force cannot exceed 45 pounds. Failures shall be corrected within 30 days.

e. Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer shall be completed as outlined in the quality control manual applicable to the unit.

41.19(5) Medical audit program. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include all of the following:

a. An imaging-pathology correlation for each biopsy performed;

b. An ongoing analysis of biopsy results and periodic review of the utilization of the procedure;

c. The number of biopsies performed;

d. The number of cancers found;

e. The number of benign lesions found;

f. The number of biopsies repeated.

[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.20(136C) Equipment and safety standards for stereotactic breast biopsy. Equipment must be specifically designed for stereotactically guided breast biopsy.

41.20(1) Stereotactic facilities shall comply with the requirements of 641—Chapters 37 and 40.

41.20(2) Annual inspections shall be conducted by an inspector from the department to ensure compliance with these rules. Identified hazards shall be promptly corrected.
[**ARC 0181D**, IAB 4/1/26, effective 7/1/26]

641—41.21(136C) Suspension, revocation, denial, and reinstatement of authorization for stereotactic breast biopsy.

41.21(1) *Suspension, revocation, or denial of authorization.* Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

a. Stereotactic facilities shall comply with the administrative enforcement action requirements of rule 641—37.10(136C).

b. If authorization is revoked, the radiation machine cannot be used until reinstated.

c. If suspension, revocation, or denial of authorization is initiated, the administrative enforcement actions in rule 641—37.10(136C) will apply.

41.21(2) *Reinstatement of authorization.*

a. An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions shall be submitted as required by the department.

b. A full reinstatement will be issued only after the department has determined the radiation machine and facility meet the requirements of these rules.
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◊ Two or more ARCs

CHAPTER 42
REGISTRATION AND SAFETY REQUIREMENTS FOR THERAPEUTIC USE OF RADIATION MACHINES, PARTICLE ACCELERATORS FOR NONHUMAN USE, AND ANALYTICAL X-RAY EQUIPMENT

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—42.1(136C) General provisions. The provisions of this chapter establish the requirements of a registrant for the use of therapeutic radiation machines.

42.1(1) The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training and experience criteria established by rule 641—42.5(136C).

42.1(2) Unless otherwise specified in rule 641—41.3(136C), all registrants are subject to the applicable requirements of 641—Chapters 37 through 40.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.2(136C) Definitions. The definitions provided in 641—Chapters 37 and 40 may also apply to the provisions of this chapter. Additionally, the following definitions set forth below are specific to this chapter.

"Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Added filtration" means any filtration that is in addition to the inherent filtration.

"Analytical X-ray equipment" means equipment used for X-ray diffraction or fluorescence analysis.

"Analytical X-ray system" means a group of components utilizing X-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

"Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, that provides a means to restrict the dimensions of the useful beam.

"Beam-scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Cold pasteurization" means the process of using radiation for destroying disease-causing microorganisms in commercial products.

"Contact therapy system" means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than five centimeters.

"Dose monitor unit" or *"DMU"* means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Fail-safe characteristics" means a design feature that causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Field flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Iowa approved" means recognized or accepted by the department as meeting the training and experience requirements established by the Mammography Quality Standards Act as amended to August 1, 2025, CFR, or any additional criteria set forth by the department. This may include but is not limited to formal approval by the department based on documentation of education, training, certification, and clinical experience.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Local components" means part of an analytical X-ray system and includes X-ray areas that are struck by X-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Megavolt (MV)" or *"mega electron volt (MeV)"* means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

"Monitor unit" or *"MU"* means the same as "dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"Normal operating procedures" means step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

"Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of the individual's body in the primary beam path during normal operation.

"Periodic quality assurance check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

"Radiation field" means the same as "useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation therapy physicist" means an individual qualified in accordance with 641—subrule 41.5(3).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Self-shielded particle accelerator" means a particle accelerator with the accelerator installed in an enclosure independent of the existing architectural structures, except the floor on which it may be placed. The enclosure must have been evaluated by a qualified expert and that evaluation approved by an appropriate regulatory authority through a device evaluation. The self-shielded accelerator is intended to contain at least that portion of material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. A particle accelerator used within a shielded part of a building, or which may temporarily or occasionally incorporate portable shielding, is not a self-shielded particle accelerator.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shielded facility" means an accelerator facility where shielding is required to be constructed on site in order to ensure compliance with the requirements of 641—Chapter 40 or where shielding supplied with

the accelerator has been evaluated by qualified experts and that evaluation approved by an appropriate regulatory authority through a device evaluation.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Target" means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Tenth-value layer" or *"TVL"* means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Virtual source" means a point from which radiation appears to originate.

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641—42.3(136C) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines, except as authorized by a registration issued in accordance with rule 641—37.8(136C). Each therapeutic radiation machine shall be registered in accordance with the requirements of 641—subrule 37.8(2).

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.4(136C) General administrative requirements for facilities using therapeutic radiation machines.

42.4(1) Administrative controls.

a. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the department.

b. The registrant or the registrant's agent shall ensure that the requirements of this chapter are met in the operation of the therapeutic radiation machine(s).

42.4(2) A therapeutic radiation machine that does not meet the provisions of these regulations cannot be used for irradiation of patients unless authorized by the department.

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641—42.5(136C) Training for external beam radiation therapy authorized users.

42.5(1) The registrant for any therapeutic radiation machine subject to rules 641—42.15(136C) and 641—42.16(136C) shall require the authorized user to be a physician who:

a. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology";

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology and has completed all of the following:

(1) 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit;

(2) 500 hours of supervised work experience;

(3) A minimum of three years of supervised clinical experience.

42.5(2) To satisfy the requirement for instruction in paragraphs 42.5(1)*"a"* and *"b,"* the classroom and laboratory training shall include all of the following:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of ionization radiation; and

d. Radiation biology.

42.5(3) To satisfy the requirement for supervised work experience in subparagraph 42.5(1)*"b"*(2), training shall be under the supervision of an authorized user and shall include all of the following:

a. Reviewing the full calibration measurements and periodic quality assurance checks;

b. Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

c. Using administrative controls to prevent a reportable radiation incident as described in 641—subrule 37.13(3);

d. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console;

e. Checking and using radiation survey meters.

42.5(4) To satisfy the requirement for a period of supervised clinical experience, training shall include all of the following:

a. One year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association;

b. An additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress as well as consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation;

(4) Postadministration follow-up and review of case histories.

42.5(5) Notwithstanding the requirements of this rule, the registrant for any therapeutic radiation machine subject to rules 641—42.15(136C) and 641—42.16(136C) may also submit the training of the prospective authorized user physician for department review.

42.5(6) A physician cannot act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.6(136C) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to rules 641—42.15(136C) and 641—42.16(136C) shall require the radiation therapy physicist to:

42.6(1) Be Iowa approved as defined in this chapter.

a. Medical physicists who are Iowa approved for radiation therapy may perform only radiation therapy services in the area of calibration and compliance surveys of external beam radiation therapy units or additional radiation therapy services as deemed appropriate by the department;

b. Medical physicists wishing to perform services other than those outlined in rule 641—42.3(136C) must be registered with the department under the provisions of rule 641—37.8(136C) as a radiation machine service provider, whether as an individual, as part of a corporation, or as any other entity included in the definition of "person" under 641—Chapter 37.

c. A medical physicist cannot perform any services unless such services are specifically listed on the Iowa approval or radiation machine provider notice issued by the department.

42.6(2) Be certified by the American Board of Radiology in, at a minimum, one of the following:

a. Therapeutic radiological physics;

b. Roentgen-ray and gamma-ray physics;

c. X-ray and radium physics;

d. Radiological physics; or

e. Therapeutic medical physics.

42.6(3) Be certified by the American Board of Medical Physics in radiation oncology physics; or

42.6(4) Be certified by the Canadian College of Physicists in Medicine; or

42.6(5) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics and have completed one year of:

a. Full-time training in therapeutic radiological physics;

b. Full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in rule 641—42.14(136C) under the supervision of a radiation therapy physicist during the year of work experience.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.7(136C) Qualifications of operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and hold a current permit to practice in radiation therapy as a radiation therapist under the provisions of 641—Chapter 38.

42.7(1) The permit holder shall make the permit available at the individual's place of employment.

42.7(2) If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.8(136C) Written safety procedures and rules. Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

42.8(1) The operator shall be able to demonstrate familiarity with these rules.

42.8(2) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.9(136C) Exposure to the useful beam. Individuals cannot be exposed to the useful beam, except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing arts purposes.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.10(136C) Records of visiting authorized users. Notwithstanding the provisions of rule 641—42.5(136C), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under all of the following conditions:

42.10(1) The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

42.10(2) The visiting authorized user meets the requirements of rule 641—42.5(136C);

42.10(3) The registrant maintains copies of all records for five years from the date of the last visit.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.11(136C) Information and maintenance record and associated information. The registrant shall maintain all the following information in a separate file or package for each therapeutic radiation machine for inspection by the department:

42.11(1) Report of acceptance testing.

42.11(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by rule 641—37.12(136C), as well as the name(s) of person(s) who performed such activities.

42.11(3) Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services.

42.11(4) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

42.11(5) Records of training specified in rule 641—42.5(136C).

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.12(136C) Record retention. All records required by rule 641—42.5(136C) shall be retained until disposal is authorized by the department unless another retention period is specifically authorized.

42.12(1) All required records shall be retained in an active file from at least the time of generation until the next department inspection.

42.12(2) Any required record generated before the last department inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the department authorizes final disposal.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.13(136C) Written directives. Each registrant shall meet all of the following.

42.13(1) *Written directive.* A written directive must be dated and signed by an authorized user prior to the administration of radiation.

a. If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

b. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose or the next fractional dose.

d. The registrant shall retain a copy of the written directive for three years.

42.13(2) *Procedures for administration.* The registrant shall have written procedures that provide all of the following information:

a. Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

b. Each administration is in accordance with the written directive;

c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by completing all of the following:

(1) Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive;

(2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

d. Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken;

e. The registrant retains a copy of the procedures for administrations for the duration of the registration.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.14(136C) General technical requirements for facilities using therapeutic radiation machines.

42.14(1) *Protection surveys.*

a. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months.

b. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist.

c. The survey shall be performed with the therapeutic radiation machine in a "BEAM-ON" condition using the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation. The survey must verify all of the following:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 37.11(3);

(2) Radiation levels in unrestricted areas do not exceed the limits specified in 641—subrule 37.11(11). In addition to the requirements of subrule 42.14(1), a radiation protection survey shall also be performed prior to any subsequent medical use and at the following frequencies:

1. After making any change in the treatment room shielding;

2. After making any change in the location of the therapeutic radiation machine within the treatment room;

3. After relocating the therapeutic radiation machine;

4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

d. The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations.

e. The survey record shall also include all of the following:

(1) The date of the measurements;

(2) The reason the survey is required;

(3) The manufacturer's name, model number, and serial number of the therapeutic radiation machine;

(4) The instrument(s) used to measure radiation levels;

(5) A plan of the areas surrounding the treatment room that were surveyed;

(6) The measured dose rate at several points in each area, expressed in microsieverts or millirems per hour;

(7) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area;

(8) The signature of the individual responsible for conducting the survey.

f. If the results of the surveys required by subrule 42.14(1) indicate any radiation levels in excess of the respective limit specified in 641—subrule 37.11(3), the registrant shall lock the control in the "OFF" position and not use the unit, except under either of the following conditions:

(1) If operation is necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding;

(2) Until the registrant has received a specific exemption in writing from the department.

42.14(2) *Modification of radiation therapy unit or room before beginning a treatment program.*

a. Survey radiation levels. If the survey required by subrule 42.14(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—subrule 37.11(11) before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—subrule 37.11(11);

(2) Perform the survey required by 641—paragraph 37.11(12)*"a"* again; and

(3) Include in the report the results of the initial survey a description of the modifications made and the results of the second survey; or

(4) Request and receive written authorization from the department that authorizes radiation levels in unrestricted areas greater than those permitted by 641—subrule 37.11(11).

b. Dosimetry equipment. The registrant shall have a calibrated dosimetry system available for use.

(1) The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL).

(2) The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

c. Calibration. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

(1) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements.

1. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph 42.14(2)*"b."*

2. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration.

3. The quality assurance check system may be the same system used to meet the requirement in paragraph 42.14(2)*"b."*

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the following:

1. The date;

2. The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraph 42.14(2)*"b"*;

3. The correction factors that were determined;

4. The names of the individuals who performed the calibration, intercomparison, or comparison and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to rule 641—42.3(136C) shall furnish a copy of the records required in subrules 42.11(1) and 42.11(2) to the department within 30 days following completion of the action that initiated the record requirement.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.15(136C) Therapeutic radiation machines of less than 500 kV.

42.15(1) *Equipment requirements.*

a. Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate cannot exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(1) 5-50 kV systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly cannot exceed 100 mrad (one mGy) in any one hour.

(2) >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction cannot exceed one rad (one cGy) in any one hour.

1. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters.

2. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly cannot exceed 30 rad (30 cGy) per hour.

(3) For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in subrule 42.15(1) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility and made available for inspection by the department.

b. Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

c. Adjustable or removable beam-limiting devices. All adjustable or removable beam-limiting devices, diaphragms, cones, or blocks cannot transmit more than 5 percent of the useful beam for the most penetrating beam used. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

d. Filter system. The filter system shall be so designed to meet all of the following:

(1) Filters cannot be accidentally displaced at any possible tube orientation;

(2) For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

(3) The air kerma rate escaping from the filter slot cannot exceed one rad (one cGy) per hour at one meter under any operating conditions; and

(4) Each filter shall be marked as to its material of construction and its thickness.

e. Tube immobilization.

(1) The X-ray tube shall be mounted in a manner that it cannot accidentally turn or slide with respect to the housing aperture.

(2) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

f. Source marking. The tube housing assembly shall be marked in a manner that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

g. Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

h. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

(1) A timer that has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

(2) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(3) The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation;

(4) The timer shall permit accurate presetting and determination of exposure times as short as one second;

(5) The timer cannot permit an exposure if set at zero;

(6) The timer cannot activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag;

(7) Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

i. Control panel functions. The control panel, in addition to the displays required by other provisions in paragraph 42.15(2)*"i,"* shall have:

(1) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

(2) An indication of whether X-rays are being produced;

(3) Means for indicating X-ray tube potential and current;

(4) The means for terminating an exposure at any time;

(5) A locking device that will prevent unauthorized use of the therapeutic radiation machine; and

(6) For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

j. Multiple tubes. When a control panel may energize more than one X-ray tube:

(1) It shall be possible to activate only one X-ray tube at any time;

(2) There shall be an indication at the control panel identifying which X-ray tube is activated;

(3) There shall be an indication at the tube housing assembly when that tube is energized.

k. Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

l. Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly.

(1) In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel.

(2) An indication of shutter position shall appear at the control panel.

m. Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present to indicate that the dose rate is very high.

42.15(2) *Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV.* In addition to shielding adequate to meet requirements of rule 641—42.17(136C), the treatment room shall meet the following design requirements.

a. Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

b. Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation, and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine cannot be used for patient irradiation unless at least one viewing system is operational.

c. Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(1) All protective barriers shall be fixed, except for entrance doors or beam interceptors;

(2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it cannot be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel;

(4) When any door referred to in subparagraph 42.15(2)*"c"*(3) is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mrad) per hour.

d. Full calibration measurements. Full calibration of a therapeutic radiation machine subject to subrule 42.15(2) shall be performed by, or under the direct supervision of, a radiation therapy physicist.

e. Initial use. The first medical use following installation or reinstallation of the therapeutic radiation machine must be:

(1) At intervals not exceeding one year; and

(2) Before medical use under the following conditions:

1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled;

2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

f. Calibration. Notwithstanding the requirements of paragraph 42.15(2)*"d"*:

(1) Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and

(2) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in paragraph 42.15(2)*"c."*

(3) To satisfy the requirements of paragraph 42.15(2)*"d,"* full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(4) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include all of the following:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube;

3. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

4. The signature of the radiation therapy physicist responsible for performing the calibration.

g. Periodic quality assurance checks. Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to this rule, that are capable of operation at greater than or equal to 50 kV.

(1) To satisfy the requirement of paragraph 42.15(2)*"g,"* quality assurance checks shall meet all of the following requirements:

1. The quality assurance checks shall be performed by the registrant in accordance with written procedures established by the radiation therapy physicist;

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed.

3. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in subparagraph 42.15(2)*"f"*(1).

4. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subparagraph 42.15(2)*"f"*(1), shall be stated.

(2) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

1. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in subparagraph 42.15(2)*"f"*(1);

2. The registrant shall use the dosimetry system described in subparagraph 42.14(2)*"c"*(2) to make the quality assurance check required in paragraph 42.15(2)*"g"*;

3. The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

4. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to this rule are performed at intervals not to exceed one month;

5. Notwithstanding the requirements of numbered paragraphs 42.15(2)*"g"*(2)"3" and "4," the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required have been performed within the 30 days prior to administration.

(3) To satisfy the requirement of numbered paragraph 42.15(2)*"g"*(2)"4," safety quality assurance checks shall ensure proper operation of the following:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. The "BEAM-ON" and termination switches;

3. Beam condition indicator lights on the access door(s), on the control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(4) The registrant shall maintain a record of each quality assurance check for three years. The record shall include all of the following:

1. The date of the quality assurance check;

2. The manufacturer's name, model number, and serial number for the therapeutic radiation machine;

3. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine;

4. The signature of the individual who performed the periodic quality assurance check.

h. Operating procedures.

(1) Therapeutic radiation machines cannot be left unattended unless secured by means identified in paragraph 42.15(1)*"i"*;

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly cannot be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console;

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any

individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—subrule 37.11(11).

(6) The therapeutic radiation machine cannot be used for irradiation of patients unless the requirements of paragraph 42.15(2)*"d"* have been met.

i. Possession of survey instrument(s).

(1) Each facility location authorized to use a therapeutic radiation machine in accordance with this rule shall have at its disposal appropriately calibrated portable monitoring equipment.

(2) As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1,000 mrem (10 mSv) per hour.

(3) The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.16(136C) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

42.16(1) *Equipment requirements.*

a. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters that is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), cannot exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

b. Except for the area defined in paragraph 42.16(1)*"a"* the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window cannot exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance.

c. Measurements shall be averaged over an area not exceeding 100 square centimeters.

d. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 as amended to August 1, 2025.

e. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraph 42.16(1)*"a"* for the specified operating conditions. Records of leakage radiation measurements shall be maintained and made available for inspection by the department.

42.16(2) *Leakage radiation through beam-limiting devices.*

a. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting device(s) cannot exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten-centimeter by ten-centimeter radiation field;

b. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including but not limited to photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance cannot exceed:

(1) A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(2) A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

42.16(3) *Measurement of leakage radiation.*

a. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material.

(1) In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose.

(2) Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters.

b. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made:

(1) With the electron beam directed into the air and using a radiation detector that has an area up to but not exceeding one square centimeter and that is suitably protected against radiation that has been scattered from material beyond the radiation detector.

(2) Using one centimeter of water equivalent buildup material.

c. Filters/wedges. Each wedge filter that is removable from the system shall be clearly marked with an identification number.

(1) For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray).

(2) If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.

(3) If the absorbed dose rate information required by paragraph 42.16(3)*"h"* relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such filter or foil shall be removable only by the use of tools.

(4) For equipment manufactured after July 9, 1997, that utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

1. Irradiation cannot be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

2. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

3. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and interchangeable beam-scattering foil(s) in use;

4. An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

d. Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 as amended to August 1, 2025.

e. Beam monitors. All therapeutic radiation machines subject to this rule shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(1) Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

(2) Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system.

(3) The detector and the system into which that detector is incorporated shall meet the following requirements:

1. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

2. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

3. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

(4) For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that:

1. The malfunctioning of one system cannot affect the correct functioning of the other system(s); and

2. The failure of any element common to both systems that could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

(5) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

1. Maintain a reading until intentionally reset;

2. Have only one scale and no electrical or mechanical scale multiplying factors;

3. Utilize a design such that increasing dose is displayed by increasing numbers;

4. In the event of power failure, the beam monitoring information at the time of failure required in this paragraph is retrievable in at least one system for a 20-minute period of time.

f. Beam symmetry.

(1) Bent-beam linear accelerators with beam-flattening filter(s) subject to subrule 42.16(1) shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in paragraph 42.16(3)*"f"* shall be able to detect field asymmetry greater than 10 percent and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

g. Selection and display of dose monitor units. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

(1) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(2) For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

(3) Irradiation cannot be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

h. Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in paragraph 42.16(3)*"e"* may form part of this system.) In addition:

(1) The dose monitor unit rate shall be displayed at the treatment control panel;

(2) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(3) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (four Gy); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in paragraph 42.16(3)*"g"* for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the department.

i. Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

(1) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above

the preselected number of dose monitor units set at the control panel have been detected by the secondary dose monitoring system;

(2) For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

j. Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

k. Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel.

(1) Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions.

(2) If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

l. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

(1) A timer shall be provided that has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

(2) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(3) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

m. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation cannot be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

(2) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

(4) An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

(6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

n. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(1) Irradiation cannot be possible until a selection of energy has been made at the treatment control panel;

(2) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

(3) Irradiation cannot be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(4) For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 as amended to August 1, 2025.

o. Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(1) Irradiation cannot be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(2) The mode of operation shall be displayed at the treatment control panel;

(3) An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(5) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

1. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value.

2. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected.

3. An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy.

4. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counterclockwise moving beam radiation therapy.

5. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by paragraph 42.16(3)*"i"*;

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

A. Occurs during stationary beam radiation therapy; or

B. Does not start or stop during moving beam radiation therapy unless such stoppage is a preplanned function.

p. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of rule 641—42.17(136C), the following design requirements are made.

(1) All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) In addition to other requirements specified in 641—paragraph 40.4(19)*"c,"* the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and whether activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced;

4. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.

q. Viewing systems. Windows, mirrors, closed-circuit television, or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine cannot be used for patient irradiation unless at least one viewing system is operational.

r. Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine cannot be used for irradiation of patients unless continuous two-way aural communication is possible.

s. Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors that will indicate when the useful beam is "ON" and when it is "OFF".

t. Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it cannot be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

u. Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraph 37.11(11)*"a,"* interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

v. Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power, including radiation and mechanical motion.

(1) This switch is in addition to the termination switch required by paragraph 42.16(3)*"j."*

(2) All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

w. Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

x. Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above ten MV prior to machining, removing, or working on therapeutic radiation machine components that may have become activated due to photoneutron production.

y. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with this rule shall have at its disposal appropriately calibrated portable monitoring equipment.

(1) As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range one mrem (ten μSv) per hour to 1,000 mrem (ten mSv) per hour.

(2) The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

z. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by subparagraph 42.16(3)*"bb"*(1) and protection surveys required by subrule 42.16(1).
2. Supervision and review of dosimetry.
3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use.
4. Quality assurance, including quality assurance check review required by paragraph 42.15(2)*"g."*
5. Consultation with the authorized user in treatment planning as needed.
6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by paragraph 42.15(2)*"e"* shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

aa. Operating procedures. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

(1) Therapeutic radiation machines cannot be made available for medical use unless the requirements of this chapter have been met;

(2) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(3) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(4) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

bb. Acceptance testing, commissioning, and full calibration measurements. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to rule this rule shall be performed by, or under the direct supervision of, a radiation therapy physicist.

(1) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45 as amended to August 1, 2025, and the manufacturer's contractual specifications and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(2) Full calibration shall include measurement of all parameters listed in Appendix A of 641—Chapter 41 and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" as amended to August 1, 2025, prepared by Radiation Therapy Task Group 45. Although it cannot be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this department.

(3) The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits at the following frequencies:

1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and

2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement, or modification does not affect all modes or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in paragraph 42.16(3)*"z."*

(4) The registrant shall use the dosimetry system described in paragraph 42.14(2)*"b"* to measure the radiation output for one set of exposure conditions.

(5) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include all of the following:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for the therapeutic radiation machine;

3. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine;

4. The signature of the radiation therapy physicist responsible for performing the calibration.

cc. Periodic quality assurance checks. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to these rules at intervals as specified in Appendix A of this chapter.

(1) To satisfy the requirement of paragraph 42.14(2)*"g,"* quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix A. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months.

(2) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system to make the periodic quality assurance checks required in paragraph 42.14(2)*"g."*

(3) The registrant shall perform periodic quality assurance checks in accordance with procedures established by the radiation therapy physicist.

(4) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine cannot be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days;

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(5) Therapeutic radiation machines subject to this rule shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week or at longer intervals as recommended by the manufacturer.

(6) Safety quality assurance checks shall ensure proper operation of all of the following:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the "BEAM-ON," interrupt and termination switches;

3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

4. Viewing systems;

5. Aural systems;

6. Electrically operated treatment room door(s) from inside and outside the treatment room;

7. At least one emergency power cutoff switch.

A. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis.

B. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(7) The registrant shall promptly repair any system that is not operating properly.

(8) The registrant shall maintain a record of each quality assurance check for three years. The record shall include all of the following:

1. The date of the quality assurance check;

2. The manufacturer's name, model number, and serial number for the therapeutic radiation machine;

3. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine;

4. The signature of the individual who performed the periodic quality assurance check.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.17(136C) Shielding and safety design requirements.

42.17(1) Each therapeutic radiation machine subject to shall be provided with such primary or secondary barriers as are necessary to ensure compliance with rule 641—37.11(136C).

42.17(2) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for department approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix B of this chapter.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.18(136C) Calibration of survey instruments.

42.18(1) The registrant shall ensure that the survey instruments used to show compliance with rule 641—42.16(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

42.18(2) To satisfy the requirements of this rule, the registrant shall:

a. Calibrate all required scale readings up to 1,000 mrem (ten mSv) per hour with an appropriate radiation source that is traceable to the NIST;

b. Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full scale;

c. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent;

d. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

42.18(3) The registrant shall retain a record of each calibration required in this rule for three years. The record shall include the following:

a. A description of the calibration procedure;

b. A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

42.18(4) The registrant may obtain the services of individuals licensed by this department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in this rule shall be maintained by the registrant.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.19(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use.

1. This rule establishes procedures for the registration or licensing and the use of particle accelerators.

2. Unless specifically required otherwise, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 through 40.

42.19(1) *Registration or license requirements.* No person shall receive, possess, use, transfer, own, or acquire a particle accelerator, except as authorized in a registration or license issued by the department and unless the following requirements are met:

a. Each accelerator shall be registered in accordance with the requirements of 641—subrule 37.8(2).

b. Accelerator facilities whose operations result in nuclear transformations that produce, or are likely to produce, radioactive material more than the exempt quantities and concentrations listed in Appendices D and E of 641—Chapter 39 are authorized by the issuance of a radioactive material license. Accelerator facilities that produce or are likely to produce radioactive material less than the exempt quantities and concentrations shall be authorized by registration.

c. For accelerator facilities required to be licensed, those operations that would require personnel monitoring due to the presence of radioactive material shall be performed only by a specific licensee. Such operations would normally include installation, testing and maintenance, and routine operations.

42.19(2) *General requirements for the issuance of a registration or license for particle accelerators.* Along with the requirements of this chapter, an application for use of a particle accelerator will be approved only if the department determines all of the following:

a. The applicant is qualified to use the accelerator in question for the purpose requested and in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the registration or license will not be detrimental to the health and safety of the public;

d. The applicant satisfies any applicable requirements set forth in this chapter;

e. The applicant has appointed a radiation safety officer responsible for the day-to-day operation of the radiation safety program;

f. The applicant and the applicant's staff have experience in the use of particle accelerators and training sufficient for application to its intended uses;

g. The applicant has an adequate training program for operators of particle accelerators.

42.19(3) *Personnel monitoring.* In addition to the requirements of 641—subrule 40.4(13), personnel monitoring shall be provided to and used by all individuals entering any area for which interlocks are

required unless a survey of the area has determined that radiation levels are below that of a high radiation area and at least one of the following conditions is met:

a. Power to an accelerator cannot be activated; or

b. An accelerated beam cannot be directed to the area.

42.19(4) *Operations.*

a. No registrant shall permit any individual to act as an operator of a particle accelerator until all of the following conditions have been met:

(1) The individual has been instructed in radiation safety and has demonstrated an understanding of that instruction;

(2) The individual has received copies of, and instruction in, this rule, the applicable requirements of the pertinent registration, and the registrant's operating and emergency procedures and has demonstrated understanding of that instruction;

(3) The individual has demonstrated competence to use the particle accelerator, related equipment, and survey instruments that will be employed.

b. The radiation safety officer or radiation safety committee, if applicable, shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

c. Along with the audit required in 641—paragraph 37.11(2)*"c,"* each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed six months.

(1) If an operator has not participated in an accelerator operation for more than six months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation.

(2) Records of the audits shall be maintained by the registrant and made available for inspection by the department for three years from the date of the audit.

d. Operators of particle accelerators used for industrial radiography shall meet the requirements of subrule 42.19(2).

42.19(5) *Shielding and safety design requirements.* A department-qualified expert shall be consulted in the design of a particle accelerator installation and shall perform a radiation survey when the accelerator is first capable of producing radiation.

a. Each particle accelerator installation shall be provided with the primary and secondary barriers necessary to ensure compliance with 641—subrules 37.11(3) and 37.11(11).

b. In addition to the requirements of this chapter, shielded facilities or self-shielded particle accelerators shall meet all of the following requirements:

(1) Authorization, through issuance of a construction permit, shall be granted following review of the initial application, including the shielding design, physical plant and site specifications, and the applicant's proposed equipment, uses, and workloads;

(2) For a shielded facility, the applicant shall submit an evaluation of the shielding design completed by a qualified expert. For a self-shielded particle accelerator, submission of an evaluation of a shielding design is not required if an evaluation has been performed by an appropriate regulatory authority. In such cases, the applicant may reference that evaluation. A copy of any shielding design evaluation shall be maintained by the applicant and made available to the department upon request;

(3) Authorization for installation and testing of an accelerator shall be given only after a determination of adequacy of testing protocols, testing safety procedures, staff training, and radiation detection instrumentation has been made;

(4) Operational use of an accelerator shall be authorized only after the department determines that all criteria specified in subrule 42.19(2) have been met.

42.19(6) *Particle accelerator controls and interlock systems.* Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified, easily discernible, and located outside the high radiation area.

a. Each entrance into a target area or other high radiation area shall be provided with two safety interlocks that shut down the machine when the barrier is breached.

b. Each safety interlock shall be on a circuit that allows it to operate independently of all other safety interlocks.

c. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

d. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, subsequently, at the main control console.

e. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

42.19(7) *Warning devices.* Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate only when radiation is being produced.

a. Each high radiation area shall have an audible warning device that shall be activated for 15 seconds prior to the possible creation of high radiation in the area. Such warning device shall be clearly discernible in all high radiation areas.

b. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 641—subrule 37.11(20).

42.19(8) *Operating and emergency procedures.*

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam, except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Records of such tests shall be maintained at the accelerator facility and made available for inspection by the department for three years.

d. All incidents in which the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or the radiation safety committee, if applicable. Documentation shall be maintained and made available for inspection by the department for three years.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety officer and the radiation safety committee, if applicable;

(2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

f. The registrant's operating and emergency procedures shall include all of the following:

(1) Operation and safety instructions on the accelerator(s) to be used;

(2) Methods for controlling access to restricted areas;

(3) Methods and occasions for locking and securing sources of radiation;

(4) Use of personnel monitoring equipment;

(5) The procedure for notifying proper personnel in the event of an accident;

(6) Maintenance of records;

(7) Inspections and maintenance of the accelerator;

(8) Steps to be taken in the case of an emergency.

g. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

42.19(9) *Radiation monitoring requirements.* A radiation protection survey shall be performed and documented by a qualified expert when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

a. Accelerator facilities shall survey with a radiation detection instrument at intervals not to exceed every 12 months. Records of this survey shall be maintained and made available for inspection by the department for three years.

b. Accelerator facilities registered or licensed pursuant to this chapter shall survey for removable contamination at intervals not to exceed six months.

c. Each time removable shields on self-shielded particle accelerators are opened, a visual survey of the shielding must be performed to observe physical damage.

(1) In addition, when these shields are returned to the closed position, a physical radiation survey shall be conducted upon initial reactivating of the accelerator.

(2) Records of this survey shall be maintained and made available for inspection by the department review for three years.

d. Accelerator facilities registered or licensed pursuant to this chapter shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation areas.

e. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

f. Upon installation, all area monitoring equipment shall be tested to ensure proper operation under operating conditions of the particle accelerator. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

g. Whenever applicable, accelerator facilities registered or licensed pursuant to this chapter shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

h. All surveys shall be made in accordance with the written procedures established by the radiation safety officer or a qualified expert.

i. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for and made available for inspection by the department.

42.19(10) *Radiation safety officer (RSO).*

a. Each registrant shall appoint a radiation safety officer who meets the following requirements:

(1) Possesses a high school diploma or a certificate of high school equivalency based on the GED test;

(2) Documents at least two years of radiation protection experience.

b. The specific duties of the RSO include but are not limited to the following:

(1) Establishing, reviewing, and overseeing operating, emergency, and ALARA procedures to ensure that the procedures are current and are in compliance with these rules;

(2) Overseeing and approving all phases of the training program for accelerator operators to ensure appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by rules 641—37.11(136C) and 641—37.14(136C);

(5) Ensuring that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

(6) Investigating and reporting to the department each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules; additionally, investigating and reporting each theft or loss of source(s) of radiation to determine the cause of such events and to take steps to prevent its recurrence;

(7) Ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures, including adequate training and experience as required by this chapter.

(8) Assuming control and having the authority to institute corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;

(9) Maintaining records as required by this chapter;

(10) Ensuring the proper storing, labeling, and use of the accelerator;

(11) Ensuring that proper inspection and maintenance programs are performed as required by this chapter;

(12) Ensuring that personnel are complying with these rules as well as the operating and emergency procedures.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

641—42.20(136C) Radiation safety requirements for analytical X-ray equipment. This rule provides special requirements for analytical X-ray equipment. The requirements of these rules are in addition to, and not in substitution for, 641—Chapters 37, 38, 39, and 40.

1. No person shall receive, possess, use, transfer, own, or acquire an analytical X-ray device except as authorized by a registration issued in accordance with rule 641—37.8(136C).

2. Each analytical X-ray device shall be registered in accordance with the requirements of 641—subrule 37.8(2).

42.20(1) *Equipment requirements.*

a. Safety device. A device that prevents the entry of any portion of an individual's body into the primary X-ray beam path or that causes the beam to be shut off upon entry into its path are required on all open-beam configurations. A registrant or licensee may apply to the department for an exemption from the requirement of a safety device. Such application shall include all of the following:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used;

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure that operators and others in the area will be informed of the absence of safety devices.

b. Warning devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of the following:

1. X-ray tube "on-off" status located near the radiation source housing if the primary beam is controlled in this manner; or

2. Shutter "open-closed" status located near each port on the radiation source housing if the primary beam is controlled in this manner.

(2) An easily visible warning light labeled with the words "X-RAY ON" or words having a similar intent shall be located:

1. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

2. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after July 1, 2026, warning devices shall have fail-safe characteristics.

c. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner that will prevent casual opening.

d. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign(s) bearing the radiation symbol and the words:

(1) "CAUTION—HIGH INTENSITY X-RAY BEAM" or words having a similar intent on the X-ray source housing; and

(2) "CAUTION—RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

(3) "CAUTION—RADIOACTIVE MATERIAL" or words having a similar intent on the source housing if the radiation source is a radionuclide.

e. Shutters. On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

f. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

(1) Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled;

(2) Each radioactive source housing or port cover, or each X-ray tube housing, shall be constructed so that with all shutters closed the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

g. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet that limits leakage radiation measured at a distance of five centimeters from its surface so that it is not capable of producing a dose in excess of 0.25 millirem (2.5 mSv) in one hour.

42.20(2) *Area requirements.*

a. Radiation levels. The local components of an analytical X-ray system shall be located and arranged, and shall include sufficient shielding or access control, so that no radiation levels exist in any area surrounding the local component group that could result in a dose to an individual present in excess of acceptable dose limits. For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

b. Surveys. Radiation surveys of all analytical X-ray systems shall be performed at all of the following frequencies:

(1) Upon installation of the equipment and at least once every 12 months thereafter;

(2) Following any change in the initial arrangement, number, or type of local components in the system;

(3) Following any maintenance requiring the disassembly or removal of a local component in the system;

(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed;

(5) Any time a visual inspection of the local components in the system reveals an abnormal condition;

(6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the allowable limits.

c. Compliance. Radiation survey measurements may not be required if a registrant or licensee can demonstrate compliance to the satisfaction of the department.

d. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign(s) bearing the radiation symbol and the words “CAUTION—X-RAY EQUIPMENT” or words having a similar intent.

42.20(3) *Operating requirements.*

a. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless that individual has obtained written approval of the radiation safety officer.

b. Bypassing. No individual shall bypass a safety device or interlock unless that individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily displayed sign bearing the words “SAFETY DEVICE NOT WORKING” or words having a similar intent shall be placed on the radiation source housing.

c. Repair or modification of X-ray tube systems. No operation involving removal of covers, shielding materials, or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

d. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

42.20(4) *Personnel requirements.*

a. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in, and demonstrated competence as to, all of the following:

(1) Identification of radiation hazards associated with the use of the equipment;

(2) Significance of the various radiation warnings, safety devices, and interlocks incorporated into the equipment or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Proper operating procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure;

(5) Proper procedures for reporting an actual or suspected exposure.

b. Personnel monitoring.

(1) Finger or wrist dosimetry devices shall be provided to, and used by, the following:

1. Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

2. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 641—subrule 37.2(1) unless evaluated by a qualified expert.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]

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

CHAPTER 42—APPENDIX A

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	Safety	
	Door interlocks	functional
	Audiovisual monitors	functional
Monthly	Dosimetry	
	X-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and electron symmetry	3%
	Safety Interlocks	
	Wedge, electron cone interlocks	functional
	Mechanical	
	Light/radiation field coincidence	2mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 degree
	Wedge position	2mm (or 2% change in transmission factor)
	Tray position	2mm
	Applicator position	2mm
	Field size indicators	2mm
	Cross-hair centering	2mm diameter
	Treatment couch position indicators	2mm/1deg
	Latching of wedges, blocking tray	functional
	Jaw symmetry[e]	2mm
	Field Light intensity	functional
Annual	Dosimetry	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%

Frequency	Procedure	Tolerance[a]
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturer's test procedures	functional
	Mechanical	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values $\pm$ the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[b] All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

[c] A constancy check with a field instrument using temperature pressure corrections.

[d] Whichever is greater. Should also be checked after change of light field source.

[e] Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

[f] Most wedges' transmission factors are field size and depth dependent.

CHAPTER 42—APPENDIX B

INFORMATION ON RADIATION REQUIRED FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and department registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans that contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—subrule 37.11(3).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans that contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including but not limited to design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and “allowed” radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans that contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including but not limited to neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation that shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerator" (1984).

D. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).

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◊ Two or more ARCs

1 Effective date of Ch 42 delayed 70 days by the Administrative Rules Review Committee. [IAC 6/23/82]
Effective date of Ch 42 delayed by the Administrative Rules Review Committee 45 days after convening of the next General Assembly pursuant to §17A.8(9). [IAB 9/29/82]

2 Subparagraph 42.1(4)*"b"*(4) is rescinded two years subsequent to the effective date of rule 470—42.1(136C).

CHAPTER 43
RADON TESTING AND ANALYSIS REQUIREMENTS

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—43.1(136B) General provisions. This chapter establishes requirements for the certification of radon measurement specialists and radon measurement laboratories. All persons performing measurements for radon or radon progeny in buildings, other than those that they own, and who provide the results of these measurements to the owner or occupant of these structures, must be certified in accordance with the provisions of this chapter.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.2(136B) Definitions. The definitions provided in 641—Chapter 44 may also apply to the provisions of this chapter. Additionally, the following definitions set forth below are specific to this chapter.

"Act" means the Iowa Radon Testing and Abatement Act (Iowa Code chapter 136B).

"ANSI" means the American National Standards Institute.

"Building" means a structure enclosed with exterior walls or fire walls, built, erected and framed of component structural parts, and designed for the housing, shelter, enclosure and support of individuals.

"Certified person" means a certified radon measurement specialist or certified radon measurement laboratory as defined by this chapter.

"Certified radon measurement laboratory" or *"certified laboratory"* means a commercial laboratory that may analyze samples or test for radon decay products and meets the provisions for certification in this chapter.

"Certified radon measurement specialist" or *"certified specialist"* means an individual who performs radon or radon progeny measurements in buildings and provides professional or expert advice on radon and radon progeny measurements, radon entry routes, and other radon-related activities; is knowledgeable in the health risk associated from exposure to radon; and who meets the provisions for certification in this chapter. This includes the initial placement and final retrieval of all measurement devices.

"Compensation" means any form of monetary gain that in any way directly or indirectly results from a radon or radon progeny measurement being conducted.

"EPA" means the United States Environmental Protection Agency.

"IEA" means the Indoor Environments Association formerly known as the American Association of Radon Scientists and Technologists (AARST).

"Laboratory" means any person performing analysis, not at a testing site, on a passive device to measure radon or radon progeny (charcoal canister, alpha-track, electret, etc.).

"NRPP" means the National Radon Proficiency Program facilitated by the Indoor Environments Association (IEA) formerly known as the AARST.

"NRSB" means the National Radon Safety Board.

"Online licensing portal" means the electronic system designated by the department through which applicants and certification holders shall submit applications, renewals, supporting documentation, and other required information for licensure, certification, credentialing, or registration.

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

"Picocuries per liter" means a quantity of radioactive material per liter of air that will produce 2.2 disintegrations per minute of radiation. It may be used as a measure of the concentration of radon gas in air. One curie is equivalent to one trillion picocuries.

"pCi/L" means a measurement of radon in picocuries per liter.

"Radon" means the radioactive noble gas radon-222.

"Radon progeny" means the short-lived radionuclides formed as a result of the decay of radon-222, including polonium-218, lead-214, bismuth-214, and polonium-214.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.3(136B) General regulatory requirements.

43.3(1) Except as provided in this chapter, no person may test for the presence of radon or radon progeny in the state of Iowa unless the person has been certified by the department. This requirement also applies to persons whose place of business is located in Iowa, or in a state other than Iowa, and who offer radon testing to residents of Iowa either directly, through the mail, or by other means.

43.3(2) Individual qualifications for radon measurement specialist. No individual may be certified as a radon measurement specialist unless all of the following conditions are met:

a. Be at least 18 years of age at the time of application;

b. Successfully complete a department-approved training course on radon/radon progeny measurements within the two years prior to application. An approved training course is a course that meets and maintains approval by the NRPP or the NRSB. This includes the NRPP Radon Measurement Professional or NRSB Radon Measurement Specialist course;

c. Achieve or exceed the minimum passing score on the national measurement professional or specialist examination provided by the NRPP or the NRSB within the two years prior to application;

d. If the requirement to meet the conditions in this chapter within the two years prior to application above cannot be met, the person may demonstrate current radon licensure, certification, or credentialing through another jurisdiction or licensing body deemed acceptable by the department;

e. Use detection devices approved by the NRPP, the NRSB, or another department-approved national radon proficiency program to measure radon. Passive detection devices must be obtained from an Iowa-certified radon measurement laboratory.

43.3(3) Requirements for continued certification. Requirements for continued certification include the following:

a. A certified person shall allow the department, its agents, employees, and contractors, upon presentation of appropriate credentials, to access the person's facilities, offices, records, and equipment without undue delay for purposes of inspection and examination. The certified person shall also allow the department, its agents, employees, and contractors to accompany the person during the performance of any radon measurement activities, for the purpose of inspecting such activities, subject to the consent of the property owner or resident on whose property the activities are being performed.

b. The certified person shall remain in compliance with the Act and this chapter.

c. The certified person shall comply with all EPA, ANSI/AARST and department-approved radon measurement and quality assurance/quality control (QA/QC) guidelines, protocols, and standards and shall conduct measurements following the standard applicable to the building being tested. The standards include the following:

(1) ANSI/AARST MS-QA-2023, *Radon Measurement Systems Quality Assurance*, as amended to August 1, 2025.

(2) ANSI/AARST MAH-2023, *Protocol for Conducting Measurements of Radon and Radon Decay Products in Homes*, as amended to August 1, 2025.

(3) ANSI/AARST MA-MFLB-2023, *Protocol for Conducting Measurements of Radon and Radon Decay Products in Multifamily, School, Commercial and Mixed-Use Buildings*, as amended to August 1, 2025.

NOTE: MA-MFLB consolidates ANSI/AARST MAMF (rev. 1/21) and ANSI/AARST MALB (rev. 1/21) into a single publication.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.4(136B) Application for certification. An application for certification or renewal of certification as a radon measurement specialist or a radon measurement laboratory shall be completed through the online licensing portal and shall contain complete and accurate information. The applicant must report any changes to the initial or renewal certification application within 14 days.

43.4(1) *Radon measurement specialist.* A person applying for a radon measurement specialist certification shall include:

a. A certificate of completion of the initial training course. If the course was completed more than two years prior to the date of the application, the person shall provide documentation that the person has

completed an average of at least four hours of approved continuing education (CE) training per year since completing the course.

b. Official documentation of the test score obtained on the NRPP, NRSB, or other department-approved radon measurement examination taken within two years prior to application, showing a minimum passing score.

c. As an alternative to paragraphs 43.4(1)*"a"* and *"b,"* applicants may provide documentation of current licensure, certification, or credentialing through another jurisdiction or licensing body acceptable to the department.

d. A QA/QC plan, or QAP, for all measurement devices and equipment to be used to perform radon measurements.

(1) The plan shall include the requirements as outlined in the ANSI/AARST standard, *Radon Measurement Systems Quality Assurance* (MS-QA), as amended to August 1, 2025, and be acceptable to the department.

(2) If passive devices are used, the name(s), address(es), and Iowa laboratory certification number of the Iowa-certified radon measurement laboratory must be included.

e. A list of any disciplinary actions taken against the applicant's license, credential, certification, registration in any profession in Iowa, another state or jurisdiction and a copy of the disciplinary action(s), including charges and disposition.

f. An example of the confidentiality waiver that the applicant would provide to the customer when requested to release test results to persons other than the owner of the building being tested, as outlined in this chapter.

g. The fee specified in this chapter.

43.4(2) *Radon measurement laboratory.* A person applying for a radon measurement laboratory certification must include:

a. Proof of approval or accreditation as a radon measurement laboratory through the NRPP or NRSB.

b. A quality assurance plan and quality control procedures for all measurements and equipment. The content of the QAP plan will follow the requirements of the ANSI/AARST MS-QA and any requirements of NRPP or NRSB.

c. The fee specified in this chapter.

43.4(3) *Supplementary statements.* The department may require the applicant to submit supplementary statements containing additional information to enable the department to determine whether an application should be approved or denied, or whether a previously issued certification should be amended, suspended, or revoked. Each application or supplementary statement shall be submitted by either the applicant personally, or a person authorized in writing by the applicant to do so on the applicant's behalf.

43.4(4) *Expiration of notice of certification.* Certifications will expire annually.

a. Radon measurement activities subject to this chapter cannot be conducted after the expiration of the certification unless a renewal application has been submitted to the department, is determined to be complete, and is approved by the department.

b. If the application is rejected, the applicant cannot conduct radon testing or measurements in the state of Iowa for compensation or under any financial arrangement.

43.4(5) *Renewal application of annual certification.* A person applying for a renewal of an annual certification shall:

a. Submit the appropriate application through the online licensing portal.

b. Have all radon testing activity and data reporting, as required by the department, up to date to within three months of the date of expiration.

c. Submit copies of CE completion certificates to the department biennially, based on the date of initial certification.

d. Pay the fee specified in this chapter.

(1) Any fees not paid through the online licensing portal must be in the form of a check or money order, made payable to the Iowa Department of Health and Human Services.

(2) The applicant must include an indication of the purpose of the fee (i.e., radon measurement certification) and certification number that the fee is to be applied to on the check or money order.

43.4(6) *Radon measurement laboratory renewal.* Any person wishing to renew a radon measurement laboratory certification must:

a. Submit the appropriate application through the online licensing portal.

b. Have all radon testing activity and data reporting, as required by the department, up to date to within three months of the date of expiration.

c. Submit proof of current approval or accreditation as a radon measurement laboratory through the NRPP or NRSB.

d. Pay the fee specified in this chapter.

43.4(7) *Reinstatement of an expired certification.* Reinstatement applications shall be submitted through the online licensing portal when a registration has not been renewed within 30 days following the expiration date. Any person wishing to reinstate an expired radon measurement certification must:

a. Submit the required application and CE documentation that was due at time of expiration. If it has been more than two years since expiration, eight hours of CE must be completed with four of those hours being an approved measurement standards review course; and

b. Pay the applicable certification and reinstatement fees.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.5(136B) Radon measurement certification fees. Any person wishing to become certified as a radon measurement specialist or as a radon measurement laboratory shall be required to pay nonrefundable fees in amounts sufficient to defray the cost of administering this chapter as outlined in the fee schedule below.

43.5(1) *Initial application fee.* Each person applying for certification under the provisions of this chapter shall pay a nonrefundable $25 application fee.

43.5(2) *Annual certification fee.*

a. Each person applying for initial certification or applying for renewal of an annual certification as a radon measurement specialist must pay a nonrefundable annual fee of $250.

b. Each person applying for initial certification or applying for renewal of an annual certification as a radon measurement laboratory must pay a nonrefundable annual fee of $500.

43.5(3) *Returned check and reinstatement fee.* Persons who fail to pay required fees to the department are subject to the following penalty(ies):

a. $40 for each payment received by the department in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the department.

b. $100 reinstatement fee when a certification has not been renewed within 30 days following the expiration date. This fee is added to the unpaid annual certification fee.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.6(136B) Enforcement actions. The department may deny, suspend, revoke, or modify the certification of a person; place a person on probation; impose a civil penalty; or refer the case to the office of the county attorney for possible criminal penalties pursuant to Iowa Code chapter 136B, or any combination thereof, when it finds that a certified person or a person who is not certified has committed any of the following actions:

43.6(1) Failure to comply with applicable state, federal or local statutes and regulations. This includes any action that might place a person with certification under this chapter in noncompliance with Iowa statutes and the requirements of this chapter;

43.6(2) Failure to submit required information or notifications in a timely manner;

43.6(3) Failure to maintain the required records;

43.6(4) Falsifying approval records, qualifications, or other information or documentation related to certification approval;

43.6(5) Failure to comply with the training standards and requirements in this chapter;

43.6(6) Submitting in the application for certification or renewal of certification false or misleading statements that the department relied upon in approving the application;

43.6(7) Knowingly making misleading, deceptive, untrue, or fraudulent representations involving radon, or engaging in unethical conduct or practices that are harmful or detrimental to the public. Proof of actual injury need not be established;

43.6(8) Using untruthful or improbable statements in advertisements. Use of these statements includes but is not limited to the presentation of information to the public by training programs that is false, deceptive, or misleading, or that is promoted through fraud or misrepresentation;

43.6(9) Falsifying reports and records required by this chapter;

43.6(10) Accepting any fee by fraud or misrepresentation;

43.6(11) Revocation, suspension, or other disciplinary action taken by a certification or licensing authority of this state, another state, territory, or country; or failure by the firm or individual to report such action in writing within 30 days of the final action by such certification or licensing authority. A stay by an appellate court cannot negate this requirement; however, if such disciplinary action is overturned or reversed by a court of last resort, the report shall be expunged from the records of the board;

43.6(12) Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order;

43.6(13) Representation by a firm or individual that the firm or individual is certified when the certification has been suspended or revoked or has not been renewed;

43.6(14) Failure to respond within 30 days of receipt of communication from the department that was sent by registered or certified mail;

43.6(15) Engaging in any conduct that subverts or attempts to subvert a department investigation;

43.6(16) Failure to comply with a subpoena issued by the department or failing to cooperate with a department investigation;

43.6(17) Failure to pay costs assessed in any disciplinary action;

43.6(18) Any condition revealed by the application, supplementary statement, report, record, inspection, or other evidence that would warrant the department's refusal to grant a certification on an original application;

43.6(19) Failure to maintain approval or accreditation as a radon measurement laboratory with the NRPP or NRSB;

43.6(20) Failure to submit radon test data as required in this chapter;

43.6(21) Violating a statute of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, including but not limited to a crime involving dishonesty, fraud, theft, embezzlement, controlled substances, substance abuse, assault, sexual abuse, sexual misconduct, or homicide. A copy of the record of conviction or plea of guilty is conclusive evidence of the violation.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.7(136B) Records and reporting requirements.

43.7(1) A certified person must submit to the department within 30 days after any radon or radon progeny testing, or at the request of the department prior to testing, all of the following:

a. The address or location of the building;

b. The name and telephone number of the owner(s) of the building where the radon testing will be conducted;

c. The results of any tests performed.

43.7(2) The results for each test conducted shall include, at a minimum:

a. The method used for radon or radon decay product testing, media tested, and conditions under which the testing was or will be performed.

b. The level or floor of building where the test(s) was or will be conducted.

c. The results of the test(s) in picocuries/liter (pCi/l) of radon gas or WL of radon decay products.

d. The date on which the test(s) was or will be conducted.

e. The purpose of the test(s).

43.7(3) Requirements of certification. A certified person shall:

a. Cooperate with the department when conducting field evaluations.

b. Notify the department within 14 days of any changes in testing results or procedures.

c. Not disclose to any other person, other than the department, the results of a test, the address, or the name of the owner of a nonpublic building that the person tested for the presence of radon gas or radon progeny, unless any of the following conditions are met:

(1) The owner of the building waives, in writing, this right of confidentiality.

(2) The person certified or credentialed pursuant to Iowa Code section 136B.1 may disclose the results of a test performed by the person for the presence of radon or radon progeny to a potential buyer of a nonpublic building when an offer to purchase has been presented by the buyer and if the potential buyer paid for the testing. Any test results disclosed shall be results of a test performed within the five years prior to the date of the disclosure.

43.7(4) Record retention. Records of radon or radon progeny testing must be maintained for a minimum of five years after the radon test is completed.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.8(136B) Continuing education.

43.8(1) All certified measurement specialists must complete at least eight hours of department-approved CE biennially on either radon measurement, mitigation or a combination of the two.

43.8(2) Persons possessing both an Iowa Measurement Specialist certification and Mitigation Specialist credential must complete 12 hours of CE biennially on either radon measurement, mitigation, or a combination of the two.

43.8(3) Department-approved CE course is a course approved by either the NRPP, NRSB for CE or other courses approved by the department.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.9(136B,280) School district employee measurement training. This section outlines the department's responsibilities for department-approved training program requirements for school district employees who intend to perform radon testing within their employing district. In accordance with Iowa Code chapter 280, which governs radon testing and mitigation in schools and is enforced by the Iowa department of education, such employees must successfully complete a radon measurement training course approved by both the department and the Iowa department of education.

43.9(1) *Approved training programs.* Training programs cannot state that they have been approved by the state of Iowa unless they have done all of the following:

a. Met the requirements of this chapter;

b. Have been approved by the department;

c. Have been approved by the Iowa department of education;

d. Have been listed on the department's website.

43.9(2) *Training course requirements.* An approved training course shall be based on the measurement requirements as found in the ANSI/AARST MA-MFLB-2023, *Protocol for Conducting Measurements of Radon and Radon Decay Products in Multifamily, School, Commercial and Mixed-Use Buildings,* as amended to August 1, 2025.

NOTE: MA-MFLB consolidates ANSI/AARST MAMF (rev. 1/21) and ANSI/AARST MALB (rev. 1/21) into a single publication).

Approved training courses must:

a. Consist, at a minimum, of five to eight instructional hours.

b. Cover, at a minimum, the following subjects that are directly applicable to the testing of school buildings:

(1) Introduction to radon and its health effects.

(2) Guidance for building managers.

(3) Review of measurement standards including:

1. Purpose and scope of testing;
2. Preparing a testing plan;
3. Test locations;
4. Testing procedures and options;
5. Quality control;

6. Conditions required before and during testing;
7. Documentation, test reports and recordkeeping;
8. Actions based on test results.

c. Conclude with a quiz to review the learned materials. The course attendee must pass the quiz with a score of 70 percent or better to receive the attendee's completion certificate.

43.9(3) *Certificate of completion.* The training provider shall provide a certificate of completion that contains, at minimum:

a. The name of the student;
b. The name of the course;
c. The course ID;
d. The name of the course provider;
e. The course date(s);
f. The number of hours for the course;
g. The signature and typed name of the training provider.

43.9(4) *Application for approval of a training course for school district employees.* A person or organization that plans to conduct or sponsor a training course shall apply to the department for approval of the course on an application furnished by the department. The application shall include:

a. The sponsoring organization's contact information;
b. The sponsoring organization's name;
c. The website URL (if any);
d. The contact person;
e. The mailing address;
f. The contact person's email address;
g. The contact person's telephone number;
h. The name of the course;
i. Whether the course was offered as a webinar online or in person;
j. The course agenda or course outline, including the approximate time allotted to each training segment;
k. A copy of the training materials provided to the student, such as manuals, notes, templates, or other materials provided to attendees;
l. A list of reference materials, texts and audiovisual materials used in the course;
m. A copy of the quiz for the course, containing at least 20 questions.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.10(136B) Exemptions. The following are exempt from the certification requirements of this chapter:

43.10(1) Persons who test for radon or radon decay products in buildings that they own.

43.10(2) Persons who perform radon tests for no compensation.

43.10(3) State officials who are conducting radon testing as part of the state's radon testing program and are approved by the department.

43.10(4) Local officials who are acting on behalf of the state or administering a local program.

43.10(5) Officials who are conducting radon testing as part of government programs in the United States or contractors working for the United States government.

43.10(6) Persons providing radon or radon progeny measurement devices to the public, but not conducting physical tests for the presence of radon or radon progeny with the measurement devices, may do so under the following conditions:

a. They must provide measurement devices obtained from a laboratory certified in Iowa.
b. A valid visible expiration date must be permanently affixed to each measurement device.
c. In addition to the required laboratory instructions regarding measurement procedures, each measurement device must be accompanied by clear directions on where to obtain additional information and interpretation for test results. The certified laboratory or a certified specialist must be included as one of the sources of information and interpretation.

[**ARC 0289D**, IAB 5/13/26, effective 7/1/26]

641—43.11(136B) Penalties. It is unlawful for an individual to function as a radon measurement specialist or radon measurement laboratory in violation of the provisions of the Iowa Radon Testing and Abatement Act or of any rule adopted pursuant to the Act. In addition to other sanctions provided in this chapter, persons convicted of violating the provisions of the Act or the rules adopted pursuant to the Act shall be guilty of a serious misdemeanor.

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These rules are intended to implement Iowa Code section 136B.5.

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CHAPTER 44
RADON MITIGATION REQUIREMENTS

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—44.1(136B) General provisions. This chapter establishes requirements for the credentialing of radon mitigation specialists. All persons performing abatement for radon or radon progeny in buildings, other than buildings that the persons occupy or are constructing for their own occupancy, must be credentialed in accordance with the provisions of this chapter.

44.1(1) The conversion of a passive mitigation system to an active mitigation system, or radon system modifications to an existing active system, must be performed by persons credentialed under this chapter.

44.1(2) Credentialed mitigation specialists are responsible for ensuring that all radon mitigation systems for which they are responsible are installed following guidelines provided in this chapter.

[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.2(136B) Definitions. The definitions provided in 641—Chapter 43 may also apply to the provisions of this chapter. Additionally, the following definitions set forth below are specific to this chapter:

"AARST" means the American Association of Radon Scientists and Technologists, also known as the IEA.

"Active mitigation system" means any system or materials installed as an active part of a ventilation system used for the purpose of reducing radon or radon progeny concentrations by means of an in-line fan.

"ANSI" means the American National Standards Institute.

"Building" means a structure enclosed with exterior walls or fire walls, built, erected and framed with component structural parts, and designed for the housing, shelter, enclosure and support of individuals.

"Compensation" means any form of monetary gain that in any way directly or indirectly results from a radon or radon progeny measurement being conducted.

"Credentialed radon mitigation specialist" or *"mitigation specialist"* means an individual who evaluates diagnostic tests to determine appropriate radon or radon progeny mitigation strategies for a building, designs mitigation systems, installs or supervises the installation of radon or radon progeny mitigation techniques on buildings, and meets the requirements for credentialing provided by this chapter.

"Diagnostic tests" means tests performed or procedures used to determine appropriate mitigation methods for a building.

"EPA" means the United States Environmental Protection Agency.

"IEA" means the Indoor Environments Association formerly known as the American Association of Radon Scientists and Technologists (AARST).

"Mitigator" means a person who installs mitigation systems for the purpose of abating radon levels within buildings.

"NRPP" means the National Radon Proficiency Program facilitated by the IEA, formerly known as the AARST.

"NRSB" means the National Radon Safety Board.

"Online licensing portal" means the electronic system designated by the department through which applicants and credential holders shall submit applications, renewals, supporting documentation, and other required information for licensure, certification, credentialing, or registration.

"Passive mitigation system" means any system or materials installed for the purpose of reducing radon or radon progeny concentrations without the use of an in-line fan and relying solely on the convective air flow upward in the vent pipe for sub-slab depressurization and consists of a vertical vent pipe routed through conditioned space from the suction pit to 12 inches above the roof.

"Picocurie per liter" means a quantity of radioactive material per liter of air that will produce 2.2 disintegrations per minute of radiation. It may be used as a measure of the concentration of radon gas in air. One curie is equivalent to one trillion picocuries.

"pCi/L" means a measurement of radon in picocuries per liter.

"Radon" means the radioactive noble gas radon-222.

"Radon system modification" means any change to an existing active radon mitigation system that alters its design, configuration, or operation, such as adding or relocating piping, fans, or suction points. This does not include routine replacement of parts with equivalent components that do not affect system function or layout.

"Radon progeny" means the short-lived radionuclides formed as a result of the decay of radon-222, including polonium-218, lead-214, bismuth-214, and polonium-214.

"Working level" or *"WL"* means the concentration of radon progeny that will result in 130,000 million electron volts of alpha particle energy released per liter of air. Working level is a measure of radon decay product concentration in air.

"Working level month" or *"WLM"* means a cumulative exposure to radon decay products calculated by multiplying the radon daughter concentration in units of working levels by the number of hours exposed and dividing by 170.

[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.3(136B) General regulatory requirements.

44.3(1) Except as provided in this chapter, no person may mitigate for radon or radon progeny in Iowa for a fee or other remuneration unless such person has been credentialed by the department. This requirement also applies to persons whose place of business is located in Iowa or in a state other than Iowa, and who offer radon mitigation services to residents of Iowa.

44.3(2) Individual qualifications for radon mitigation specialist. No individual may be credentialed as a radon mitigation specialist unless all of the following conditions are met:

a. Be at least 18 years of age at the time of application.

b. Possess three years of relevant professional work experience. Professional work experiences may include:

(1) Relevant postsecondary education, which may be substituted on a year-for-year basis for two of the three years of relevant professional work experience.

(2) Relevant professional work experience, which includes the design or construction of buildings, or associated heating, ventilation, and air-conditioning systems, or closely-related activities approved by the department.

(3) Relevant postsecondary education, which includes a college curriculum in architecture, engineering, building construction, or the physical sciences.

c. Successful completion of department-approved training courses on both radon and radon progeny measurements and on radon mitigation within the two years prior to application. An approved training course is a course that meets and maintains approval by the NRPP or the NRSB. For measurement, this includes the NRPP Radon Measurement Professional or NRSB Radon Measurement Specialist course and for mitigation this includes the NRPP or NRSB Radon Mitigation Specialist courses.

d. Achieve or exceed the minimum passing score on the national mitigation professional or specialist examination provided by the NRPP or the NRSB within the two years prior to application.

44.3(3) Requirements for continued credentialing. Requirements for continued credentialing include the following:

a. An Iowa credentialed person shall allow the department, its agents, employees, and contractors, upon presentation of appropriate credentials, to access to their facilities, offices, records, and equipment without undue delay for purposes of inspection and examination. The credentialed person shall also allow the department, its agents, employees, and contractors to accompany the person during the performance of any radon abatement activities, for the purpose of inspecting such activities, subject to the consent of the property owner or resident on whose property the activities are being performed.

b. The credentialed person shall remain in compliance with Iowa Code chapter 136B and this chapter.

c. The credentialed person shall comply with all requirements as stated in the ANSI/AARST mitigation standards as amended to August 1, 2025, applicable to the building being mitigated. The standards include the following:

(1) ANSI/AARST SGM-SF-2023, Soil Gas Mitigation Standards for Existing Homes

(2) ANSI/AARST SGM-MFLB-2023, Soil Gas Mitigation Standards for Existing Multifamily, School, Commercial and Mixed-Use Buildings

44.3(4) A credentialed person shall:

a. Fully cooperate with the department or its agents when field evaluations are conducted.

b. Be present during scheduled visits by the department.

c. Not disclose to any other person, except to the department or its agents, the addressee or owner of a nonpublic building, the radon levels present in the building or abatement measures needed or performed, unless the building owner waives, in writing, this right of confidentiality.

d. Ensure that each building is tested for radon levels before (premitigation) and after (postmitigation) mitigation work is performed. This requirement is not binding if the building owner waives these testing requirements prior to the start of the mitigation activities on a form furnished by the department. The credentialed person shall maintain record of such waivers.

(1) Such tests shall be of sufficient type, duration and consistency and shall be performed at such times and under such ventilation conditions as to allow for comparison of premitigation and postmitigation radon levels.

(2) Premitigation and postmitigation radon tests shall be performed using a department-approved test device by one of the following:

1. An independent measurement specialist who is not employed by the same firm as the mitigation specialist performing the mitigation.

2. The homeowner, occupant, or other person responsible for the building.

(3) Postmitigation radon tests shall be started no sooner than one day after mitigation is completed and within 30 days after installation.

e. Install a mitigation system that reduces the radon level to below 4 pCi/L in the area or the level of the building where the mitigation system is installed.

[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.4(136B) Application for credentialing.

44.4(1) An application for credentialing or renewal of credentials as a radon mitigation specialist shall be completed through the online licensing portal and shall contain complete and accurate information.

44.4(2) The applicant must report any changes to the initial or renewal certification application within 14 days.

44.4(3) Application as a radon mitigation specialist. A person applying for a radon mitigation specialist shall include:

a. A certificate of completion of initial radon measurement and mitigation courses as outlined in subrule 44.3(2).

b. If either course was completed more than two years prior to the date of the application, documentation that the person has completed an average of at least four hours of approved continuing education (CE) training per year since completing the course. The certificate of completion must indicate all of the following:

(1) The name of the individual receiving the training;

(2) The name of the course and course ID assigned by either the NRPP or NRSB;

(3) The dates of the course;

(4) The signature of primary instructor;

(5) Official documentation of the test scores obtained on the NRPP, NRSB, or other department-approved radon mitigation examination taken within two years prior to application, showing a minimum passing score;

(6) Proof of three years of relevant work experience. One or more of the following is required:

1. A detailed resume providing proof of three years of relevant work experience.

2. A combination of a detailed resume and college transcript providing proof of at least one year of relevant work experience and up to two years of relevant postsecondary education as outlined in paragraph 44.3(2)*"b."*

3. Disclosure of any past disciplinary actions, if applicable, and include a list of any disciplinary actions taken against the applicant's license, credential, certification, registration in any profession in

Iowa or another state or jurisdiction, and a copy of the disciplinary action(s), including any charges and disposition.

4. An acceptable mitigation worker protection plan. The plan shall include the elements outlined in Section 11 of the applicable standard for the building type being mitigated, as referenced in paragraph 44.3(3)*"c."* The worker protection plan shall apply to all mitigation installation activities.

5. An acceptable quality assurance plan (QAP). The plan shall apply to all mitigation installation activities and includes but is not limited to:

- A description of all diagnostic tests performed to determine the mitigation strategy, names of the individuals performing each diagnostic test, and any other related services offered.
- Ensuring all instruments are properly calibrated according to the manufacturer's recommendations.
- A description of all mitigation materials and systems offered.

(7) An example of the operation, maintenance and monitoring (OM&M) information package that will be provided to the building owner for the mitigation system installed.

1. The contents of the OM&M information package shall include the elements outlined in section 10.1 of the applicable standard for the building type being mitigated, as referenced in paragraph 44.3(3)*"c."*

2. The OM&M information package must include the phone number for the Iowa radon program.

(8) A copy of the mitigation waiver as outlined in paragraph 44.3(4)*"d."*

(9) The fee specified in rule 641—44.6(136B).

44.4(4) Supplementary statements. The department may require the applicant to submit supplementary statements containing additional information to enable the department to determine whether an application should be approved, denied, or whether a previously issued credential should be amended, suspended, or revoked. Each application or supplementary statement shall be submitted by either the applicant personally, or a person authorized in writing by the applicant to do so on the applicant's behalf.

44.4(5) Expiration of notice of credential. Credentials will expire annually.

a. Radon mitigation activities subject to this chapter cannot be initiated after the expiration of the credential unless a renewal application has been submitted to the department, is determined to be complete, and is approved by the department.

b. All radon mitigation activities initiated prior to the expiration of the credential must be completed within 30 days of the expiration date if renewal is not completed and approved by the department.

c. If the application is rejected, the applicant cannot conduct radon mitigation activities in the state of Iowa for compensation or under any financial arrangement.

[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.5(136B) Renewal application of annual credentialing.

44.5(1) *Credential renewal.* A person applying for a renewal of an annual credential shall:

a. Submit the appropriate application through the online licensing portal.

b. Include the number of mitigation systems installed for the renewal period by providing all of the following at or before time of renewal through the online licensing portal:

(1) Building owner name;

(2) Building owner phone number;

(3) Physical address of installation location, including street address, city, state and zip code;

(4) Installation date;

(5) Employer at time of installation.

c. Submit copies of CE completion certificates to the department biennially, based on the date of initial credentialing.

d. Pay the fee specified in rule 641—44.6(136B).

44.5(2) *Reinstatement of an expired credential.* Reinstatement applications shall be submitted through the online licensing portal when a registration has not been renewed within 30 days following the expiration date. Any person wishing to reinstate an expired radon measurement certification must complete the following:

a. Submit the required application and CE documentation that was due at time of expiration. If it has been more than two years since expiration, eight hours of CE must be completed with four of those hours being an approved mitigation standards review course; and

b. Pay the applicable credentialing and reinstatement fees.

[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.6(136B) Radon mitigation credentialing fees. Any person wishing to become credentialed as a radon mitigation specialist shall pay nonrefundable fees in amounts sufficient to defray the cost of administering the rules of this chapter, as outlined in the fee schedule below.

44.6(1) *Initial application fee.* Each person applying for initial credentialing under the provisions of this chapter shall pay a nonrefundable $25 application fee.

44.6(2) *Annual credentialing fee.*

a. Each person applying for credentialing must pay a nonrefundable initial fee of $150.

b. Each person applying for annual renewal must pay an annual fee of $150 or a surcharge fee of $40 per mitigation system installed for systems costing more than $200, whichever amount is greater.

c. For fee calculation purposes, one mitigation system installation is considered to be the installation of an interconnected system that contains one or more fans installed on a single riser, one or more suction points, and one or more exhausts. For systems with single or multiple fans installed on separate risers and installed in separate locations, each riser constitutes a separate installation.

d. If a person elects not to renew a credential the subsequent year, all outstanding surcharge fees shall be paid in full within 30 days following the credential's expiration date.

44.6(3) *Returned check and reinstatement fees.* Persons who fail to pay required fees to the department are subject to the following penalties:

a. $40 fee for each payment received by the department in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the department.

b. $100 reinstatement fee when a certification has not been renewed within 30 days following the expiration date. This fee is added to the unpaid annual credentialing fee.

[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.7(136B) Enforcement actions. The department may deny, suspend, revoke, or modify the credentials of a person, place on probation, impose a civil penalty, or refer the case to the office of the county attorney for possible criminal penalties pursuant to Iowa Code chapter 136B, or any combination thereof, when it finds that a credentialed person or a person who is not credentialed has committed any of the following actions:

44.7(1) Failure to comply with applicable state, federal, or local statutes and regulations. This includes any action that might place a person with certification under this chapter in noncompliance with Iowa statutes and the requirements of this chapter.

44.7(2) Failure to submit required information or notifications in a timely manner.

44.7(3) Failure to maintain the required records in rule 641—44.8(136B) and in the applicable ANSI/AART mitigation standard listed in paragraph 44.3(4)*"c."*

44.7(4) Falsifying approval records, qualifications, or other information or documentation related to licensing approval.

44.7(5) Failure to comply with the training standards and requirements in paragraph 44.3(4)*"c."*

44.7(6) Submitting in the application for credentialing, renewal of credentialing, or supplementary statement false or misleading statements that the department relied upon in approving the application.

44.7(7) Knowingly making misleading, deceptive, untrue, or fraudulent representations involving radon, or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

44.7(8) Using untruthful or improbable statements in advertisements. Use of these statements includes but is not limited to the presentation of information to the public by training programs that is false, deceptive, or misleading, or that is promoted through fraud or misrepresentation.

44.7(9) Falsifying reports and records required by this chapter.

44.7(10) Accepting any fee by fraud or misrepresentation.

44.7(11) Revocation, suspension, or other disciplinary action taken by a certification or licensing authority of this state, another state, territory, or country; or failure by the firm or individual to report such action in writing within 30 days of the final action by such certification or licensing authority. A stay by an appellate court cannot negate this requirement; however, if such disciplinary action is overturned or reversed by a court of last resort, the report shall be expunged from the records of the board.

44.7(12) Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

44.7(13) Representation by a firm or individual that the firm or individual is certified when the certification has been suspended or revoked or has not been renewed.

44.7(14) Failure to respond within 30 days of receipt of communication from the department that was sent by registered or certified mail.

44.7(15) Engaging in any conduct that subverts or attempts to subvert a department investigation.

44.7(16) Failure to comply with a subpoena issued by the department or failing to cooperate with a department investigation.

44.7(17) Failure to pay costs assessed in any disciplinary action.

44.7(18) Any condition revealed by the application, supplementary statement, report, record, inspection, or other evidence, that would warrant the department's refusal to grant credentialing on an original application.

44.7(19) Failure to complete the installation of a radon mitigation system within 30 days of the start date or date contracted to start.

44.7(20) Failure to correct any violation of department-approved standards or rules found during a previous inspection, or any violation found on an inspection that, as determined by the department, jeopardizes the safety of the building or other occupants.

44.7(21) Accepting compensation for installing ineffective radon remedies or for not dropping radon levels below 4 pCi/L in the area or level of the building where a radon mitigation system was installed.

44.7(22) Accepting compensation for installing active radon mitigation systems that are not acceptable to the department or that do not comply with the requirements of this chapter.

44.7(23) Failure to fully cooperate with the department or its agents when field evaluations are conducted.

44.7(24) Failure to attend a scheduled meeting or inspection set up by the department or its agents, when the person holding the credentials was previously notified and agreed to the time and location of the inspection.

[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.8(136B) Records and reporting requirements. A credentialed radon mitigation specialist shall maintain records to include a report of each mitigation activity for a minimum of five years. Each report shall include at a minimum all of the following:

44.8(1) The address or location of the building.

44.8(2) The name and phone number of the owner(s) of the building where the radon mitigation is conducted.

44.8(3) A written description of each mitigation system, the materials installed, the diagnostic test results, and the cost of each system.

44.8(4) The name of the certified radon measurement specialist or technician used to perform radon or radon progeny testing before and after radon mitigation of a building. This requirement does not apply if the building owner has waived the testing requirement set forth in paragraph 44.3(4)*"d"* and the mitigation specialist maintains a copy of the signed waiver.

44.8(5) The results of any premitigation or postmitigation radon or radon progeny measurements performed and the measurement methods utilized. This requirement does not apply if the building owner has waived the testing requirement set forth in paragraph 44.3(4)*"d"* and the mitigation specialist maintains a copy of the signed waiver.

44.8(6) The results of the postmitigation radon measurements performed, including measurement methods utilized, and all pertinent dates. This requirement does not apply if the building owner has waived

the testing requirement set forth in paragraph 44.3(4)*"d"* and the mitigation specialist maintains a copy of the signed waiver.
[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.9(136B) Continuing education.

44.9(1) All credentialed individuals must complete at least eight hours of department-approved CE biennially on either radon mitigation, measurement, or a combination of the two.

44.9(2) Persons possessing both an Iowa Measurement Specialist certification and Mitigation Specialist credential must complete 12 hours of CE biennially on either radon measurement, mitigation, or both.

44.9(3) A department-approved CE course is a course approved by either NRPP, NRSB or other courses approved by the department.
[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.10(136B) Exemptions. The following are exempt from the credentialing requirements of this chapter:

44.10(1) Persons who mitigate radon or radon decay products in buildings that they occupy.

44.10(2) Persons mitigating radon or radon decay products as part of scientific research approved by the department.

44.10(3) Persons who install passive radon mitigation systems either as a standalone system or as part of radon-resistant new construction building techniques.
[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

641—44.11(136B) Penalties. It is unlawful for an individual to function as a radon mitigation specialist in violation of the provisions of Iowa Code chapter 136B. Persons convicted of violating the provisions of Iowa Code chapter 136B or this chapter shall be guilty of a serious misdemeanor.
[**ARC 0290D**, IAB 5/13/26, effective 7/1/26]

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

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CHAPTER 45
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS, PARTICLE ACCELERATORS FOR NONHUMAN USE, ANALYTICAL X-RAY EQUIPMENT, AND WELL-LOGGING
[Prior to 8/5/92, see 641—41.4(136C)]
Rescinded **ARC 0183D**, IAB 4/1/26, effective 7/1/26

CHAPTER 46
MINIMUM REQUIREMENTS FOR TANNING FACILITIES
Transferred to 481—Chapter 496, IAC Supplement 4/2/25

CHAPTERS 47 to 49
Reserved

CHAPTER 50
ORAL HEALTH
Rescinded **ARC 9320C**, IAB 5/28/25, effective 8/1/25

CHAPTER 51
DENTAL SCREENING

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/1/30

641—51.1(135) Definitions.

"Admitting official" means the superintendent of schools or the superintendent's designated representative if a public school; if an accredited nonpublic school, the governing official of the school.

"Applicant" means any person seeking first-time enrollment in kindergarten or ninth grade in a public or accredited nonpublic elementary school or high school in Iowa.

"Dental hygienist" means a person licensed to practice as a dental hygienist.

"Dentist" means a person licensed to practice as a dentist.

"Electronic signature" means a confidential personalized digital key, code, or number that is used for secure electronic data transmission and that identifies and authenticates the signatory.

"Elementary school" means kindergarten through grade six in an Iowa school district or accredited nonpublic school.

"Gum infection" means that gum (gingival) tissue is red, bleeding, or swollen.

"High school" means grades 9 through 12 in an Iowa school district or accredited nonpublic school.

"Injury" means soft tissue laceration or a broken or dislodged tooth.

"I-Smile" means the department program designed to increase access to dental care for children and to ensure a dental home.

"I-Smile coordinator" means a designated dental hygienist who is employed by or under contract with a local public health agency to administer the I-Smile dental home program.

"Local board of health" means a county, city, or district board of health as defined in Iowa Code section 137.102.

"Needs dental care" means that tooth decay or a white spot lesion is suspected in one or more teeth or that gum infection is suspected.

"Needs urgent dental care" means that obvious tooth decay is present in one or more teeth, there is evidence of injury or severe infection, or the child is experiencing pain.

"No obvious problems" means a child's hard and soft tissues appear to be visually healthy and there is no apparent reason for the child to be seen before the next routine dental checkup.

"Nurse" means a person licensed to practice as a registered nurse or advanced registered nurse practitioner.

"Physician" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery.

"Physician associate" means a person licensed to practice as a physician associate.

"Recorder" means a dentist, dental hygienist, physician, physician associate, or nurse who is authorized to record screening information and sign the Certificate of Dental Screening form.

"Severe infection" means excessive bleeding, swelling, or pus discharge; or an abscess.

"Signature" means an original signature, or authorized use of stamped signature, or electronic signature of a dentist, dental hygienist, physician, physician associate, or nurse.

"Tooth decay" means a visible cavity or hole in a tooth with brown or black coloration, or a retained root.

"White spot lesion" means a demineralized area of a tooth, usually appearing as a chalky, white spot or white line near the gum line. A white spot lesion is considered an early indicator of tooth decay, especially in primary teeth.

[**ARC 9321C**, IAB 5/28/25, effective 8/1/25; Editorial change: IAC Supplement 6/10/26]

641—51.2(135) Persons included. The dental screening requirements specified in this chapter apply to all persons seeking first-time enrollment in kindergarten or ninth grade in a public or accredited nonpublic elementary school or high school in Iowa.

[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.3(135) Persons excluded. Exclusions to these rules are permitted on an individual basis for religious and financial hardship reasons. Applicants approved for a religious or financial hardship exemption shall submit to the admitting official a valid department certificate of dental screening exemption.

51.3(1) Religious exemption. A religious exemption may be granted to an applicant if the dental screening conflicts with a genuine and sincere religious belief.

a. The certificate of dental screening exemption for religious reasons shall attest that the dental screening conflicts with a genuine and sincere religious belief and that the belief is in fact religious and not based merely on philosophical, scientific, moral, personal, or medical opposition to dental screenings.

b. The certificate of dental screening exemption for religious reasons shall be signed and dated by the applicant or, if the applicant is a minor, by the parent or guardian.

c. To be valid, the certificate of dental screening exemption for religious reasons shall be the department certificate or a form approved in writing by the department.

51.3(2) Financial hardship exemption. A financial hardship exemption may be granted to an applicant who is unduly burdened by the cost of a dental screening.

a. The certificate of dental screening exemption for financial hardship reasons shall attest that dental screening would cause a genuine financial burden to the applicant.

b. The certificate of dental screening exemption for financial hardship reasons shall be signed and dated by a dentist, dental hygienist, physician, physician associate, or nurse.

c. The certificate of dental screening exemption for financial hardship reasons shall include the provider type and the provider's name, business address, and telephone number.

d. To be valid, the certificate of dental screening exemption for financial hardship reasons shall be the department certificate or a form approved in writing by the department.

51.3(3) A faxed copy, photocopy, or electronic copy of the valid certificate of dental screening exemption is acceptable.

[**ARC 9321C**, IAB 5/28/25, effective 8/1/25; Editorial change: IAC Supplement 6/10/26]

641—51.4(135) Dental screening components.

51.4(1) A dental screening is a visual assessment and is noninvasive and nondiagnostic.

51.4(2) Dental instrumentation is not needed for a dental screening.

51.4(3) A dental screening can identify obvious or suspected oral health conditions that need or that might need examination by a dentist.

51.4(4) The dental screening shall include the following steps:

a. Visual inspection of the soft tissues, including the lips, cheeks, gums, tongue, floor of mouth, and roof of mouth, to assess infection or injury.

b. Visual inspection of all tooth surfaces to assess tooth decay, white spot lesions, or injury.

c. Documentation of the screening and treatment needs according to rule 641—51.8(135).

[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.5(135) Dental screening providers.

51.5(1) *Elementary school.* A dental screening for elementary school enrollment shall be performed by a licensed dentist, a licensed dental hygienist, a licensed physician, a licensed physician associate, or a licensed nurse.

51.5(2) *High school.* A dental screening for high school enrollment shall be provided by a licensed dentist or a licensed dental hygienist.

[**ARC 9321C**, IAB 5/28/25, effective 8/1/25; Editorial change: IAC Supplement 6/10/26]

641—51.6(135) Timeline for valid dental screening.

51.6(1) Elementary school. To be valid, a minimum of one dental screening shall be performed on an applicant no earlier than three years of age but no later than four months after the enrollment date.

51.6(2) High school. To be valid, a minimum of one dental screening shall be performed on an applicant no earlier than one year prior to the enrollment date and no later than four months after the enrollment date.

51.6(3) A dental screening may also be deemed valid by the department if the department determines that the applicant has substantially complied with the dental screening requirements.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.7(135) Proof of dental screening. The applicant or, if a minor, the parent or guardian of a child enrolled in elementary school or high school shall submit a valid department certificate of dental screening to the admitting official of the school district or accredited nonpublic elementary school in which the applicant wishes to enroll.

51.7(1) To be valid, the certificate of dental screening shall be the department certificate or a form approved in writing by the department.

a. The Certificate of Dental Screening form is available on the department's website or by calling the department.

b. The certificate of dental screening shall include all information required by rule 641—51.8(135).

c. The certificate of dental screening may also be deemed valid by the department if the department determines that the information on the certificate substantially complies with the dental screening requirements.

51.7(2) A faxed copy, photocopy, or electronic copy of the valid certificate of dental screening is acceptable.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.8(135) Dental screening documentation.

51.8(1) *Student information.* A person authorized to perform a dental screening required by this chapter shall record the following student information or ensure that such information is recorded on the certificate of dental screening provided or approved in writing by the department in cooperation with the department of education:

a. Name (first and last); and

b. Birth date.

51.8(2) *Screening information.* A person authorized to perform a dental screening required by this chapter shall record the following screening information on the certificate of dental screening provided or approved in writing by the department in cooperation with the department of education:

a. Date of dental screening;

b. Treatment needs (no obvious problems, needs dental care, needs urgent dental care);

c. Provider type;

d. Provider name and telephone number; and

e. Provider or recorder signature and credentials.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.9(135) Ensuring dental screening services. Each public and accredited nonpublic school, in collaboration with the department, shall ensure that the parent or guardian of a student enrolled in the school has complied with the dental screening requirement. Parents or guardians of students who do not have a valid certificate of dental screening shall be provided with community dental screening referral resources, including contact information for the I-Smile coordinator, the department, or a dental society.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.10(135) Records. It shall be the duty of the admitting official of an elementary school or a high school to ensure that a valid certificate of dental screening or certificate of dental screening exemption is on file for each child enrolled.

51.10(1) The admitting official shall ensure that all certificates of dental screening are properly completed according to rule 641—51.7(135).

51.10(2) The admitting official shall ensure that all certificates of dental screening exemption are properly completed according to subrules 51.3(1) and 51.3(2).

51.10(3) The admitting official shall keep the certificates of dental screening or certificates of dental screening exemption on file at the school in which the applicant is enrolled and assist the applicant or the applicant's parent or guardian.

51.10(4) The local board of health or its designee, the department of education, and the department or its designee shall have the right to have access to the certificates of dental screening and certificates of dental screening exemption of students enrolled in elementary schools and high schools.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.11(135) Reporting.

51.11(1) It shall be the duty of each local board of health or its designee to audit the certificates of dental screening and certificates of dental screening exemption in the schools within the local board's jurisdiction to determine compliance with Iowa Code section 135.17.

51.11(2) By May 31 annually, each local board of health shall furnish the department with evidence for the preceding school year that each child enrolled in any public or accredited nonpublic school within the local board's jurisdiction met the dental screening requirement.

51.11(3) The evidence shall be in the form of a report that includes:

a. Name of school,

b. Enrollments by grade,

c. The number of valid certificates of dental screening by grade,

d. The number of valid certificates for religious exemptions by grade, and

e. The number of valid certificates for financial hardship exemptions by grade.

[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.12(135) Release of dental screening information.

51.12(1) *Between a dentist, dental hygienist, physician, physician associate, or nurse, and the elementary school or high school that the child attends.* A dentist, dental hygienist, physician, physician associate, or nurse shall disclose a student's dental screening information, including the student's name and date of birth; the name of the student's parent or guardian; the month, day and year of the screening; and the screening results and treatment needs to an elementary school or a high school upon written or verbal request from the elementary school or high school. Written or verbal permission from a student or the student's parent or guardian is not required to release this information to an elementary school or a high school.

51.12(2) *Among dentists, dental hygienists, physicians, physician associates, or nurses.* Dental screening information, including the student's name, date of birth, name of parent or guardian, the month, day and year of the screening, and the screening results and treatment needs shall be provided by one dentist, dental hygienist, physician, physician associate, or nurse to another health care provider without written or verbal permission from the student or the student's parent or guardian.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25; Editorial change: IAC Supplement 6/10/26]

641—51.13(135) Referral requirements. Parents or guardians of students who need dental care or need urgent dental care shall be referred to the parent's or guardian's dentist of choice. Students without a dentist or who have difficulty accessing dental care shall be referred to a local I-Smile coordinator or local public health agency for assistance with completion of dental care. This assistance may include locating dentists, scheduling appointments, and identifying payment sources.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

641—51.14(135) Provider training. For the purpose of quality assurance and consistency, the department will make training and training materials available for dental screening providers.
[**ARC 9321C**, IAB 5/28/25, effective 8/1/25]

These rules are intended to implement Iowa Code section 135.17.

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[Editorial change: IAC Supplement 6/10/26]

CHAPTER 52
VISION SCREENING

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—52.1(135) Definitions.

"Advanced registered nurse practitioner" or *"ARNP"* means the same as defined in rule 655—7.1(17A,124,147,152).

"Autorefractor" means a method of vision screening involving skiascopy methods or wave-front technology to evaluate the refractive error of each eye. Depending on the autorefractor being used, this method allows for immediate results interpreted by the operator or the instrument as a pass or fail.

"Community-based organization" means a public or private nonprofit organization of demonstrated effectiveness that is representative of a community or significant segments of a community and that provides educational or related services to individuals in the community that include utilizing approved age-appropriate, acceptable child vision screening tests approved by the department.

"Comprehensive eye examination" means a clinical diagnostic assessment performed by an optometrist or ophthalmologist to assess a person's level of vision and to detect any abnormality or diseases.

"Elementary school" means an Iowa public or accredited nonpublic school that a kindergarten or third grade student would attend.

"Iowa KidSight" means a joint project of the lions clubs of Iowa and the university of Iowa, department of ophthalmology and visual sciences, dedicated to enhancing the early detection and treatment of vision impairments in Iowa's young children (target population six months of age through kindergarten age) through screening and public education.

"IRIS" means the immunization registry information system as established in 641—Chapter 7.

"Online vision screening" means a vision screening test administered from the internet to a child to assess vision and includes vision test results and recommendations.

"Ophthalmologist" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to Iowa Code chapter 148 and board-certified in ophthalmology as a specialist in medical and surgical eye problems.

"Optometrist" means a person licensed to practice optometry pursuant to Iowa Code chapter 154.

"Photoscreening" means a method of vision screening employing an automated technique that uses the red reflex of the eye to screen for eye problems and produces immediate readable results and a timely report of the results thereafter.

"Physician" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to Iowa Code chapter 148.

"Physician associate" means a person licensed to practice as a physician associate pursuant to Iowa Code chapter 148C.

"Potential vision impairment" means that a child's vision appears to be compromised and there is reason for the child to be seen by an ophthalmologist or optometrist.

"Student vision card" means a card distributed by the Iowa optometric association to all schools in Iowa pursuant to Iowa Code section 280.7A. The student vision card recommends children receive a complete eye health examination.

"Vision screening" means an eye testing program that is age and developmentally appropriate and that assesses visual acuity or other risk factors contributing to refractive errors and other vision conditions.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25; Editorial change: IAC Supplement 6/10/26]

641—52.2(135) Persons included and persons excluded.

52.2(1) The child vision screening requirements specified in this chapter apply to all persons seeking first-time enrollment in kindergarten and third grade in a public or accredited nonpublic elementary school in Iowa.

52.2(2) Persons shall be included or excluded as established in Iowa Code section 135.39D.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25]

641—52.3(135) Child vision screening components.

52.3(1) The requirement for a child vision screening may be satisfied pursuant to Iowa Code section 135.39D.

52.3(2) All vision screening methods, including emerging vision screening technologies, shall be age-appropriate and will be approved by the department. A list of acceptable child vision screening tests will be reviewed and updated annually by the department and will be listed on the department's website.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25]

641—52.4(135) Timeline for valid vision screening.

52.4(1) *Kindergarten.* To be valid, a minimum of one child vision screening shall be performed on a child no earlier than one year prior to the date of the child's enrollment in kindergarten and no later than six months after the date of the child's enrollment in kindergarten.

52.4(2) *Grade three.* To be valid, a minimum of one child vision screening shall be performed on a child no earlier than one year prior to the date of the child's enrollment in the third grade and no later than six months after the date of the child's enrollment in the third grade.

52.4(3) *Substantial compliance.* A child vision screening may also be deemed valid by the department if the department determines the child has substantially complied with the child vision screening requirements.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25]

641—52.5(135) Proof of child vision screening.

52.5(1) The parent or guardian of a child enrolled in kindergarten or third grade shall ensure that evidence of a child vision screening is submitted to the school district or accredited nonpublic elementary school in which the child is enrolled either electronically through IRIS pursuant to subrule 52.5(2) or in hard copy or electronic form pursuant to subrule 52.5(3).

52.5(2) If the child's vision screening results were electronically submitted to IRIS, the parent or guardian may notify the school district or accredited nonpublic elementary school of such submission to satisfy the requirement for evidence of a child vision screening.

52.5(3) If evidence of the child vision screening is not electronically submitted to IRIS, the parent or guardian shall provide evidence of the child vision screening in hard copy or electronic form directly to the school. Hard copy or electronic evidence of the vision screening shall include the child's first name, last name, date of birth and ZIP code; evidence of the vision screening, including the date of screening, left eye results, right eye results (if available), vision screening result of "pass" or "fail," and designation of "yes" or "no" for referral made; and the name of the provider who performed the vision screening.

52.5(4) Submission of a faxed copy, photocopy, or electronic copy of the child vision screening results is acceptable.

52.5(5) If a parent or guardian chooses for a child to receive a comprehensive eye examination completed by an ophthalmologist or optometrist in lieu of a vision screening, the parent or guardian may submit a completed student vision card to satisfy the requirement of this rule.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25]

641—52.6(135) Child vision screening reporting.

52.6(1) A person authorized to perform a child vision screening required by this chapter shall report results of the child vision screening to the department.

a. An ophthalmologist or optometrist shall report the results in written form, either electronically or by hard copy, to the parent or guardian to be forwarded to the department via the school or shall report the results via IRIS if available.

b. A pediatrician's or family practice physician's office, a free clinic, a child care center, a local public health department, a public or accredited nonpublic school, or a community-based organization or an ARNP or physician associate shall report the results in written form, either electronically or by hard copy, to the parent or guardian to be forwarded to the department via the school or shall report the results via IRIS if available.

c. Results from an online vision screening administered from the internet shall be generated in an electronic or hard-copy report to the parent or guardian to be forwarded to the department via the school or the results shall be reported via IRIS if available.

d. The results of an autorefractor or photoscreening vision screening, including those performed by Iowa KidSight, shall be reported to the parent or guardian in written form, either electronically or by hard copy, to be forwarded to the department via the school or shall be reported via IRIS if available.

52.6(2) The department will collect and maintain results of the vision screenings submitted electronically, via hard copy or through IRIS.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25; Editorial change: IAC Supplement 6/10/26]

641—52.7(135) School requirements.

52.7(1) Each public and accredited nonpublic elementary school, in collaboration with the department, shall provide the parents or guardians of students enrolled in the school with vision screening referral resources prior to enrollment or during the enrollment period.

52.7(2) Each public and accredited nonpublic elementary school shall provide to parents or guardians of students for whom evidence of a child vision screening is not submitted community eye health referral resources, including but not limited to contact information for the local public health department, maternal and child health agency, Iowa KidSight, the department, or an optometric or ophthalmology society.

52.7(3) Each public and accredited nonpublic elementary school shall arrange for the following to be forwarded to the department:

a. Child vision screening results or comprehensive eye examination results provided by parents or guardians;

b. A list of students whose parents or guardians indicate that the students' results were reported through IRIS; and

c. Any other evidence of vision screening or comprehensive eye examination provided to the school.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25]

641—52.8(135) Iowa's child vision screening database module and follow-up. The department may develop and maintain a statewide child vision screening database module in IRIS to collect and maintain child vision screening results, to ensure students receive the required vision screening, and to monitor eye health.

52.8(1) The database module will consist of vision screening information, including identifying and demographic data.

52.8(2) Database module reporting will comply with rule 641—52.6(135).

52.8(3) Unauthorized uses of database module. The database module information shall not be used to:

a. Market services to students or nonstudents;

b. Assist in bill collection services; or

c. Locate or identify students or nonstudents for any purpose other than those expressly provided in this rule.

52.8(4) Confidentiality of database module information. Child vision screening information, including identifying and demographic data maintained in the database module, is confidential and may not be disclosed except under the following limited circumstances:

a. The department may release information from the database module to the following:

(1) The person who received the child vision screening or the parent or guardian of the person who received the child vision screening;

(2) Users of the database module that complete an agreement with the department that specifies the conditions under which the database module can be accessed and that have been issued an organization code and username by the department;

(3) Persons or entities requesting child vision screening data in an aggregate form that does not identify an individual either directly or indirectly;

(4) Agencies that complete an agreement with the department that specifies conditions for access to database module information and how that information will be used;

(5) A representative of a state or federal agency, or an entity bound by that state or federal agency, to the extent the information is necessary to perform a legally authorized function of the agency or the department. The state or federal agency is subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa; or

(6) Licensed health care providers, agencies, and other persons involved with vision screenings, eye examinations, follow-up services, and intervention services as necessary to administer this chapter.

b. Approved database module users shall not release child vision screening data except to the person who received the child vision screening; the parent or guardian of the person who received the child vision screening; health records staff of schools; medical, optometry, ophthalmology or health care providers providing continuity of care; and other approved users of the database module.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25]

641—52.9(135) Referral requirements.

52.9(1) If a vision screening identifies a potential vision impairment in a child, the person who performed the vision screening or the person's designee shall, if the person is not an ophthalmologist or optometrist, refer the child to an ophthalmologist or optometrist for a comprehensive eye examination.

52.9(2) Persons performing vision screenings or the persons' designee shall contact parents or guardians of children identified as having potential vision impairment based on the results of a vision screening required pursuant to this chapter or a comprehensive eye examination required pursuant to subrule 52.9(1) in order to provide information on obtaining necessary vision correction.

[**ARC 9269C**, IAB 5/14/25, effective 7/1/25]

These rules are intended to implement Iowa Code section 135.39D.

[Filed ARC 1924C (Notice ARC 1838C, IAB 1/21/15), IAB 4/1/15, effective 5/6/15]

[Filed ARC 9269C (Notice ARC 8528C, IAB 12/11/24), IAB 5/14/25, effective 7/1/25]

[Editorial change: IAC Supplement 6/10/26]

CHAPTER 53
Reserved

CHAPTER 54
CONCUSSION OR OTHER BRAIN INJURY RETURN-TO-PLAY PROTOCOL

Chapter rescission date pursuant to Iowa Code section 17A.7: 12/1/30

641—54.1(280) Definitions. For the purpose of these rules, the following definitions apply:

"Asymptomatic" means the student is no longer showing signs, symptoms, or behaviors consistent with a concussion or other brain injury.

"Contest" means the same as defined in Iowa Code section 280.13C(2).

"Extracurricular interscholastic activity" means the same as defined in Iowa Code section 280.13C(2).

"Licensed health care provider" means the same as defined in Iowa Code section 280.13C(2).

"Medical clearance" means written clearance from a licensed health care provider releasing the student following a concussion or other brain injury to return to or commence participation in any extracurricular interscholastic activity.

"Rest" means a recovery state at which physical and cognitive activities are reduced or removed with the intent to eliminate the signs, symptoms, or behaviors of brain injury.

"Return-to-learn plan" means the plan developed by personnel of a school district or accredited nonpublic school based on guidance developed as required under Iowa Code section 280.13C(6)*"b"* to provide adjustments or accommodations as the student returns to the classroom.

"Return-to-play" means the gradual, step-wise approach to returning a student to participation in any extracurricular interscholastic activity following a concussion or other brain injury.

[**ARC 9618C**, IAB 10/15/25, effective 12/1/25]

641—54.2(280) Return-to-play protocol. The return-to-play protocol will be developed by the Iowa high school athletic association and Iowa girls high school athletic union and be disseminated to Iowa public schools and accredited nonpublic schools. The protocol will be based on current evidence-based practice and will include the following process:

54.2(1) *Return-to-play process.*

a. No student will return to contest or practice the same day as a suspected concussion or other brain injury.

b. A student suspected of having a concussion will be evaluated by a licensed health care provider trained in the evaluation and management of concussion and other brain injuries as soon as feasible.

c. A student who has been removed from participation will receive written medical clearance prior to starting the return-to-play protocol.

d. The return-to-play steps shall be conducted under the guidance of a licensed health care provider following current best practice and as set forth by the Iowa high school athletic association and Iowa girls high school athletic union, with provision for delayed return-to-play steps as necessary.

e. Return-to-play may begin when the student is still symptomatic, after a brief period of rest.

f. No contact- or collision-related activities will be performed as part of the return-to-play steps until the student has written medical clearance from a licensed health care provider and has returned to pre-injury academic function.

54.2(2) Reserved.

[**ARC 9618C**, IAB 10/15/25, effective 12/1/25]

These rules are intended to implement Iowa Code section 280.13C.

[Filed ARC 4193C (Notice ARC 4034C, IAB 9/26/18), IAB 12/19/18, effective 1/23/19]

[Filed ARC 9618C (Notice ARC 9490C, IAB 8/20/25), IAB 10/15/25, effective 12/1/25]

CHAPTER 55
ADVISORY COUNCIL ON BRAIN INJURIES

[Prior to 9/30/92, see Persons with Disabilities Division[431] Ch 3]

Rescinded **ARC 9322C**, IAB 5/28/25, effective 8/1/25

CHAPTER 56
BRAIN INJURY SERVICES PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 1/1/31

641—56.1(135) Definitions. For purposes of this chapter, the following definitions apply:

"Assessment" means the review of the member's current functioning with regard to the member's situation, needs, strengths, abilities, desires and goals.

"Brain injury services waiver" means the same as defined in Iowa Code section 135.22B.

"Cost share" means the portion an individual is responsible to pay for services received by the individual.

"Countable income," when determining initial and ongoing eligibility for the brain injury services program, means all earned and unearned income unless specifically exempted in 441—subrule 86.2(2).

"Family size," for purposes of establishing initial and ongoing eligibility under the brain injury services program, means all persons living together who are children and who are parents of those children as defined in 441—subrule 86.2(3).

"Member" means an individual who has applied for and been found eligible to participate in the waiver-eligible component or the cost-share component of the brain injury services program.

"Program" means the department's brain injury services program.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26]

641—56.2(135) Waiver-eligible component. Persons eligible for the brain injury services waiver and on the waiting list for the waiver are eligible for the waiver-eligible component. The program may provide funding for the nonfederal share of the cost of services if the appropriation for the medical assistance program does not have sufficient funding designated to do so.

56.2(1) Provision of funding under this component is not an entitlement and is subject to funding availability.

56.2(2) A person who receives support under the waiver-eligible component of the program is not eligible to receive support under the cost-share component of the program.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26]

641—56.3(135) Cost-share component. Persons determined ineligible for the brain injury services waiver due to fiscal or functional criteria or persons who are eligible for the waiver but for whom funding was not authorized or available to provide waiver eligibility are eligible for the cost-share component of the program.

56.3(1) An individual must meet all of the following requirements:

a. The individual is aged one month through 64 years.

b. The individual has a brain injury as defined in Iowa Code section 135.22.

c. The individual is a resident of Iowa and either a United States citizen or a qualified alien as defined in 8 U.S.C. Section 1641 as amended to August 1, 2025.

d. The individual meets the cost-share component's financial eligibility requirements and is willing to pay a cost share for the cost-share component.

56.3(2) Financial eligibility and cost share. The department will use countable income to determine initial and ongoing eligibility for the program. Cost share will be as follows:

a. Individuals who are at 300 percent or below the federal poverty level for a family of the same size will not be assessed a cost share.

b. Individuals whose countable income is between 301 percent and 350 percent of the federal poverty level for a family of the same size will be assessed a 10 percent cost share for services that will be payable to the service provider.

c. Individuals whose countable income is between 351 percent and 400 percent of the federal poverty level for a family of the same size will be assessed a 20 percent cost share for services that will be payable to the service provider.

d. Individuals whose countable income is above 400 percent of the federal poverty level for a family of the same size will be assessed a 30 percent cost share for services that will be payable to the service provider.

56.3(3) The cost-share component must be the source of last resort for payment; the program will not pay for services when the provision of those services is mandated by law or administrative rule to be the responsibility of another governmental unit, private agency or program. Brain injury cost-share services are not available to an individual who receives services or funding under any type of medical assistance home- and community-based services waiver.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26]

641—56.4(135) Application process.

56.4(1) The department will provide the application materials, including the waiver application and any denial letter, financial assessment, and functional assessment regarding the person in an agreed-upon format.

56.4(2) The department will determine eligibility within 45 days of receipt of complete application materials.

a. After determining if the applicant's service needs fit within the scope of the program, the department will inform the discharge planner or case manager on behalf of the applicant or the applicant's legal representative of the applicant's eligibility.

b. The case manager will establish an interdisciplinary team for each member and, with the team, identify the member's plan based on the member's needs and desires as well as the availability and appropriateness of services. The case manager will notify the department of the service plan.

c. The date of eligibility for applicants deemed eligible for the cost-share component will be the date when both the service eligibility and financial eligibility assessments have been completed.

d. The department will notify the applicant or the applicant's legal representative within seven days of the date eligibility determination is completed.

56.4(3) After determining an applicant's eligibility, if no payment slot is available, the program will enter the applicant on a waiting list according to the following:

a. The date a completed application is date-stamped in a county office of the department. If more than one application is received on the same date, applicants will be entered on the waiting list on the basis of the applicant's month of birth, with January designated as month one.

b. As slots become available, applicants will be selected from the waiting list based on their order on the waiting list to maintain the number of persons approved for participation in the program.

56.4(4) The member or the member's legal representative shall complete and sign a Brain Injury Functional Assessment form indicating the member's choice of caregiver.

56.4(5) The member's case manager will initiate development of the consumer's service plan and commencement of services. All service plans must be approved by the program.

56.4(6) The department will not pay the cost of services provided to a member prior to approval of eligibility.

56.4(7) The program will make the final determination as to whether program funding will be authorized under the cost-share component.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26]

641—56.5(135) Service providers and reimbursement.

56.5(1) A service provider must either be certified to provide services under the brain injury services waiver or have a contract with a county to provide services and apply to become certified to provide services under the brain injury services waiver within 90 days of the date that services commence.

56.5(2) The reimbursement rate payable for the cost of a service provided under the cost-share component is the rate payable under the medical assistance program. However, if the service provider does not have a medical assistance program reimbursement rate, the rate will be the amount payable under the county contract.

56.5(3) All service providers must contract with the department and will be paid retroactively to the date of service eligibility.

56.5(4) Service providers will be responsible for billing and collection of any cost share from an individual as determined by the department.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26]

641—56.6(135) Available services/service plan.

56.6(1) Services available will be consistent with the services offered through the Medicaid home- and community-based services waiver.

56.6(2) Service plans must reflect use of all services, including non-cost-shared services, to ensure that no duplication of services occurs.

56.6(3) All service plans must be submitted, either electronically or in hard-copy format, to the program for approval prior to implementation.

56.6(4) Any change to the service plan must be approved by the program.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26]

641—56.7(135) Redetermination.

56.7(1) The department will annually conduct a complete financial redetermination of continuing eligibility for the program after consultation with the case manager and the interdisciplinary team.

56.7(2) The department will also conduct a redetermination of continuing eligibility when a change in financial or functional circumstances occurs that affects eligibility.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26]

641—56.8(135) Appeal rights. Any individual denied funding under either the waiver-eligible or the cost-share component of the program may appeal pursuant to 441—Chapter 2506.

[**ARC 9705C**, IAB 11/12/25, effective 1/1/26; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code section 135.22B.

[Filed emergency 5/9/07—published 6/6/07, effective 5/9/07]
[Filed 7/13/07, Notice 6/6/07—published 8/1/07, effective 9/5/07]
[Filed ARC 9705C (Notice ARC 9527C, IAB 9/3/25), IAB 11/12/25, effective 1/1/26]
[Editorial change: IAC Supplement 6/10/26]

CHAPTER 57
PLUMBING AND MECHANICAL SYSTEMS BOARD—
DECLARATORY ORDERS
Rescinded **ARC 8003C**, IAB 5/15/24, effective 6/19/24

CHAPTER 58
PLUMBING AND MECHANICAL SYSTEMS BOARD—
AGENCY PROCEDURE FOR RULE MAKING
Rescinded **ARC 8004C**, IAB 5/15/24, effective 6/19/24

CHAPTER 59
PLUMBING AND MECHANICAL SYSTEMS BOARD—FAIR INFORMATION
PRACTICES AND PUBLIC RECORDS
Rescinded **ARC 8005C**, IAB 5/15/24, effective 6/19/24

CHAPTER 60
PLUMBING AND MECHANICAL SYSTEMS BOARD—
NONCOMPLIANCE REGARDING CHILD SUPPORT, NONPAYMENT OF STATE DEBT,
AND NONCOMPLIANCE REGARDING STUDENT LOAN REPAYMENT
Rescinded **ARC 8006C**, IAB 5/15/24, effective 6/19/24

CHAPTER 61
STATE MECHANICAL CODE
Transferred to 481—Chapter 426, IAC Supplement 4/2/25

CHAPTER 62
PLUMBING AND MECHANICAL SYSTEMS BOARD—
MILITARY SERVICE, VETERAN RECIPROCITY, AND SPOUSES OF ACTIVE DUTY SERVICE
MEMBERS
Rescinded **ARC 8007C**, IAB 5/15/24, effective 6/19/24

CHAPTERS 63 to 66
Reserved

CHAPTER 67
BLOOD LEAD TESTING

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—67.1(135) Definitions. For purposes of this chapter, the following definitions apply:

"Applicant" means any person seeking first-time enrollment in kindergarten in a public or accredited nonpublic elementary school in Iowa.

"Transfer student" means an applicant from any school outside Iowa who is seeking enrollment in kindergarten in a school in Iowa.

[**ARC 9070C**, IAB 4/2/25, effective 6/1/25]

641—67.2(135) Persons included. The blood lead testing requirement specified in this chapter applies to all applicants and transfer students as defined in this chapter.

[**ARC 9070C**, IAB 4/2/25, effective 6/1/25]

641—67.3(135) Persons excluded. Exclusions to these rules are permitted on an individual basis for religious reasons and for children determined by the department to be at very low risk for elevated blood lead levels. The parent or guardian of an applicant or transfer student approved for a religious exemption or an exemption for very low risk shall submit to the board of directors of each school district and the authorities in charge of each nonpublic school a valid department certificate of blood lead testing exemption.

[**ARC 9070C**, IAB 4/2/25, effective 6/1/25]

641—67.4(135) Records. Within the constraints of the privacy rights of the parents or guardians and students, the local board of health, the department of education, and the department or its designee have the right to access the department's determination that a child has received a blood lead test and the certificates of blood lead testing exemption of children enrolled in kindergarten.

[**ARC 9070C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code chapter 135.

[Filed 7/10/08, Notice 5/21/08—published 7/30/08, effective 9/3/08]

[Filed ARC 9070C (Notice ARC 8720C, IAB 1/8/25), IAB 4/2/25, effective 6/1/25]

CHAPTER 68
CONTROL OF LEAD-BASED PAINT HAZARDS

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—68.1(135) Definitions.

"Certified elevated blood lead (EBL) inspector/risk assessor" or *"inspector"* means a person who has met the requirements of rule 641—70.5(135) for certification or interim certification and who has been certified by the department.

"Chewable surface" means an interior or exterior surface painted with lead-based paint that a young child can mouth or chew.

"Child-occupied facility" means a building, or portion of a building, constructed prior to 1978, visited by the same child under the age of six years on at least two different days within any week (Sunday through Saturday period, provided that each day's visit lasts at least three hours and the combined weekly visits last at least six hours).

"Clearance testing" means an activity conducted following interim controls, lead abatement, paint stabilization, standard treatments, ongoing lead-based paint maintenance, or rehabilitation to determine that the hazard reduction activities are complete. Clearance testing includes a visual assessment, the collection and analysis of environmental samples, the interpretation of sampling results, and the preparation of a report.

"Deteriorated paint" means any interior or exterior paint or other coating that is cracking, flaking, chipping, peeling, or chalking, or any paint or coating located on an interior or exterior surface that is otherwise damaged or separated from the substrate of a building component.

"Dripline" means the area within three feet surrounding the perimeter of a building.

"Dust-lead hazard" means surface dust in residential dwellings or child-occupied facilities that contains a mass-per-area concentration of lead greater than or equal to 40 micrograms per square foot on floors, 250 micrograms per square foot on interior windowsills, and 400 micrograms per square foot on window troughs based on wipe samples. A dust-lead hazard is present in a residential dwelling or child-occupied facility when the weighted arithmetic mean lead loading for all single-surface or composite samples of floors and interior windowsills is greater than or equal to 40 micrograms per square foot on floors, 250 micrograms per square foot on interior windowsills, and 400 micrograms per square foot on widow troughs based on wipe samples. A dust-lead hazard is present on floors, interior windowsills, or window troughs in an unsampled residential dwelling in a multifamily dwelling if a dust-lead hazard is present on floors, interior windowsills, or window troughs, respectively, in at least one sampled residential unit on the property. A dust-lead hazard is present on floors, interior windowsills, or window troughs in an unsampled common area in a multifamily dwelling if a dust-lead hazard is present on floors, interior windowsills, or window troughs, respectively, in at least one sampled common area in the same common area group on the property. If dust samples are not taken, it may be assumed that surfaces in rooms with hazardous lead-based paint or where renovation, remodeling, or repainting has occurred recently are dust-lead hazards.

"Elevated blood lead" or *"EBL"* means one venous blood level greater than or equal to 20 micrograms per deciliter or at least two venous blood levels of 15 to 19 micrograms per deciliter.

"Elevated blood lead child" or *"EBL child"* means any child who has had one venous blood lead level greater than or equal to 20 micrograms per deciliter or at least two venous blood lead levels of 15 to 19 micrograms per deciliter.

"Elevated blood lead inspection" or *"EBL inspection"* means an inspection to determine the sources of lead exposure for an EBL child and the provision within ten working days of a written report explaining the results of the investigation to the property owner and occupant of the residential dwelling or child-occupied facility being inspected and to the parents of the EBL child. An inspector shall not determine that a residential dwelling is free of lead-based paint as a result of an EBL inspection.

"Friction surface" means an interior or exterior surface that is subject to abrasion or friction, including but not limited to certain window, floor, and stair surfaces.

"Hazardous lead-based paint" means lead-based paint that is present on a friction surface where there is evidence of abrasion or where the dust-lead level on the nearest horizontal surface underneath the friction surface (e.g., the windowsill or floor) is equal to or greater than the dust-lead hazard level, lead-based paint that is present on an impact surface that is damaged or otherwise deteriorated from impact, lead-based paint that is present on a chewable surface, or any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of a residential building or child-occupied facility.

"Impact surface" means an interior or exterior surface that is subject to damage by repeated sudden force, such as certain parts of doorframes.

"Lead-based paint" means any paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram of lead per square centimeter or more than 0.5 percent by weight. Lead-based paint is present on any surface that is tested and found to contain lead equal to or in excess of 1.0 milligram per square centimeter or more than 0.5 percent by weight and on any surface like a surface tested in the same room equivalent that has a similar painting history and that is found to be lead-based paint.

"Lead-based paint hazard" means hazardous lead-based paint, a dust-lead hazard, or a soil-lead hazard.

"Local board" means the local board of health as authorized by Iowa Code chapter 137.

"Mid-yard" means an area of a residential yard approximately midway between the dripline of a residential building and the nearest property boundary or between the driplines of a residential building and another building on the same property.

"Occupant" means any person living, sleeping, cooking or eating in, or having any actual possession of a dwelling or dwelling unit.

"Owner" means any person who, alone or jointly with others, (1) has legal title to any dwelling, with or without accompanying actual possession thereof, or (2) has charge, care, or control of any dwelling by acting as the agent of the owner or as the executor, administrator, trustee, or guardian of the estate of the owner.

"Paint-lead hazard" means the presence of hazardous lead-based paint in a residential dwelling or a child-occupied facility.

"Play area" means an area of frequent soil contact by children of less than six years of age as indicated by but not limited to factors including the following: the presence of play equipment, toys, or other children's possessions; observations of play patterns; or information provided by parents, residents, caregivers, or property owners.

"Residential building" means a building containing one or more residential dwellings.

"Residential dwelling" means (1) a detached single-family dwelling unit, including the surrounding yard, attached structures such as porches and stoops, and detached buildings and structures, including but not limited to garages, farm buildings, and fences; or (2) a single-family dwelling unit in a structure that contains more than one separate residential dwelling unit, that is used or occupied, or intended to be used or occupied, in whole or part, as the home or residence of one or more persons.

"Retaliation" means harassment, termination of the tenancy, discontinuation of utilities or other services, and any other action taken against the lessee.

"Soil-lead hazard" means bare soil on residential real property or on the property of a child-occupied facility that contains total lead greater than or equal to 400 parts per million for the dripline, mid-yard, and play areas. A soil-lead hazard is present in a dripline, mid-yard, or play area when the soil-lead concentration from a composite sample of bare soil is greater than or equal to 400 parts per million. If soil samples are not taken, it may be assumed that bare soil within 3 feet of the foundation of a garage or other structure built prior to 1978 is a soil-lead hazard.

[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.2(135) EBL inspections required. The local board will appoint a certified inspector to conduct EBL inspections in residential dwellings and child-occupied facilities where an EBL child lives, visits, or has recently lived. All owners and occupants shall allow access to the residential dwellings and child-occupied facilities that the certified inspector desires to inspect.

[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.3(135) Refusal of admittance. If the inspector appointed by the local board is refused entry to a property, then the inspector may make a complaint under oath to any magistrate of the county. The magistrate may issue a warrant directing the owner or occupant to allow the inspector to conduct an EBL inspection and directing a peace officer to accompany the inspector during the EBL inspection/risk assessment.

[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.4(135) Lead hazard reduction required.

68.4(1) When the certified inspector appointed by the local board determines that hazardous lead-based paint, a dust-lead hazard, or a soil-lead hazard is present in a residential dwelling unit or child-occupied facility where an EBL child lives, frequently visits, or has recently resided, the inspector shall issue a written notice to the owner within two weeks of the inspection and receipt of any laboratory results. The written notice shall require the owner to complete lead hazard reduction in a time period determined by the inspector. If the occupant who occupies the residential dwelling at the time that this written notice is issued vacates the residential dwelling, the residential dwelling shall not be leased or occupied by any other person until the inspector issues a written notice that the lead hazard reduction has been completed.

68.4(2) The owner of any residential dwelling or child-occupied facility that has been determined to contain hazardous lead-based paint, a soil-lead hazard, or a dust-lead hazard shall correct these hazards within the time period allowed by the inspector in the written notice. The following methods shall be used for lead hazard reduction. These methods do not require the services of a lead abatement contractor certified in accordance with rule 641—70.5(135). However, other local, state, or federal regulations may require the use of a contractor who has completed an eight-hour lead-safe work practices course or a lead abatement contractor or lead abatement worker certified in accordance with rule 641—70.5(135).

a. On a surface that contains hazardous lead-based paint but is not chewable and does not have evidence of impact or friction, the lead-based paint hazard shall be reduced by removing all loose and deteriorated paint from the surface, preparing the surface for repainting, and repainting the surface with a lead-free coating.

b. On a surface that contains hazardous lead-based paint and is chewable or has evidence of impact or friction, the lead-based paint hazard shall be reduced by treating the surface 1 inch back from the edge or corner through one of the following methods:

(1) All lead-based paint on the treatment area shall be removed to the bare substrate. The surface shall be prepared for repainting and repainted with a lead-free coating.

(2) The treatment area shall be covered with a permanently affixed lead-free material such as plastic, wood, or vinyl. Carpet may be used on floors and stair treads.

c. Dust-lead hazards shall be reduced by thoroughly cleaning the affected surface.

d. Soil-lead hazards shall be reduced by planting grass or groundcover, applying sod, or covering the affected area with 6 inches of bark, gravel, or other material.

e. Lead hazard reduction shall be conducted using lead-safe work practices to protect the safety of the occupants and workers. Occupants shall not enter the work area while work is underway. The following are prohibited methods of lead hazard reduction:

(1) Open-flame burning or torching of lead-based paint.

(2) Machine sanding or grinding or abrasive blasting or sandblasting of lead-based paint unless used with high-efficiency particulate air (HEPA) exhaust control that removes particles of 0.3 microns or larger from the air at 99.97 percent or greater efficiency.

(3) Uncontained water blasting of lead-based paint.

(4) Dry scraping or dry sanding of lead-based paint except in conjunction with the use of a heat gun or around electrical outlets.

(5) Operating a heat gun at a temperature above 1,100 degrees Fahrenheit.

68.4(3) The inspector shall inspect all areas identified as hazards after lead hazard reduction is complete. The inspector may conduct clearance testing pursuant to 641—Chapter 70 to ensure that no dust-lead hazards exist after the work is complete. Within two weeks of verifying that all lead hazard reduction has been completed as required, the inspector shall issue a written notice to the owner and

occupant stating that the lead hazard reduction has been completed and that the repaired surfaces must be maintained in good condition.
[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.5(135) Retaliation prohibited.

68.5(1) The lessor of a dwelling, the employees of the lessor, and agents or persons acting on behalf of the lessor shall not retaliate against lessees of residential dwellings and child-occupied facilities whose occupants or visitors have been tested for lead poisoning and shall not discourage the occupants or visitors from being tested for lead poisoning.

68.5(2) An action taken against the lessee is not considered retaliation if it is supported by reasonable cause unrelated to the testing of an occupant for lead poisoning or if it is shown to have occurred as a result of an accident or mistake and not to be the intentional act of the lessor of a dwelling, the employees of the lessor, or agents or persons acting on behalf of the lessor.
[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.6(135) Enforcement. The inspector appointed by the local board will have the duty and responsibility of enforcing this chapter.

68.6(1) Penalties are as provided in Iowa Code section 137.117.

68.6(2) Upon failure of any person to correct a hazard identified through this chapter in the time specified by the inspector appointed by the local board, the local board may direct or cause the correction of said hazards. All expenses incurred thereby may be recovered by suit in the name of the local board, or the local board may certify the amount of the expenses, together with a description of the property, to the county treasurer, who will enter the same into the tax roll as costs for removing a lead hazard, and the amounts will be collected as other taxes.
[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.7(135) Hearings. In the event any person is aggrieved by any order of the inspector, the person may appeal to the local board in writing within ten days of the date of such order. The appeal shall state the reasons for requesting the order to be rescinded or modified. The local board will review the action of the inspector. The local board will order compliance with the order or may, with cause, modify or withdraw the order. Any order of the local board may be appealed within ten days to the district court for the county in which the local board is located.
[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.8(135) Variances. The inspector may determine that a chewable surface that would otherwise be identified as a hazard by this chapter is not causing or does not have reasonable potential to cause lead exposure and is not required to be corrected through lead hazard reduction. The inspector shall document the reason for this determination in the inspection report. However, the inspector shall not, under any circumstances, determine that any other surface meeting the definition of hazardous lead-based paint does not need to be corrected through lead hazard reduction.
[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.9(135) Injunction. Nothing in this chapter prevents a local board from pursuing injunctive relief or other relief as allowed by law.
[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

641—68.10(135) Effective date. This chapter will be in effect in a jurisdiction after a local board adopts it.
[**ARC 9071C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code section 135.102.

[Filed 7/16/04, Notice 5/26/04—published 8/4/04, effective 9/8/04]
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CHAPTER 69
RENOVATION, REMODELING, AND REPAINTING—LEAD HAZARD NOTIFICATION PROCESS

Transferred to 481—Chapter 469, IAC Supplement 4/2/25

CHAPTER 70
LEAD-BASED PAINT ACTIVITIES

Transferred to 481—Chapter 470, IAC Supplement 4/2/25

CHAPTER 71
EMERGENCY INFORMATION SYSTEM ON PESTICIDES FOR USE BY HEALTH CARE PROVIDERS DURING MEDICAL EMERGENCIES

Rescinded **ARC 9073C**, IAB 4/2/25, effective 6/1/25

CHAPTER 72
CHILDHOOD LEAD POISONING PREVENTION PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—72.1(135) Definitions.

"Approved program" means a program that meets the requirements of Iowa Code section 135.104 and has been approved by the department.

"Local board" means a county, district, or city board of health.

[**ARC 9074C**, IAB 4/2/25, effective 6/1/25]

641—72.2(135) Approved programs.

72.2(1) A local board of health representing a geographic area with a population of at least 15,000 is eligible to apply for status as an approved program pursuant to Iowa Code section 135.104, which sets forth the eligibility requirements contained in the application.

72.2(2) A local board wishing to apply for status as an approved program shall make application to the department in the format available from the department. All materials submitted as part of the application for status as an approved program are public records.

[**ARC 9074C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code sections 135.100 through 135.105.

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CHAPTER 73
SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC)

[Prior to 7/29/87, Health Department[470] Ch 73]
Rescinded **ARC 9168C**, IAB 4/30/25, effective 7/1/25

CHAPTER 74
FAMILY PLANNING SERVICES

[Prior to 7/29/87, Health Department[470] Ch 74]
Rescinded **ARC 9169C**, IAB 4/30/25, effective 7/1/25

CHAPTER 75
DISTRIBUTION OF FEDERAL FUNDS RESTRICTIONS—PROVIDER IDENTIFICATION AND ATTESTATION

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—75.1(88GA,ch85,90GA,ch19) Definitions.

"Administer" means to implement programs through contracts entered into by the department and selected private, governmental, and nonprofit organizations to provide programming directly to participants. "Administer" does not mean the evaluation of programs or the management of federal performance measures data collection. "Administer" also does not mean providing training and technical assistance.

"CAPP" means the community adolescent pregnancy prevention program using federal temporary assistance for needy families block grant funds appropriated to the department.

"Family planning" means the promotion of reproductive and family health through education, prevention of pregnancy, planning for pregnancy, and reproductive health services.

"FPP" means the state-funded family planning program that is a limited insurance coverage for men and women who are 12 to 54 years of age.

"Nonprofit health care delivery system" means an Iowa nonprofit corporation that controls, directly or indirectly, a regional health care network consisting of hospital facilities and various ambulatory and clinic locations that provide a range of primary, secondary, and tertiary inpatient, outpatient, and physician services.

"PREP" means the personal responsibility education program as specified in 42 U.S.C. Section 713 (as amended to January 1, 2024).

"SRAE" means the Sexual Risk Avoidance Education Grant Program authorized pursuant to Section 510 of Title V of the federal Social Security Act, 42 U.S.C. Section 710) as amended by the Consolidated Appropriations Act of 2022 (Public Law 117-103) and extended by division B, Title I, section 142, of the Further Additional Continuing Appropriations and Other Extensions Act, 2024 (Public Law 118-35), and the Further Consolidated Appropriations Act, 2024.

"Title X" refers to the federal requirements contained in 42 CFR Subpart A, Part 59 (as amended to August 1, 2024), and the Program Guidelines for Project Grants for Family Planning Services.

[**ARC 9170C**, IAB 4/30/25, effective 7/1/25]

641—75.2(88GA,ch85,90GA,ch19) Identification numbers. The department will assign a unique identification number to each distinct location of a nonprofit health care delivery system receiving funds from the department to administer programs under:

75.2(1) The Title X family planning program;

75.2(2) PREP;

75.2(3) SRAE;

75.2(4) FPP; and

75.2(5) CAPP grants.

[**ARC 9170C**, IAB 4/30/25, effective 7/1/25]

641—75.3(88GA,ch85,90GA,ch19) Attestation. Each applicant, grantee, grantee contractor, or grantee subcontractor, and each distinct location of a nonprofit health care delivery system receiving funds from the department as enumerated in rule 641—75.2(88GA,ch85,90GA,ch19) shall provide to the department, on forms prescribed by the department, a signed attestation that abortions are not performed at the distinct location.

[**ARC 9170C**, IAB 4/30/25, effective 7/1/25]

These rules are intended to implement 2019 Iowa Acts, chapter 85, sections 98 through 100, and 2023 Iowa Acts, chapter 19, section 346.

[Filed ARC 4829C (Notice ARC 4672C, IAB 9/25/19), IAB 12/18/19, effective 1/22/20]

[Filed ARC 9170C (Notice ARC 8530C, IAB 12/11/24), IAB 4/30/25, effective 7/1/25]

CHAPTER 76
MATERNAL AND CHILD HEALTH PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—76.1(135) Definitions.

"Care/service coordination" or *"care coordination"* means a comprehensive, family-centered approach that proactively engages and links clients and families to needed health care services, including medical, dental, emotional, behavioral, and health education services. Care coordination encompasses a specific set of activities that promote a client's potential for optimal health and facilitate quality outcomes. By working with the client, family, and other involved disciplines, a care coordinator can promote seamless access and a holistic approach to service provision. Care coordination incorporates the following:

1. Meaningful assessment of needs and concerns.
2. Shared development of care plans.
3. Mobilization of agency and community resources.
4. Continued monitoring and follow-up.
5. Clear and transparent communication.
6. Complete documentation.

"Children and youth with special health care needs" or *"CYSHCN"* means children and youth with chronic physical, developmental, behavioral, or emotional conditions that require health and related services of a type or amount beyond that required by children and youth generally.

"CHSC" means child health specialty clinics, a statewide program for children and youth with special health care needs authorized under Title V of the Social Security Act as amended to August 1, 2024.

"Client" means an individual who receives MCH services through a contract agency.

"Contract agency" means a private nonprofit or public agency that has a contract with the department to provide MCH services and receives funds from the department for that purpose.

"DHHS" means the United States Department of Health and Human Services.

"Family," for the purpose of establishing eligibility, means a group of two or more persons related by birth, marriage or adoption or residing together and functioning as one socioeconomic unit. For the purpose of these rules, a pregnant woman is considered as two individuals when calculating the number of individuals in the family. If a pregnant woman is expecting multiple births, the family size is thereby increased by the number expected in the multiple birth.

"Family planning" means the promotion of reproductive and family health by the prevention of and planning for pregnancy, and reproductive health education.

"Gap filling" means direct health care services supported by Title V staff or resources that are not otherwise accessible in the community.

"Hawki" means healthy and well kids in Iowa and is the child health insurance program in Iowa as authorized in Title XXI of the Social Security Act as amended to August 1, 2024.

"Health care services" means services provided through MCH contract agencies.

"Health professional" means an individual who possesses specialized knowledge in a health or social science field or is licensed to provide health care.

"Medicaid" means the Medicaid program authorized by Title XIX of the Social Security Act, as amended to August 1, 2024, and funded through the Iowa department of health and human services from the DHHS.

"Presumptive eligibility determination" means temporary Medicaid eligibility that pays for medical services while a formal Medicaid decision is being made by the department. Presumptive eligibility is available for children, youth, and pregnant women.

"Title V" means Title V of the Social Security Act and the federal requirements contained in the Omnibus Reconciliation Act of 1989 (Public Law 101-239, as amended to August 1, 2024) that address the MCH and CYSHCN programs.

"Title X" means the program authorized in the federal regulations found in 42 CFR Subpart A, Part 59, published in the Federal Register on June 3, 1980, as amended to August 1, 2024, and the Program Guidelines for Project Grants for Family Planning Services as amended to August 1, 2024.

"Title XIX" means the Medicaid program authorized in the Social Security Act, as amended to August 1, 2024, and funded through the department from the DHHS.

"Title XXI" means the child health insurance program authorized in the Social Security Act, as amended to August 1, 2024, and implemented in Iowa as the hawki program as administered by the department.

"WIC" means the Special Supplemental Nutrition Program for Women, Infants, and Children, funded through the department from the United States Department of Agriculture.

[**ARC 9171C**, IAB 4/30/25, effective 7/1/25]

641—76.2(135) Client eligibility criteria. The certification process to determine eligibility for direct health care under the program shall include the following requirements:

76.2(1) *Age.*

a. Maternal health program—no age restrictions.

b. Child health program—birth through 21 years of age.

c. CYSHCN program—birth through 21 years of age.

76.2(2) *Income.*

a. Income guidelines will be the same as those established for the state's Title XXI program. Guidelines are published annually by DHHS. Department income guidelines will be adjusted following any change in DHHS guidelines.

b. Income information will be provided by the individual.

c. Proof of Title XIX, Title XXI (hawki), or WIC eligibility will automatically serve in lieu of an application.

d. All income of family members as defined by DHHS poverty guidelines will be used in calculating the individual's gross income for purposes of determining initial and continued eligibility.

e. Income will be calculated as follows:

(1) Annual income will be estimated based on the individual's income for the past three months unless the individual's income will be changing or has changed, or

(2) In the case of self-employed families the past year's income tax return (adjusted gross income) will be used in estimating annual income unless a change has occurred,

(3) Terminated income will not be considered.

f. Individuals will be screened for eligibility for Title XIX, Title XXI (hawki), and WIC. If an individual's income falls within the eligibility guidelines for Title XIX, Title XXI (hawki), or WIC, the individual may be referred to the department or other enrollment source to apply for coverage. Children, youth and pregnant women will be considered for Title XIX presumptive eligibility.

g. An individual whose income is above the poverty level established by Title XXI and below 302 percent of the federal poverty guidelines will qualify for services on a sliding fee scale, as determined by the local agency's cost for the service. The department provides annual guidelines based on poverty levels established annually by DHHS. An individual whose income is at or above 302 percent will qualify for services at full fee.

h. Eligibility determinations must be performed at least once annually. Should the individual's circumstances change in a manner that affects third-party coverage or Title XIX/Title XXI eligibility, eligibility determinations will be completed more frequently.

76.2(3) *Residency.* Individuals must be currently residing in Iowa.

76.2(4) *Pregnancy.* An individual applying for the prenatal program shall have verification of pregnancy by an independent health provider, the maternal health contract agency, a family planning (Title X) agency, or a positive home pregnancy test.

76.2(5) *Children and youth with special health care needs.* An individual applying for CHSC services will be determined to have a special health care need as defined by the federal MCHB. Care/service coordination, family support or other non-clinic services are provided at no charge to the family. Clinic services are provided without charge to families with adjusted gross incomes below 185 percent of the

federal poverty guidelines. Families above this threshold are responsible for payment according to a sliding fee scale based on tax exemptions, adjusted gross income, and extenuating circumstances.
[**ARC 9171C**, IAB 4/30/25, effective 7/1/25]

641—76.3(135) Client application procedures for MCH services. A person or the parent or guardian of a minor desiring direct health services other than those provided to children and youth with special health care needs may apply to a contract agency using a manner prescribed by the department. Individuals requesting presumptive eligibility must complete a form prescribed by the department, or the alternate form authorized by the medical assistance advisory council.
[**ARC 9171C**, IAB 4/30/25, effective 7/1/25]

These rules are intended to implement Iowa Code section 135.11.

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CHAPTER 77
LOCAL BOARDS OF HEALTH
[Prior to 7/29/87, Health Department[470] Ch 77]

Chapter rescission date pursuant to Iowa Code section 17A.7: 11/1/30

641—77.1(137) Definitions. For the purpose of these rules, the following definitions apply:

"Core public health functions" means the functions of assessment, policy development, and assurance.

1. Assessment: regular collection, analysis, interpretation, and communication of information about health conditions, risks, and assets in a community.

2. Policy development: development, implementation, and evaluation of plans and policies, for public health in general and priority health needs in particular, in a manner that incorporates scientific information and community values and in accordance with state public health policy.

3. Assurance: ensuring by encouragement, regulation, or direct action that programs and interventions that maintain and improve health are carried out.

"District" means the same as defined in Iowa Code section 137.102.

"District board" means the same as defined in Iowa Code section 137.102.

"District health department" means the same as defined in Iowa Code section 137.102.

"Environmental health services" means services focused on the environment to support population-based health services.

"Essential public health services" means those activities carried out by public health that fulfill the core functions.

"Local board of health" means the same as defined in Iowa Code section 137.102.

"Personal health services" means services focused on the care of individuals.

"Population-based health services" means services focused on the health status of population groups and their environments.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.2(137) Local boards of health—roles and responsibilities. Public health is responsible for safeguarding the community's health. This goal is pursued through three core functions: assessment, policy development and assurance.

77.2(1) Assessment: regularly and systematically collect, assemble, analyze, and make available information on the health of the community, including statistics on health status, community health needs, personal health services, and epidemiologic and other studies of health problems. A local board of health may perform the following essential public health services:

a. Monitor health status to identify community health problems;

b. Diagnose and investigate health problems and health hazards in the community; and

c. Evaluate effectiveness, accessibility, and quality of personal, population-based, and environmental health services.

77.2(2) Policy development: exercise responsibility to serve the public interest in the development of comprehensive public health policies. This core function can be accomplished by promoting use of a scientific knowledge base in decision making about public health and by taking the lead in public health policy development.

a. A local board of health may perform the following essential public health services:

(1) Develop policies and plans that support individual and community health efforts; and

(2) Research new insights and innovative solutions to health problems and health threats.

b. A local board of health shall perform the following essential public health services:

(1) Enforce laws and regulations that protect public health and enforce lawful orders of the department;

(2) Make and enforce reasonable rules and regulations not inconsistent with the law or the rules of the department as may be necessary for the protection and improvement of public health; and

(3) Employ persons as necessary for the efficient discharge of the board's duties. Employment practices shall meet the requirements of Iowa Code chapter 8A, subchapter IV, or any civil service provision adopted under Iowa Code chapter 400.

77.2(3) Assurance: assure constituents that services necessary to achieve agreed-upon goals are provided either by encouraging action by other entities (private or public sector), by requiring such action through regulation, or by providing services directly. Each local board of health must involve key policymakers and the general public in determining a set of high-priority personal and population-based health services. A local board of health may perform the following essential public health services:

a. Link people to needed personal health services; provide such personal, population-based and environmental health services as deemed necessary for the promotion and protection of the health of the public; and charge reasonable fees for personal health services;

b. Ensure the competence of the public health, environmental health, and personal health care workforce;

c. Inform, educate, and empower people about health issues;

d. Mobilize community partnerships to identify and solve health problems;

e. Issue licenses and permits and charge reasonable fees in relation to the construction or operation of nonpublic water supplies or private sewage disposal systems;

f. Engage in joint operations by:

(1) Contracting with colleges and universities; the department; other public, private, and nonprofit agencies; and individuals; or

(2) Forming a district health department to provide personal and population-based health services; and

g. Enforce, by written agreement with the council of any city within its jurisdiction, appropriate ordinances of the city relating to public health.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.3(137) Organization of local boards of health.

77.3(1) *Qualifications.* Members of a local board of health should have experience or education related to the core public health functions, essential public health services, public health, environmental health services, personal health services, population-based services, or community-based initiatives.

77.3(2) *Officers of local boards of health.* Each local board of health shall, at its first meeting during any calendar year, elect one of its members to serve as chairperson until the first meeting of the following calendar year.

a. The local board of health may elect a vice-chairperson, secretary, or other such officers as it may deem advisable.

b. In case of a vacancy of the office of chairperson, a successor, who shall serve the remainder of the term, shall be elected at the next meeting of the board.

77.3(3) *Meetings of local boards of health.* The place, date and time of regular meetings of the local board of health shall be determined by vote of the board, and such meetings shall comply with the provisions of the open meetings law in Iowa Code chapter 21.

a. Each local board of health shall meet at least six times per year.

b. Special meetings of a local board of health may be called, as needed, by the chairperson or by any three board members. The local board of health shall provide at least 24 hours' notice of special meetings, except in case of emergency.

c. A majority of the members of a local board of health shall be considered a quorum, and an affirmative vote of the majority of the members present is necessary for action taken by a local board of health. The majority shall not include any member who has a conflict of interest, and a statement by the member that a conflict of interest exists shall be conclusive for this purpose.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.4(137) Expenses of local board of health members.

77.4(1) The following may be considered necessary expenses of local board of health members:

a. Travel in private car on local board of health business at the same rate as provided for a public officer or employee in Iowa Code section 70A.9.

b. Lodging and meal expenses, including sales tax on lodging and meals.
c. Expense of public transportation when traveling on local board of health business.
d. Miscellaneous expenses related to performance of duties as approved by the local board of health.
e. Training and education expenses.

77.4(2) This rule shall not be construed as requiring the payment of reimbursement to any person or as prohibiting local boards of health from imposing additional restrictions or administrative requirements on expenses of their members.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.5(137) Dissolution of city boards. A city board of health may voluntarily dissolve by submitting notice to the department. The notice shall set an effective date for the action.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.6(137) Request to form district board of health. The county boards of health of any two or more geographically contiguous counties may at any time submit to the department a written request to form a district board of health in accordance with Iowa Code section 137.106.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.7(137) Review, approval or denial of district board of health formation.

77.7(1) Upon receipt of the application form and all information contained in rule 641—77.6(137), the department will review such information and shall determine, within 30 days, whether the required elements have been presented by the proposed district and will provide notice of approval of district board of health formation, including effective dates, to the county board of health of each county in the district and to the board of supervisors of each county in the district.

77.7(2) Upon receipt of the notice of approval of district board of health formation, each appointing authority shall, prior to the effective date of district board of health formation, appoint district board of health members as specified in Iowa Code section 137.105.

77.7(3) The department has the authority to deny formation of a district board of health if the application fails to conform with Iowa Code chapter 137 or this chapter.

77.7(4) The department will notify, in writing, all local boards of health in the proposed district of the reason and rationale for the denial of the district board of health formation within 30 days of the decision.

77.7(5) The local boards of health in the proposed district have the right to request reconsideration of the decision by submitting the request to the department within 30 days of receiving notice of the decision.

77.7(6) The department will reconsider the request by the local boards of health. The reconsideration shall not constitute a contested case hearing. The department's final decision following reconsideration shall constitute final agency action pursuant to Iowa Code section 17A.19, and judicial review of any such decision shall be treated as other agency action.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.8(137) Adding to a district board of health. A county may be added to an existing district board of health by submission and approval of a request as specified in Iowa Code sections 137.106 and 137.107.

[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

641—77.9(137) Withdrawal from a district board of health. A county may voluntarily withdraw from a district board of health by submitting a request for withdrawal to the department for approval. The request shall include a timeline and plan to reestablish a county board of health or to join a different district board of health to provide the core public health functions and essential public health services to the county's geographic area.

77.9(1) If the department approves the request for withdrawal of the applicant county from the district board of health, an effective date will be set for the action and the department will notify the district board of health and the board of supervisors of the applicant county.

77.9(2) The ownership of property and equipment shall follow the guidelines submitted in the original request to form the district board of health.

77.9(3) The remaining counties in the district shall submit an application including the information specified in rule 641—77.6(137) to the department for review as provided in Iowa Code section 137.107.
[**ARC 9561C**, IAB 9/17/25, effective 11/1/25]

These rules are intended to implement Iowa Code chapter 137.

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CHAPTER 78
PERSONAL RESPONSIBILITY EDUCATION PROGRAM AND TITLE V STATE SEXUAL RISK AVOIDANCE EDUCATION GRANT PROGRAM FUNDING AND RESTRICTIONS

Rescinded **ARC 9172C**, IAB 4/30/25, effective 7/1/25

CHAPTER 79
PUBLIC HEALTH NURSING

[Prior to 7/29/87, Health Department[470] Ch 79]
Rescinded IAB 4/11/07, effective 7/1/07; see 641—Ch 80

CHAPTER 80
LOCAL PUBLIC HEALTH SERVICES
[Prior to 8/3/94, "Homemaker-Home Health Aide Services"]
[Prior to 4/11/07, see also 641—Ch 79]

Chapter rescission date pursuant to Iowa Code section 17A.7: 11/1/30

641—80.1(135) Definitions. For the purposes of these rules, the following definitions apply:

"Allocation" means the process to distribute funds.

"Appropriation" means the funding amount approved in the state budget.

"Contractor" means a local board of health.

"Core public health functions" means the same as defined in 641—Chapter 77.

"Elderly" means an individual aged 60 years and older.

"Essential public health services" means a framework for public health to promote and protect the health of all people in all communities.

"Formula" means the mathematical calculation applied to the state appropriation and granted to each local board of health pursuant to Iowa Code section 135.11(10) to determine the amount of available funds to be distributed to each county.

"Local board of health" or *"LBOH"* means a county or district board of health as defined in Iowa Code chapter 137.

"Low income" means the U.S. Census Bureau's small area income and poverty estimates (SAIPE) used to determine low income.

"LPHS" means local public health services.

"Public health intervention" means an organized effort to promote behaviors and habits that can improve physical, mental, and emotional health for specific groups of people.

[**ARC 9562C**, IAB 9/17/25, effective 11/1/25]

641—80.2(135) Contractor assurances. A contractor may directly provide or subcontract all or part of the delivery of essential public health services and public health interventions and will ensure the terms of its contract with the department are fulfilled.

[**ARC 9562C**, IAB 9/17/25, effective 11/1/25]

641—80.3(135) Utilization of LPHS contract funding. A contractor may bill the department for staff time, salaries and benefits, and other necessary costs to implement the approved essential public health services and interventions.

[**ARC 9562C**, IAB 9/17/25, effective 11/1/25]

641—80.4(135) LPHS funds.

80.4(1) Allocation for LPHS funds to each contractor is determined by the following formula:

a. Eighteen percent of the total LPHS funds will be divided so that an equal amount is available for use in each county in the state.

b. Eight percent of the total LPHS funds will be allocated to each county according to the county's population based upon the published data of the U.S. Census Bureau, which is the most recent data available three months prior to the release of the LPHS application.

c. Forty-four percent of the total LPHS funds will be allocated according to the proportion of state residents who are elderly persons living in a county based upon the bridged-race population estimates produced by the U.S. Census Bureau in collaboration with the National Center for Health Statistics (NCHS).

d. Thirty percent of the total LPHS funds will be allocated according to the proportion of state residents who are low-income persons living in a county based upon the U.S. Census Bureau's SAIPE.

80.4(2) The department will annually determine the potential for unused funds from contracts. Reallocation of the funds will be at the discretion of the department.

[**ARC 9562C**, IAB 9/17/25, effective 11/1/25]

These rules are intended to implement Iowa Code section 135.11(10).

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[1] May 16, 2018, effective date of ARC 3747C [80.2, 80.3, 80.4(4)*"f"*(6), 80.5(2)*"a"*(4), 80.6] delayed until the adjournment of the 2019 General Assembly by the Administrative Rules Review Committee at its meeting held May 8, 2018.

CHAPTER 81
GENERAL RULES FOR MIGRATORY LABOR CAMPS
[Prior to 7/29/87, Health Department[470] Ch 81]
Transferred to 481—Chapter 481, IAC Supplement 4/2/25

CHAPTER 82
OFFICE OF MINORITY AND MULTICULTURAL HEALTH
Rescinded **ARC 3604C**, IAB 1/31/18, effective 3/7/18

CHAPTER 83
EARLY CHILDHOOD IOWA COUNCIL
Rescinded IAB 6/2/10, effective 7/7/10

CHAPTER 84
STATE SUBSTITUTE MEDICAL DECISION-MAKING BOARD
Rescinded IAB 6/2/10, effective 7/7/10

CHAPTER 85
LOCAL SUBSTITUTE MEDICAL DECISION-MAKING BOARDS
Rescinded **ARC 3605C**, IAB 1/31/18, effective 3/7/18

CHAPTER 86
PLACES WHERE DEAD HUMAN BODIES ARE PREPARED
FOR BURIAL OR ENTOMBMENT
[Prior to 7/29/87, Health Department[470] Ch 86]
Transferred to 481—Chapter 907, IAC Supplement 4/2/25

CHAPTER 87
HEALTHY FAMILIES IOWA (HFI)
Rescinded **ARC 9173C**, IAB 4/30/25, effective 7/1/25

CHAPTER 88
VOLUNTEER HEALTH CARE PROVIDER PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 3/1/31

641—88.1(135) Definitions. For the purpose of these rules, the following definitions will apply:

"Charitable organization" means the same as defined in Iowa Code section 135.24.

"Defend" means that the office of the attorney general will provide the individual volunteer health care provider and protected clinic with legal representation at no cost to the individual volunteer health care provider or protected clinic.

"Field dental clinic" means the same as defined in Iowa Code section 135.24.

"Free clinic" means the same as defined in Iowa Code section 135.24.

"Health care facility" means a residential care facility, a nursing facility, or an intermediate care facility for persons with an intellectual disability.

"Health care provider" means the same as defined in Iowa Code section 135.24.

"Health care services" means services received from a health care provider at a protected clinic or sponsor entity, as provided in Iowa Code section 135.24 and these rules, and approved in a protection agreement or sponsor entity agreement. The agreement covers "health care services" that are volunteer, uncompensated services. For those services to qualify as volunteer, uncompensated services under this chapter, the individual volunteer health care provider, health care provider, protected clinic, or sponsor entity will receive no compensation for any services provided under the agreement and shall not bill or accept compensation from the person, or any public or private third-party payor, for the specific services provided.

"Indemnify" means that the state of Iowa will pay all sums that the individual volunteer health care provider or protected clinic holding a protection agreement with the VHCPP is legally obligated to pay as damages because of any claim made against the individual volunteer health care provider or protected clinic that arises out of the provision of free health care services rendered or that should have been rendered by the individual volunteer health care provider or protected clinic.

"Individual volunteer health care provider" means any one of the health care providers defined in Iowa Code section 135.24 who has a fully executed protection agreement with the VHCPP.

"License" means a license, certification or registration issued to a person by a licensing authority that evidences the granting of authority to engage in a profession or occupation.

"Major surgical procedure" means a surgical procedure not ordinarily performed in a private provider's office, free clinic, or specialty health care provider office and includes the surgery performed in a hospital as defined in Iowa Code section 135B.1(3) or an organized outpatient health facility.

"Minor surgical procedure" means a surgical procedure ordinarily performed in a private provider's office, free clinic, or specialty health care provider office.

"Organized outpatient health facility" means a facility defined in Iowa Code section 10A.711.

"Permanent site" means a site at which free health care services will be provided on a continuous basis.

"Protected clinic" means field dental clinic, free clinic, or specialty health care provider office providing free care to the uninsured and underinsured. Each protected clinic has a signed protection agreement that provides for defense and indemnification of the protected clinic. The protection agreement will allow the protected clinic to deliver health care services to uninsured and underinsured persons as an agent of the state.

"Protection agreement" means a signed contract providing for defense and indemnification between an individual volunteer health care provider or protected clinic and the VHCPP. This agreement will allow the individual health care provider or protected clinic to deliver health care services to uninsured and underinsured persons as an agent of the state. The agreement covers "health care services" that are volunteer, uncompensated services. For those services to qualify as volunteer, uncompensated services under this chapter, the individual volunteer health care provider, health care provider, and protected clinic will receive no compensation for any services provided under the agreement and will not bill or accept

compensation from the person, or any public or private third-party payor, for the specific services provided by the individual volunteer health care provider covered by the agreement.

"Specialty health care provider office" means the same as defined in Iowa Code section 135.24.

"Sponsor entity" or *"sponsor entity clinic"* means a hospital, clinic, free clinic, health care facility, health care referral program, charitable organization, specialty health care provider office, organized outpatient health facility, or field dental clinic. Each sponsor entity has a fully executed sponsor entity agreement. The sponsor entity agreement will allow an individual volunteer health care provider to deliver health care services to uninsured and underinsured persons as an agent of the state.

"Sponsor entity agreement" means a signed contract between the VHCPP and a hospital, clinic, free clinic, health care facility, health care referral program, charitable organization, specialty health care provider office, organized outpatient health facility, or field dental clinic allowing an individual volunteer health care provider to deliver free health care services through the VHCPP at the sponsor entity location.

"Temporary site" means a site at which free health care services will be provided for a short period of time not to exceed three days. "Temporary site" includes but is not limited to temporary health fairs, flu shot clinics, and temporary sites that provide back-to-school physicals.

"Underinsured" means that a person does not have adequate insurance, which is determined on cost-exposure to family income with at least one of three indicators: (1) out-of-pocket medical expenses equal to or greater than 10 percent of income; (2) out-of-pocket medical expenses equal to or greater than 5 percent of income if income is less than 200 percent of the federal poverty level; and (3) health plan deductibles equal to or greater than 5 percent of income.

"Volunteer health care provider program" or *"VHCPP"* means the volunteer health care provider program of the department.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.2(135) Eligibility for the volunteer health care provider program.

88.2(1) *Individual volunteer health care provider eligibility.* To be eligible for protection as an employee of the state under Iowa Code chapter 669 for a claim arising from covered health care services, an individual volunteer health care provider shall satisfy each of the following conditions at the time of the act or omission allegedly resulting in injury:

a. The individual volunteer health care provider must hold an active unrestricted license, registration, or certification to practice in Iowa under Iowa Code chapter 147A, 148, 148A, 148B, 148C, 149, 151, 152, 152B, 152E, 153, 154, 154B, 154C, 154D, 154F, or 155A. The individual volunteer health care provider shall provide a sworn statement attesting that the license, registration, or certification to practice is free of restrictions. The statement shall describe any disciplinary action that has ever been taken against the individual volunteer health care provider by any professional licensing, registering, or certifying authority or health care facility, including any voluntary surrender of license, registration, or certification or other agreement involving the individual volunteer health care provider's license, registration, or certification to practice or any restrictions on practice, suspension of privileges, or other sanctions. The statement shall also describe any malpractice suits that have been filed against the individual volunteer health care provider. The statement provided by a pharmacist shall also describe any disciplinary action that has ever been taken against any pharmacy in which the pharmacist has ever been owner, partner, or officer.

b. Application. The applicant shall submit the following information on forms provided by the VHCPP:

(1) The individual volunteer health care provider's current licensure identification number and expiration date;

(2) The health care services to be voluntarily provided meet all of the following:

1. The services fall under the individual volunteer health care provider's licensed scope of practice;
2. The services are covered health care services listed in paragraph 88.4(1)*"d"*; and
3. The individual volunteer health care provider applicant is willing to voluntarily provide the health care services to those persons who are uninsured and underinsured for the public health purpose of improved health, prevention of illness/injury, and disease management.

c. Agreement. The individual volunteer health care provider shall have a signed and current protection agreement with the VHCPP that identifies the covered health care services within the respective

scope of practice and conditions of defense and indemnification as provided in rules 641—88.4(135) and 641—88.5(135).

(1) The protection agreement is only valid during the time that the individual volunteer health care provider maintains a current unrestricted license and only for voluntary services provided in conjunction with a sponsor entity or protected clinic that has its own valid VHCPP protection agreement in effect at the time of service provision.

(2) The protection agreement with the VHCPP will provide that the individual volunteer health care provider shall:

1. Perform only those health care services identified and approved by the VHCPP;
2. Promptly notify the VHCPP of any changes in licensure status;
3. Maintain proper records of the health care services provided;
4. Make no representations concerning eligibility for the VHCPP or eligibility of services for indemnification by the state except as authorized by the department;
5. Cooperate fully with the state in the defense of any claim or suit relating to participation in the VHCPP, including attending hearings, depositions and trials and assisting in securing and giving evidence, responding to discovery and obtaining the attendance of witnesses;
6. Accept financial responsibility for personal expenses and costs incurred in the defense of any claim or suit related to participation in the VHCPP, including travel, meals, compensation for time and lost practice, and copying costs, and agree that the state will not compensate the individual volunteer health care provider for the individual volunteer health care provider's expenses or time needed for the defense of the claim or suit;
7. Receive no direct monetary compensation of any kind for services provided in the VHCPP; and
8. Comply with the protection agreement with the VHCPP concerning approved health care services.

88.2(2) *Protected clinic eligibility.* To be eligible for protection as a state agency under Iowa Code chapter 669 for a claim arising from the provision of covered health care services at a protected clinic, the protected clinic will satisfy each of the following conditions at the time of the act or omission allegedly resulting in injury:

a. The protected clinic will comply with subrules 88.3(1) through 88.3(5).

b. The protected clinic will, upon request from the department, provide to the department a list of all health care providers who provided health care services at the protected clinic at the time of a claim made against the individual health care provider or protected clinic that arises out of the provision of free health care service rendered or that should have been rendered by the individual volunteer health care provider or protected clinic.

c. The protected clinic will only be covered under the VHCPP for the provision of covered health care services by a health care provider providing health care services at the protected clinic who either:

(1) Holds a current individual volunteer health care provider protection agreement with the VHCPP, or

(2) Holds current professional liability insurance coverage and an active unrestricted license, registration, or certification to practice in Iowa under Iowa Code chapter 147A, 148, 148A, 148B, 148C, 149, 151, 152, 152B, 152E, 153, 154, 154B, 154C, 154D, 154F, or 155A.

d. The protected clinic will submit a list of the clinic board of directors and contact information for the board of directors, if applicable.

e. If the protected clinic is a charitable organization within the meaning of Section 501(c)(3) of the Internal Revenue Code, the protected clinic will provide proof of Section 501(c)(3) status to the VHCPP.

f. A protected clinic may allow health care profession students to volunteer at the protected clinic provided that the following conditions are satisfied:

(1) The college, university, or other health care profession educational institution provides professional liability insurance that covers the students;

(2) The protected clinic or the health care profession institution provides general liability and professional liability insurance that covers the students; and

(3) The students provide only those services or activities as are authorized by the education agreement, and such services and activities are provided under the on-site supervision of a health care provider.

88.2(3) *Sponsor entity or sponsor entity clinic.* As a condition of sponsoring individual volunteer health care providers in the VHCPP, a hospital, clinic, free clinic, health care facility, health care referral program, charitable organization, specialty health care provider office, organized outpatient health facility, or field dental clinic shall comply with subrules 88.3(1) through 88.3(5).
[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.3(135) Sponsor entity and protected clinic.

88.3(1) Licensure. The sponsor entity or protected clinic shall be licensed to the extent directed by law for the facility in question.

88.3(2) If the sponsor entity or protected clinic is a charitable organization within the meaning of Section 501(c)(3) of the Internal Revenue Code, the sponsor entity or protected clinic shall provide proof of Section 501(c)(3) status to the VHCPP.

88.3(3) Application. The sponsor entity or protected clinic shall submit the following information on forms provided by the VHCPP:

a. By category, the patient groups to be served;

b. The health care services to be provided;

c. The site where free health care services are to be provided;

d. Classification of each site as a permanent site or temporary site; and

e. The services that will be provided to those persons who are uninsured and underinsured for the public health purpose of improved health, prevention of illness/injury, and disease management.

88.3(4) Agreement. A signed and current sponsor entity agreement or protected clinic agreement will exist with the VHCPP that will:

a. Provide that the individual volunteer health care provider or health care provider within a protected clinic and the individual volunteer health care provider within a sponsor entity will perform only those health care services identified and approved by the VHCPP;

b. Identify by category the patient groups to be served;

c. Identify the sites at which the free health care services will be provided;

d. Identify as a permanent site or temporary site for the provision of free health care services through the VHCPP;

e. Provide that the sponsor entity or protected clinic will maintain proper records of health care services for a period of seven years from the date of service or, in the case of a minor, for a period of one year after the minor has reached the age of majority; and

f. Provide that the sponsor entity agrees that only the individual volunteer health care provider or protected clinic covered under a current VHCPP protection agreement at the time of the service provision in a claim is afforded protection under Iowa Code section 135.24 and that the state assumes no obligation to the sponsor entity, its employees, officers, or agents. The sponsor entity or protected clinic shall submit a statement, that will be submitted on forms provided by the VHCPP, attesting that the sponsor entity or protected clinic and its staff, employees and volunteers agree to:

(1) Cooperate fully with the state in the defense of any claim or suit relating to participation in the VHCPP, including attending hearings, depositions and trials and assisting in securing and giving evidence, responding to discovery and obtaining the attendance of witnesses;

(2) Accept financial responsibility for the sponsor entity's or protected clinic's expenses and costs incurred in the defense of any claim or suit related to participation in the VHCPP, including travel, meals, compensation for time and lost practice, and copying costs, and agree that the state will not compensate the sponsor entity or protected clinic for expenses or time needed for the defense of the claim or suit;

(3) Receive no direct monetary compensation of any kind for health care services provided in the sponsor entity or protected clinic; and

(4) Comply with the sponsor entity agreement or protected clinic agreement with the VHCPP concerning approved health care services.

88.3(5) General liability insurance. The sponsor entity or protected clinic shall submit proof of general liability insurance for the clinic site.
[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.4(135) Covered health care services. An individual volunteer health care provider holding a current protection agreement with the VHCPP will be afforded the protection of an employee of the state under Iowa Code chapter 669, and a protected clinic holding a current protection agreement with the VHCPP will be afforded protection as an agency of the state under Iowa Code chapter 669, only for claims for injury alleged to have been proximately caused by an individual volunteer health care provider's provision of covered health care services or solely on the basis of the individual volunteer health care provider's participation in the sponsor entity or protected clinic.

88.4(1) Covered health care services are only those that are:

a. Identified in the protection agreement with the VHCPP;

b. In compliance with these rules;

c. Provided by or under the direct supervision of the individual volunteer health care provider;

d. Health care services of:

(1) Advanced registered nurse practitioners for: well-child examinations; annual adult examinations; diagnosis and treatment of acute and chronic conditions; health education; health maintenance; immunizations; and minor surgical procedures. Certified registered nurse anesthetists may provide anesthesia services for major surgical procedures only if the following conditions are satisfied:

1. The surgery is performed in a hospital as defined in Iowa Code section 135B.1(3) or an organized outpatient health facility;

2. The hospital or organized outpatient health facility at which the surgery is performed has executed a sponsor entity agreement;

3. The physician performing the surgery provides or ensures the provision of adequate presurgical and postsurgical care, including any follow-up necessary to address postoperative complications; and

4. The physician performing the surgery is an individual specialty health care provider or part of a group of specialty health care providers that has registered with the department as a specialty health care provider office.

(2) Audiologists for: testing, measurement and evaluation related to hearing and hearing disorders and associated communication disorders for the purpose of nonmedically identifying, preventing, modifying or remediating such disorders and conditions including the determination and use of appropriate amplification; patient instruction/counseling; patient habilitation/rehabilitation; and referrals.

(3) Bachelor social workers for: psychosocial assessment and intervention through direct contact with clients; referral to other qualified resources for assistance; performance of social histories; problem identification; establishment of goals and monitoring of progress; interviewing techniques; counseling; social work administration; supervision; evaluation; interdisciplinary consultation and collaboration.

(4) Chiropractors for: examinations; diagnosis and treatment; health education; and health maintenance.

(5) Dental assistants for: intraoral services; extraoral services; infection control; radiography; and removal of plaque or stain by toothbrush, floss, or rubber cup coronal polish.

(6) Dental hygienists for: assessments and screenings; health education; health maintenance; and preventive services (cleaning, X-rays, sealants, fluoride treatments, fluoride varnish).

(7) Dentists for: dental examinations; diagnosis and treatment of acute and chronic conditions; health education; health maintenance; and minor surgical procedures.

(8) Emergency medical care providers for: airway/ventilation/oxygenation; assisted medications—patient's; cardiovascular/circulation; immobilization; IV initiation/maintenance/fluids; and medication administration—routes.

(9) Independent social workers for: psychosocial assessment, diagnosis, and treatment; performance of psychosocial histories; problem identification; evaluation of symptoms and behavior; assessment of psychosocial and behavioral strengths and weaknesses and effects of the environment on behavior; psychosocial therapy; differential treatment planning; and interdisciplinary consultation.

(10) Licensed practical nurses for: supportive or restorative care.

(11) Marital and family therapists for: marital and family therapy; and application of counseling techniques in the assessment and resolution of emotional conditions.

(12) Master social workers for: psychosocial assessment, diagnosis, and treatment; performance of psychosocial histories; problem identification; evaluation of symptoms and behavior; assessment of psychosocial and behavioral strengths and weaknesses and effects of the environment on behavior; psychosocial therapy; differential treatment planning; and interdisciplinary consultation.

(13) Mental health counselors for: mental health counseling; and counseling services involving assessment, referral and consultation.

(14) Occupational therapists for: evaluation and treatment of problems interfering with functional performance in persons impaired by physical illness or injury, emotional disorder, congenital or developmental disability or the aging process.

(15) Optometrists for: examinations; diagnosis and treatment of the human eye and adnexa; health education; and health maintenance.

(16) Pharmacists for: drug dispensing; patient counseling; health screenings and education; and immunizations.

(17) Physical therapists for: interpretation of performance, tests, and measurements; evaluation and treatment of human capabilities and impairments; use of physical agents, therapeutic exercises, and rehabilitative procedures to prevent, correct, minimize, or alleviate a physical impairment; establishment and modification of physical therapy program; treatment planning; and patient instruction/education.

(18) Physicians and physician associates for: well-child examinations; annual adult examinations; diagnosis and treatment of acute and chronic conditions; health education; health maintenance; immunizations; and minor surgical procedures. Physicians may perform major surgical procedures only if the following conditions are satisfied:

1. The surgery is performed in a hospital as defined in Iowa Code section 135B.1(3) or an organized outpatient health facility;
2. The hospital or organized outpatient health facility at which the surgery is performed has executed a sponsor entity agreement;
3. The physician provides or ensures the provision of adequate presurgical and postsurgical care, including any follow-up necessary to address postoperative complications; and
4. The physician performing the surgery is an individual specialty health care provider or part of a group of specialty health care providers that has registered with the department as a specialty health care provider office.

(19) Podiatrists for: examinations; diagnosis and treatment; health education; health maintenance; and minor surgical procedures.

(20) Psychologists for: counseling and the use of psychological remedial measures with persons with adjustment or emotional problems.

(21) Registered nurses for: well-child examinations; annual adult examinations; treatment of acute and chronic conditions; health education; health maintenance; and immunizations.

(22) Respiratory therapists for: diagnostic and therapeutic use of administration of medical gases, aerosols, and humidification, not including general anesthesia; pharmacologic agents relating to respiratory care procedures; bronchopulmonary hygiene; specific diagnostic and testing techniques employed in the medical management of patients to assist in diagnosis, monitoring, treatment, and research of cardiopulmonary abnormalities; and pulmonary function testing.

(23) Speech pathologists for: testing, measurement and evaluation related to the development and disorders of speech, fluency, voice or language for the purpose of nonmedically preventing, ameliorating, modifying or remediating such disorders and conditions; patient instruction/counseling; patient habilitation/rehabilitation; and referrals.

88.4(2) Experimental procedures or procedures and treatments that lack sufficient evidence of clinical effectiveness are excluded from the VHCPP.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26; Editorial change: IAC Supplement 6/10/26]

641—88.5(135) Defense and indemnification. The state will defend and indemnify an individual volunteer health care provider or a protected clinic for a claim arising from the VHCPP only to the extent provided by Iowa Code chapter 669 and section 135.24. Persons or entities other than the participating individual volunteer health care provider or protected clinic are not considered state employees or state

agencies under Iowa Code chapter 669. Defense and indemnification of the individual volunteer health care provider or a protected clinic under Iowa Code chapter 669 and section 135.24 will occur only if all of the following are met:

88.5(1) The claim involves medical injury alleged to have been proximately caused by health care services that were identified and approved in the protection or sponsor agreement with the VHCPP and then only to the extent the health care services were provided by or under the direct supervision of the individual volunteer health care provider, including claims based on negligent delegation of health care, or the individual volunteer health care provider is named as a defendant solely because of the individual volunteer health care provider's participation in the protected clinic or sponsor entity clinic.

88.5(2) The claim arises from covered health care services that were performed at a site identified and approved in the protection agreement with the VHCPP.

88.5(3) The claim arises from covered health care services provided through a protected clinic or sponsor entity clinic identified and approved in the individual volunteer health care provider's protection agreement with the VHCPP and that meets the necessities of rule 641—88.2(135).

88.5(4) The individual volunteer health care provider, health care provider, protected clinic, or sponsor entity clinic that provided the health care services receives no direct monetary compensation of any kind and no promise to pay compensation for the health care services that allegedly resulted in medical injury.

88.5(5) The health care services are provided to a patient who is a member of a patient group identified in the sponsor entity or protected clinic protection agreement with the VHCPP.

88.5(6) The individual volunteer health care provider, protected clinic, or sponsor entity clinic is eligible and registered as provided in rule 641—88.2(135) or the care is provided by a health care provider who holds current professional liability insurance coverage and an active unrestricted license to practice in Iowa under Iowa Code chapter 147A, 148, 148A, 148B, 148C, 149, 151, 152, 152B, 152E, 153, 154, 154B, 154C, 154D, 154F, or 155A and has been approved by the VHCPP.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.6(135) Term of agreement.

88.6(1) *Individual volunteer health care provider.* The protection agreement with the VHCPP will expire five years from the date of execution. Individual volunteer health care providers may apply for renewal by filing an application at least 30 days prior to expiration of the protection agreement.

88.6(2) *Protected clinic.* The protection agreement with the VHCPP will expire five years from the date of execution. The protected clinic may apply for renewal by filing an application at least 30 days prior to expiration of the protection agreement. It is anticipated that temporary sites may change over the five-year period. An updated list of temporary site location or service provision changes will be provided to the department for review and acceptance at least one week prior to service provision at the temporary site. Location or service provision changes to permanent sites will necessitate a protection agreement amendment.

88.6(3) *Sponsor entity.* The sponsor entity agreement with the VHCPP will expire five years from the date of execution. Sponsor entities may apply for renewal by filing an application at least 30 days prior to expiration of the sponsor entity agreement. It is anticipated that temporary sites may change over the five-year period. An updated list of temporary site location or service provision changes will be provided to the department for review and acceptance at least one week prior to service provision at the temporary site. Location or service provision changes to permanent sites will necessitate a protection agreement amendment.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.7(135) Reporting necessities and duties.

88.7(1) Upon obtaining knowledge or becoming aware of any injury allegedly arising out of the negligent rendering of, or the negligent failure to render, covered health care services under the VHCPP, a participating individual volunteer health care provider, protected clinic, or sponsor entity will provide to the VHCPP, as soon as practicable, written notice containing, to the extent obtainable, the circumstance of the alleged injury, the names and addresses of the injured, and any other relevant information.

88.7(2) Upon obtaining knowledge or becoming aware of an injury as defined in subrule 88.7(1), the participating protected clinic or sponsor entity will promptly take all reasonable steps to prevent further or other injury from arising out of the same or similar incidents, situations or conditions.

88.7(3) A participating individual volunteer health care provider, protected clinic, or sponsor entity will immediately notify the Iowa Department of Justice, Special Litigation Division, Hoover State Office Building, Des Moines, Iowa 50319, of service or receipt of an original notice, petition, suit or claim seeking damages from the individual volunteer health care provider, protected clinic or sponsor entity related to participation in the VHCPP.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.8(135) Revocation of agreement. The VHCPP may deny, suspend, revoke, or condition the agreement of an individual volunteer health care provider, protected clinic or sponsor entity for cause, including but not limited to:

1. Failure to comply with the protection agreement or sponsor entity agreement with the VHCPP.
2. Violation of state law governing the respective scope of practice or other law governing the health care services provided under the VHCPP.
3. Making false, misleading, or fraudulent statements in connection with the VHCPP, including determination of eligibility of the individual volunteer health care provider, protected clinic, or sponsor entity or handling of a claim against the individual volunteer health care provider, protected clinic, sponsor entity or the state.
4. Evidence of substance abuse or intoxication affecting the provision of health care services under the VHCPP.
5. Reasonable grounds to believe that the individual volunteer health care provider or health care provider may have provided incompetent or inadequate care to a patient under the VHCPP or is likely to do so.
6. Reasonable grounds to believe that the individual volunteer health care provider's, protected clinic's, or sponsor entity's participation in the VHCPP may expose the state to undue risk.
7. Failure to immediately notify the VHCPP of any disciplinary action brought against the individual volunteer health care provider by the applicable state licensing board.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.9(135) Procedure for revocation of agreement. A proceeding for revocation of an individual volunteer health care provider's protection agreement or a protected clinic's protection agreement or a sponsor entity's agreement for participation will be conducted as a contested case proceeding pursuant to Iowa Code chapter 17A. Iowa Code section 17A.18 does not preclude emergency summary suspension of a protection agreement or a sponsor entity agreement. The VHCPP will immediately notify the appropriate licensing board and the appropriate protected clinic or sponsor entity of revocation of an individual volunteer health care provider's protection agreement.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.10(135) Effect of suspension or revocation. If the VHCPP suspends or revokes an individual volunteer health care provider's protection agreement, sponsor entity protection agreement, or protected clinic's protection agreement, the action will suspend or revoke future protection but will not negate defense and indemnification coverage for covered acts or omissions that occurred during the effective dates of the protection agreement.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.11(135) Protection denied.

88.11(1) *Protection denied—appeal procedure.* An applicant who has been denied protection by the VHCPP may appeal the decision according to the provisions set forth in 441—Chapter 2506.

88.11(2) Reserved.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26; Editorial change: IAC Supplement 6/10/26]

641—88.12(135) Board notice of disciplinary action. The applicable state licensing board will notify the VHCPP of the initiation of a contested case against a protected individual volunteer health care provider or the imposition of disciplinary action, including providing copies of any contested case decision or settlement agreement with the protected individual volunteer health care provider upon request of the VHCPP.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.13(135) Effect of eligibility protection. A fully executed protection agreement of an individual volunteer health care provider or protected clinic as eligible for participation in the VHCPP by the applicable state licensing board and the department is solely a determination that the state will defend and indemnify the individual volunteer health care provider or the protected clinic to the extent provided by Iowa Code section 135.24 and these rules. The protection is not an approval or indication of ability or competence and will not be represented as such. The protected clinic or sponsor entity through which the individual volunteer health care provider provides free health care services will retain responsibility for determining that health care personnel are competent and capable of adequately performing the health care services to be provided.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

641—88.14(135) Reporting by a protected clinic or sponsor entity. A reporting form will be provided by the VHCPP to the participating protected clinic or sponsor entity at the time the protected clinic or sponsor entity agreement is approved by the VHCPP. Within 60 days following each calendar quarter, the protected clinic or sponsor entity will provide a report to the VHCPP. At a minimum, the report will include the number of clinic patients receiving free health care services and patient demographics by age, ethnicity, and insurance status.

[**ARC 9956C**, IAB 1/7/26, effective 3/1/26]

These rules are intended to implement Iowa Code section 135.24.

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[Editorial change: IAC Supplement 6/10/26]

CHAPTER 89
PARENTAL NOTIFICATION OF INTENT TO TERMINATE A PREGNANCY THROUGH ABORTION

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—89.1(135L) Definitions.

"Abortion" means an abortion as defined in Iowa Code chapter 146C.

"Court" means juvenile court.

"Grandparent" means the same as defined in Iowa Code chapter 135L.

"Licensed physician" means a physician as licensed by the Iowa board of medicine.

"Medical emergency" means the same as defined in Iowa Code chapter 135L.

"Minor" means the same as defined in Iowa Code chapter 135L.

"Parent" means the same as defined in Iowa Code chapter 135L.

[**ARC 9174C**, IAB 4/30/25, effective 7/1/25]

641—89.2(135L) Notification of parent prior to the performance of abortion on a pregnant minor.

89.2(1) Notification is made to the parent pursuant to Iowa Code section 135L.3, unless a judicial waiver is granted as provided in Iowa Code section 135L.3, or unless any of the conditions of rule 641—89.3(135L) have been met.

a. The notification form shall be in duplicate and may be provided by the department and include, at a minimum, the following:

(1) The name of the minor.

(2) Notification of the intent to terminate the pregnancy.

(3) The name, address, and relationship of the person to be notified.

b. The licensed physician who performs the abortion will keep the original notification form as a part of the minor's medical record relating to the termination of the pregnancy.

c. A copy of the completed notification form is provided to the pregnant minor.

89.2(2) Reserved.

[**ARC 9174C**, IAB 4/30/25, effective 7/1/25]

641—89.3(135L) Notification procedures in the event of an exception.

89.3(1) The licensed physician who performs the abortion will keep all written documentation as a part of the minor's medical record relating to the termination of the pregnancy.

89.3(2) Upon receipt of the written statement from the pregnant minor, the licensed physician who performs the abortion provides notification to a grandparent of the pregnant minor, specified by the pregnant minor, in the manner in which the notification of a parent was prescribed in rule 641—89.2(135L).

a. The notification form shall be in duplicate and may be provided by the department, and include, at a minimum, the following:

(1) The name of the minor.

(2) Notification of the intent to terminate the pregnancy.

(3) The name, address, and relationship of the person to be notified.

(4) A declaration that informs the grandparent of the pregnant minor that the grandparent of the pregnant minor may be subject to civil action if the grandparent accepts notification.

(5) A provision that the grandparent of the pregnant minor may refuse acceptance of notification and a provision that the grandparent immediately contact the licensed physician if refusing acceptance of the notification.

b. A copy of the completed notification form is to be provided to the pregnant minor.

[**ARC 9174C**, IAB 4/30/25, effective 7/1/25]

These rules are intended to implement Iowa Code chapter 135L.

[Filed emergency 11/14/96 after Notice 10/9/96—published 12/4/96, effective 1/1/97]

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CHAPTER 90
STATE MORTALITY REVIEW COMMITTEE

Chapter rescission date pursuant to Iowa Code section 17A.7: 4/1/30

641—90.1(135) Definitions.

"Child abuse assessment" means an assessment performed in accordance with Iowa Code section 232.71B.

"Child fatality" means the death of a child under the age of 18.

"Committee" means the state mortality review committee.

"Maternal death" means any death occurring while a woman is pregnant or within one year of the end of the pregnancy from any cause. This includes deaths resulting from abortions, ectopic pregnancies and all deaths during pregnancy, childbirth, puerperium or deaths from complications of childbirth.

"Multidisciplinary team" means the group of individuals as defined in Iowa Code section 235A.13.

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.2(135) Agency. The state mortality review committee is established in the department. The department will provide staffing and administrative support to the committee.

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.3(135) Membership. Committee membership will be determined pursuant to Iowa Code section 135.43(2).

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.4(135) Officers. The committee will elect a chairperson, a vice chairperson, and other officers as deemed necessary by the committee. Officers will be elected at the first meeting of each fiscal year. Vacancy in the office of the chairperson will be filled by elevation of the vice chairperson. Vacancy in the office of the vice chairperson will be filled by election at the next meeting after the vacancy occurs. The chairperson will preside at all meetings of the committee. If the chairperson is absent or unable to act, the vice chairperson will perform the duties of the chairperson. When so acting, the vice chairperson will have all the powers of and be subject to all restrictions upon the chairperson. The vice chairperson will also perform such other duties as may be assigned by the chairperson.

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.5(135) Subcommittees.

90.5(1) The committee may establish temporary or permanent subcommittees pursuant to Iowa Code sections 135.40, 135.43 and 135.110.

90.5(2) The committee shall establish appointment provisions, membership terms, operating guidelines, and other operational requirements for any subcommittees established.

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.6(135) Liaisons. Liaisons will be designated pursuant to Iowa Code section 135.43(5).

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.7(135) Meetings. The committee will meet pursuant to Iowa Code section 135.110(3).

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.8(135) Duties and responsibilities.

90.8(1) The committee will be responsible for the duties established in Iowa Code sections 135.43(3) and 135.110(1).

90.8(2) The committee will conduct comprehensive, multidisciplinary reviews of maternal deaths or other deaths in Iowa to residents to identify factors associated with the deaths and make recommendations for system changes to prevent future deaths.

The department annually shall systematically ascertain maternal deaths using birth, fetal death and death vital records.

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.9(135) Disclosure of information.

90.9(1) The committee and subcommittees shall have access to patient records and other confidential information. In preparation for review of an individual death by the committee or subcommittee, the chairperson of the committee or the chairperson's designee is authorized to gather all information pertinent to the review. A person in possession or control of medical, investigative or other information pertaining to a child death, child abuse, domestic abuse, maternal death, or other death review with an established subcommittee shall allow the inspection and reproduction of the information by the department, upon the request of the department, to be used only in the administration and for the duties of the committee. A person does not incur legal liability by reason of releasing information to the department as mandated under and in compliance with this rule.

The committee and subcommittees will maintain the confidentiality of all information and records used in the review, including disclosure of information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

90.9(2) In the event of a maternal death, the certifying physician shall indicate that circumstance on the certificate of death.

90.9(3) Any person, hospital, sanatorium, or other organization shall make available to the department for inspection records, reports, statements, interviews or other data necessary to fulfill the duties of the committee or subcommittees.

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

641—90.10(135) Immunity and liability. Committee and subcommittee members are immune from any liability, civil or criminal, as established in Iowa Code section 135.43(8). A person who releases or discloses confidential data, records, or any other type of information in violation of this chapter is guilty of a serious misdemeanor.

[**ARC 8971C**, IAB 2/19/25, effective 4/1/25]

These rules are intended to implement 2024 Iowa Acts, Senate File 2385, and Iowa Code sections 135.40, 135.43, 135.108, 135.110, and 135.111.

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CHAPTER 91
IOWA DOMESTIC ABUSE DEATH REVIEW TEAM
Rescinded **ARC 8972C**, IAB 2/19/25, effective 4/1/25

CHAPTER 92
IOWA FATALITY REVIEW COMMITTEE
Rescinded **ARC 8973C**, IAB 2/19/25, effective 4/1/25

CHAPTER 93
MANDATORY REPORTER TRAINING CURRICULA
Rescinded **ARC 4704C**, IAB 10/9/19, effective 11/13/19

CHAPTER 94
CHILD PROTECTION CENTER GRANT PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 11/1/30

641—94.1(135) Definitions. For the purposes of these rules, the following definitions apply:

"Child abuse" means the same as defined in Iowa Code section 232.68(2).

"Child protection center" or *"child advocacy center"* means a comprehensive, child-focused program, designed by communities to meet their needs, based in a facility that allows law enforcement, child protection professionals, prosecutors, and the mental health and medical communities to work together to handle child abuse cases. "Child advocacy center" is synonymous with "child protection center."

"Department service area" means one of the five geographic areas designated by the department for the provision of family well-being and protection services.

[**ARC 9563C**, IAB 9/17/25, effective 11/1/25]

641—94.2(135) Goals. A child protection center's goals for victims of child abuse allegations shall be:

1. To provide consistent and expedient response and follow-up to abuse reports.
2. To coordinate activities to investigate, prosecute, and treat child abuse.
3. To advocate for medical and mental health resources to effectively help the child and the child's family.
4. To reduce the number of interviews and interactions with a victim.
5. To provide consistent and compassionate support for the child and the child's family.
6. To ensure that the child is not further victimized by the system designed to protect the child.
7. To increase successful prosecutions.

[**ARC 9563C**, IAB 9/17/25, effective 11/1/25]

641—94.3(135) Review process.

94.3(1) The department will establish a request for proposal and application process for organizations eligible to receive funding. The department will establish a process to review applications, including receiving input from a review committee. The review process and review criteria will be described in the request for proposals.

94.3(2) The director will create a committee to review proposals and make recommendations to the director. At a minimum, committee membership will be in accordance with Iowa Code section 135.118(3).

94.3(3) While implementation of the grant program is subject to the availability of funding, if sufficient funding is available, the department will, at a minimum, award a grant to a child protection center in or available to each department service area.

[**ARC 9563C**, IAB 9/17/25, effective 11/1/25]

641—94.4(135) Eligibility and criteria. To be eligible for a child protection center grant, an organization shall:

94.4(1) Have acquired partial membership rank as a child advocacy center from the National Children's Alliance and shall identify a plan to acquire full membership rank within one year of receiving a state grant.

94.4(2) Have in place an interagency memorandum of understanding that meets the requirements of Iowa Code section 135.118. The applicant shall provide in the application written information in the following areas:

a. Data, statistics and facts from an assessment of need and assets in the community to support a child protection center for children.

b. Identification of barriers to the child protection center to reach the purpose and goals for children as may exist in federal, state, or local rules, regulations, codes, policies, or procedures.

c. A plan to request and advocate waivers of federal, state, or local rules, regulations, codes, policies, or procedures to remove or reduce barriers.

d. The child protection center's access to information regarding all suspected or confirmed child abuse/neglect victims in the identified service area.

e. The child protection center's provision of 24-hour access to center staff for support, questions, and referrals regarding child abuse.

f. Identification of matching local funds to support and sustain the child protection center in the community.

g. A plan for community education on prevention of child abuse and neglect.

h. Collaboration agreements with providers of human services, child health services, early education services, and all other potential community partners to support the purpose and goals of the child protection center.

i. The child protection center's ability to access and utilize alternate funds for activities provided.

[**ARC 9563C**, IAB 9/17/25, effective 11/1/25]

641—94.5(135) Appeals. An applicant may appeal the denial of a properly submitted grant application. Appeals will be governed by 441—Chapter 2506.

[**ARC 9563C**, IAB 9/17/25, effective 11/1/25; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code section 135.118.

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[Filed ARC 9563C (Amended Notice ARC 9411C, IAB 7/23/25; Notice ARC 8553C, IAB 12/25/24), IAB 9/17/25, effective 11/1/25]

[Editorial change: IAC Supplement 6/10/26]

CHAPTER 95
VITAL RECORDS: GENERAL ADMINISTRATION
[Prior to 12/12/12, see [641] Ch 96, 98.1, Chs 103, 104]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—95.1(144) Definitions. For the purpose of 641—Chapters 95 through 100, the following definitions apply:

"Administrative costs" means costs for the registration, collection, preservation, modification and certification of records, including but not limited to costs related to copying, regular mailing, searching, staffing, and maintenance of systems.

"Advanced registered nurse practitioner" or *"ARNP"* means the same as defined in Iowa Code section 152.1.

"Age of majority" means the chronological moment when a child legally assumes majority control over the child's own person and actions and decisions, thereby terminating the legal control and legal responsibilities of the child's parents over and for the child. The period of minority extends to the age of 18 years, but every minor attains majority by marriage.

"Amendment" means a change made by the state registrar upon request from an entitled person as described in rule 641—95.8(144) to an obvious error, omission, or transposition of letters in a word of common knowledge one year or more after the event.

"Birth center" means a facility or institution, that is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur following a normal, uncomplicated, low-risk pregnancy.

"Birthing institution" means a private or public hospital licensed pursuant to Iowa Code chapter 135B that has a licensed obstetric unit or is licensed to provide obstetric services.

"Burial-transit permit" means the same as described in Iowa Code section 144.32.

"Certificate" or *"record"* means the written or electronic legal document containing the facts of an event.

"Certificate of birth resulting in stillbirth" means the same as described in Iowa Code section 144.31A.

"Certificate of nonviable birth" means a document issued based upon a nonviable birth.

"Certified copy" means an official copy of a registered vital record that is authenticated by the state registrar or county registrar. A certified copy contains a statement certifying the facts are true and accurate as recorded, is printed on security paper, and has authentication seals and signatures. A certified copy excludes all entries indicated as confidential or for statistical information.

"Commemorative certificate" means the same as described in Iowa Code section 144.45A.

"Competent and disinterested person" means an individual of legal age who is acquainted with both applicants who plan to marry.

"Confidential information" means data or information that is on a vital record, is not considered public information, and is restricted as to its release pursuant to Iowa Code chapter 144 or other provision of federal or state law.

"Correction" means a change made by the state registrar upon observation, upon query, or upon request from an entitled person as described in rule 641—95.8(144) to an obvious error, omission, or transposition of letters in a word of common knowledge within one year and prior to the first anniversary of the event.

"County registrar" means the same as described in Iowa Code section 331.601(4). If the office of the county recorder has been abolished, "county registrar" means the office to which the duties are assigned by the county board of supervisors.

"County resident copy" means a properly filed, clearly marked working copy of a decedent's death certificate that is sent to and recorded by the county registrar of the county of the decedent's residence in the event the death occurred outside the county of the decedent's residence.

"Court of competent jurisdiction" means the appropriate court for the type of action. When used to refer to inspection of an original certificate of birth based upon an adoption, "court of competent jurisdiction" means the court in which the adoption was ordered.

"Cremated remains" means the same as defined in Iowa Code section 144.1.

"Cremation" means the same as defined in Iowa Code section 144.1.

"Custody" means guardianship or control of vital records, including both physical possession, referred to as physical custody, and legal responsibility, referred to as legal custody, unless one or the other is specified. The state registrar will not transfer legal custody of vital records to another agency for purposes of granting public access until all the records have been purged of all confidential information.

"Day" means calendar day.

"Dead body" means the same as defined in Iowa Code section 144.1.

"Death" means the condition as defined in Iowa Code section 702.8.

"Declaration of paternity registry" means a registry for a putative father to declare paternity pursuant to Iowa Code section 144.12A. The declaration does not constitute an affidavit of paternity filed pursuant to Iowa Code section 252A.3A.

"Delayed birth record" means the registration of a live birth event occurring in Iowa one or more years after the date of birth that is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Delayed death record" means the registration of a death event occurring in Iowa one or more years after the date of death that is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Delayed marriage record" means the registration of a marriage event occurring in Iowa one or more years after the event that is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Disinterment permit" means a permit that allows the removal of a dead human body or fetus from its original place of burial, entombment, or interment for the purpose of autopsy or reburial.

"Electronic access" means authority given by the state registrar to a county registrar to access electronic vital records through the electronic statewide vital records system for purposes of retrieving information. The state registrar will provide guidelines for electronic access and the retrieval of information from the electronic statewide vital records system.

"Electronic statewide vital records system" means the combined vital records system for registration of birth records, registration of death records, issuance of certified copies of vital records by the state registrar and county registrar, and fee accounting.

"Emancipated minor" means a person younger than 18 years of age who has obtained the age of majority by court order.

"Fetal death" means the same as defined in Iowa Code section 144.1.

"Filing" means the same as defined in Iowa Code section 144.1.

"Final disposition" means the same as defined in Iowa Code section 144.1.

"Foundling" means a living infant of unknown parentage whose place of birth is where the infant is found and whose date of birth shall be determined by approximation.

"Funeral director" means a person licensed in Iowa to practice mortuary science pursuant to Iowa Code chapter 156.

"Gestational surrogate arrangement" or *"surrogate mother arrangement"* means the same as defined in Iowa Code section 710.11.

"Health care provider" means the same as defined in Iowa Code section 144.29A.

"Hospital" means the same as defined in Iowa Code section 135B.1.

"Induced termination of pregnancy" means the same as defined in Iowa Code section 144.29A.

"Institution" means a facility as defined in Iowa Code section 144.1(9), including "hospital" as defined in Iowa Code section 135B.1(3) but not including "birth center" as defined in Iowa Code section 10A.711(3).

"Institutional health facility" means a hospital as defined in Iowa Code section 135B.1, including a facility providing medical or health services that is open 24 hours per day, seven days per week and that is a hospital emergency room or a health care facility as defined in Iowa Code section 135C.1.

"Jurisdiction" means the state or county to which legal authority for the system of vital statistics has been granted by statute.

"Last name" means surname.

"Lineal consanguinity" means the existence of a line of descent in which one person is descended in a direct lineal relationship to another: as between the registrant and the registrant's parent, grandparent, great-grandparent, and so upward, in the direct ascending line; or between the registrant and the registrant's child, grandchild, great-grandchild and so downward in the direct descending line; or any siblings of the registrant.

"Live birth" means the same as defined in Iowa Code section 144.1.

"Marriage license valid date" means the day on which the marriage license becomes valid and on or after which the parties are authorized to marry. When the marriage license valid date is computed, the date of application shall be excluded. The marriage license shall become valid after the expiration of three calendar days after the date of application unless earlier validated by a court of competent jurisdiction.

"Medical certification" means a statement that attests that the medical information reported on the certificate of death or fetal death is accurate to the best of the medical certifier's knowledge.

"Medical certifier" means an Iowa-licensed physician, physician associate, advanced registered nurse practitioner, or medical examiner who attests that the death event has taken place and who determines the cause and manner of death.

"Medical examiner" means the medical legal officer who makes the determination of the cause of death in nonroutine deaths such as nonnatural, sudden, or unattended deaths or other deaths that affect the public interest.

"Modification" means any change made to a record that has been accepted and registered, such as a correction, an amendment, a change after adoption or paternity determination, or any other change.

"Mutual consent voluntary adoption registry" means a registry that authorizes adult adopted children, adult siblings, and the biological parents of adult adoptees to register to obtain identifying birth information.

"Natural cause of death" means a death due to a disease or the aging process and not due to external causes.

"Newborn safe haven registration" means the registration of the birth of a living infant of unknown parentage who has been abandoned or left at some unknown time after birth in a location other than the place of delivery.

"Non-birthing institution" means a private or public hospital licensed pursuant to Iowa Code chapter 135B that does not have a licensed obstetric unit or is not licensed to provide obstetric services but may provide obstetric services on an emergency basis.

"Non-institution birth" means a live birth that occurs outside of an institution and not en route to an institution.

"Nonnatural cause of death" means the same as defined in Iowa Code section 144.28(1).

"Nonviable birth" means an unintentional, spontaneous fetal demise occurring after demonstration of a doppler-detected heartbeat and prior to the twentieth week of gestation during a pregnancy that has been verified by a health care provider.

"Notification of record search" means the document issued to the applicant when the record requested cannot be located through a search of registered records. The document contains a certification statement, is printed on security paper, and has authentication seals and signatures.

"Officiant" means:

1. A judge of the Iowa supreme court, court of appeals, or district court, including a district associate judge, an associate juvenile judge, or a judicial magistrate, and including a senior judge as defined in Iowa Code section 602.9202(3), or
2. A person ordained or designated as a leader of the person's religious faith.

"Physician" means an individual licensed pursuant to Iowa Code chapter 148.

"Physician associate" means an individual licensed pursuant to Iowa Code chapter 148C.

"Presumptive death" means a death event presumed to have occurred in Iowa where no human body is found and a court of competent jurisdiction has determined the death has occurred.

"Putative father" means a man who is alleged to be or who claims to be the biological father of a child born to a woman to whom the man is not married at the time of the conception or birth of the child or at any time during the period between the conception and birth of the child.

"Record of death" means the compilation of those entries of a death, whether electronic or paper, that are contained in indexed systems that record the death event occurring in Iowa. "Record of death" includes the certificate of death.

"Record of fetal death" means the compilation of those entries of a fetal death, whether electronic or paper, that are contained in indexed systems that record a fetal death event occurring in Iowa. "Record of fetal death" includes the certificate of fetal death.

"Record of foreign-born adoption" means the compilation of those entries of a live birth event for a child born in a foreign country and adopted by an Iowa resident. "Record of foreign-born adoption" includes the certificate of foreign birth and shall not constitute U.S. citizenship.

"Record of live birth" means the compilation of those entries of a live birth event, whether electronic or paper, that are contained in indexed systems that record a live birth event occurring in Iowa. "Record of live birth" includes the certificate of live birth.

"Record of marriage" means the compilation of those entries of a marriage event, whether electronic or paper, that are contained in indexed systems that record a marriage event occurring in Iowa. "Record of marriage" includes the certificate of marriage.

"Registrant" means the person named on the certificate as the person who was born, died, or was married.

"Registration" means the same as defined in Iowa Code section 144.1.

"Report of dissolution or annulment" means the statistical report of dissolution or annulment, whether electronic or paper, excluding all entries indicated as confidential or for statistical information only.

"Report of termination of pregnancy" means the aggregated compilation of the information received by the department on terminations of pregnancies for each information item listed, with the exception of the report tracking number, the health care provider code, and any set of information for which the number is so small that the confidentiality of any person to whom the information relates may be compromised.

"Research" means the systematic investigation designed primarily to develop or contribute to scientific, medical, public health or psychosocial disciplines and generalized knowledge and not for private gain.

"Sealed" means the removal from inspection of any copy of an original certificate in the custody of the county registrar and the state registrar.

"Security paper" means standardized paper for issuing certified copies of vital record events that meets, at a minimum, national requirements for security features embedded within the paper to deter tampering, counterfeiting, photocopying, or imaging in order to help prevent fraudulent use of the certified copy and prevent identity theft.

"Single parent birth" means any record of live birth for which there is a reference or statement on the certificate or entry that directly indicates "no" regarding "born in wedlock" or "married"; or any record of live birth for which there is reference or statement on the certificate or entry that either parent is "unknown" or "anonymous"; or any certificate or entry that reflects the omission or absence of the name of the father of the child.

"Spontaneous termination of pregnancy" means the same as defined in Iowa Code section 144.29A(7) *"c."*

"Standard birth registration" means a vital record of a live birth event that occurred in Iowa that was submitted and accepted for registration within one year of the event.

"State registrar" means the director of the department or the director's designee.

"Stillbirth" means the same as defined in Iowa Code section 136A.2.

"System of vital statistics" or *"system"* means the same as defined in Iowa Code section 144.1.

"Uncertified copy" means an unofficial copy of a registered vital record that is not printed on security paper and that does not contain any authentication by the issuing jurisdiction. Uncertified copies shall contain an overstamp such as: "Not for Legal Purposes," "Administrative Use Only," "Deceased," "For Genealogical Purposes Only," "Working Copy," or any other overstamp as authorized by the state registrar.

"Vital records" means certificates or reports of birth, death, fetal death, marriage, dissolution, annulment, and related data.

"Vital statistics" means data derived from reports, certificates, and records of live birth, death, fetal death, induced termination of pregnancy, marriage, dissolution of marriage or annulment, and data related thereto.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26; Editorial change: IAC Supplement 6/10/26]

641—95.2(144) Vital records and statistics. The department will install, maintain, and operate the system of vital statistics throughout the state. No official system for the registration of births, deaths, fetal deaths, adoptions, marriages, dissolutions, and annulments shall be maintained in the state or any of its political subdivisions other than the one provided for in Iowa Code chapter 144, including but not limited to a system maintained by any agency or private entity.

95.2(1) No person shall prepare or issue any certificate that purports to be an original certified copy or a copy of a certificate of birth, death, fetal death, adoption, marriage, dissolution, or annulment except as provided for in Iowa Code chapter 144 and authorized by the state registrar.

95.2(2) The state registrar and the county registrar will not maintain or issue copies of any vital record of an event occurring outside the state registrar's or county registrar's jurisdiction except as provided for in Iowa Code chapter 144 and authorized by the state registrar.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.3(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand. Official designated forms used for the express purpose of creating a vital record event will not be accessible to the general public unless authorized by rule.

95.3(1) The forms supplied or approved for reporting vital events will be used for official purposes as provided for by law, rules and instructions of the state registrar.

95.3(2) No forms, except those furnished or approved by the state registrar, can be used in the reporting of vital events or the making of copies of vital records.

95.3(3) Security paper used to report vital events will be maintained in a secure location accessible only to the state and county registrars and their employees for administrative purposes.

95.3(4) Security paper will be used to issue certified copies of Iowa vital records and will be maintained in a secure location accessible only to the state and county registrars and their employees for administrative purposes.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.4(144) Information by others.

95.4(1) Any person having knowledge of the facts shall furnish information the person possesses regarding any birth, death, fetal death, adoption, marriage, dissolution, or annulment, upon demand of the state registrar.

95.4(2) Every person in charge of an institution, or the person's designee, shall maintain a record of personal particulars and data concerning each person admitted or confined to the institution pursuant to Iowa Code section 144.47. This record shall include information required by the standard certificate of birth, death, and fetal death forms issued under the direction of the state registrar. The record shall be made at the time of admission based on the information provided by such person, but when information cannot be obtained from the person, it shall be obtained from the most knowledgeable relative or person acquainted with the facts. The name and address of the person providing the information shall be a part of the record.

95.4(3) Records maintained under this rule shall be retained for a period of not less than ten years and shall be made available for inspection by the state registrar upon demand.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.5(144) Handling of vital records.

95.5(1) State equipment and state vital records shall not be handled or accessed except by the state registrar, the state registrar's employees, or other authorized personnel for administrative purposes.

95.5(2) The county registrar will provide assistance to the public in accessing vital records designated as public records in the custody of the county registrar.
[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.6(144) Fees.

95.6(1) *Fees for services provided by state registrar or county registrar.* The following fees will be charged and remitted for the various services provided by the state registrar or the county registrar.

a. The state registrar or county registrar, as applicable, will charge a fee of $20 for a certified copy of a vital record. If, following a search, no record is found and no certified copy is printed, the $20 fee may be retained.

b. The state registrar will charge a fee of $15 to prepare an adoption certificate, amend a certificate, amend a certificate of live birth to reflect a legal change of name, prepare a delayed certificate, process other administrative or legal actions, prepare a noncertified copy of an original certificate of birth pursuant to Iowa Code sections 144.23A and 144.24A, or prepare copies of supporting documents on file in the state registrar's office. No fee will be charged for establishment of paternity.

c. The state registrar will charge a fee of $25 to file a completed application for the mutual consent voluntary adoption registry.

d. The state registrar will charge a fee of $5 to update applicant information maintained in the mutual consent voluntary adoption registry and the declaration of paternity registry.

e. The state registrar will charge a fee of $15 to amend an abstract or other legal documentation in support of the preparation of a new certificate.

f. The state registrar will charge a fee of $35 to issue a commemorative copy of a certificate of birth or a certificate of marriage pursuant to Iowa Code section 144.45A. Fees collected will be deposited in the emergency medical services fund established in Iowa Code section 135.25.

g. The state registrar will charge a fee of $15 for the purpose of issuing an uncertified copy of a certificate of birth resulting in stillbirth pursuant to Iowa Code section 144.31A.

h. The state registrar will charge a fee of $15 for the purpose of issuing a certificate of nonviable birth pursuant to Iowa Code section 144.31B.

95.6(2) *Overpayments.* Any overpayment of $5 or less received by the state registrar for the copying of vital records or for the preparation or amending of a certificate will not be refunded and will be retained by the department.

95.6(3) *Certified copy of modified vital record.* When an individual is in possession of a previously issued certified copy of a vital record and the original record is subsequently modified, the individual may request and receive a certified copy of the modified record without charge if the certified copy prior to modification is relinquished to the registrar's office that issued the certified copy, unless otherwise directed by the state registrar.

95.6(4) *Search of county registrar's records—fee for uncertified copy.* A person who is requesting an uncertified copy of a vital record in the custody of the county registrar shall conduct the search of the county files to locate the record. If a copy is requested, the county registrar may charge a fee pursuant to Iowa Code section 22.3. The fee will be retained by the county.

95.6(5) *Distribution of fees.*

a. All fees collected by the county registrar and the state registrar will be distributed as follows:

(1) For fees collected by a county registrar, the county registrar will retain $4 of each $20 fee collected by that office. The remaining fees will be sent to the state registrar and will be divided as follows:

1. For a birth certificate or a marriage certificate, the state registrar will receive $13, and $3 will be deposited in the general fund of the state, except for the fee collected pursuant to paragraph 95.6(1)*"f."*

2. For a death certificate, the state registrar will receive $1, the office of the state medical examiner will receive $13, and $2 will be deposited in the general fund of the state.

(2) Fees collected by the state registrar will be divided as follows:

1. For a birth certificate or a marriage certificate, the state registrar will retain $14 and $6 will be deposited in the general fund of the state.

2. For a death certificate, the state registrar will retain $4, the office of the state medical examiner will receive $13, and $3 will be deposited in the general fund of the state.

b. All fees retained by the state registrar will be added to the vital records fund established by the department pursuant to Iowa Code section 144.46A.

c. All fees received by the office of the state medical examiner will be added to the operating budget established for the operation of that office.

95.6(6) *Fee for search to verify vital statistics record.* A fee will be charged by the state registrar for each search conducted for the purpose of providing verification of vital statistics data to an agency authorized to receive such data under subrule 95.12(2).

a. The amount of the fee will be determined in an agreement with the department and will be dependent on the nature and scope of the project and the resources needed to obtain the data requested.

b. The state registrar will retain the full amount of all fees collected under this subrule in the vital records fund established pursuant to Iowa Code section 144.46A.

95.6(7) *Fee for researcher access to vital statistics data.* A fee shall be charged to each researcher who is provided access to vital statistics data in accordance with Iowa Code section 144.44 and the required agreement executed with the department. The amount of the fee will be based on the nature and scope of the research project and resources required to obtain the data requested.

a. The state registrar will allocate the fees for copies of birth, marriage, and death certificates provided to researchers pursuant to the distribution of fees set forth in subrule 95.6(5).

b. The state registrar will retain in the vital records fund established pursuant to Iowa Code section 144.46A the full amount of fees collected from researchers for searching files or records to create a data file.

95.6(8) *Service member who died while on active duty—waiver of fee.* The certified copy fee for a birth certificate or a death certificate of a service member, as defined in Iowa Code section 29A.90, who died while on active duty will be waived for a period of one year from the date of death. Application for the certified copy shall be made by an entitled family member as described in rule 641—95.8(144) of the deceased service member or the entitled family member's legal representative. Documentation shall be submitted at the time of application to substantiate the date of death and active duty status.

95.6(9) *Retention of applications and reports.* An application for a certified copy of a vital record in Iowa will be retained by the county registrar for a minimum of six months from date of issuance of the certified copy. All financial reports for vital records fees will be retained by the county registrar for a minimum of three calendar years.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.7(144) General public access of vital records in the custody of the county registrar. A vital record may be in the custody of the county registrar if the event occurred in that county and the record is not excluded by statute or definition for purposes of confidentiality.

95.7(1) There will be public access and the right to inspect all vital records in the custody of the county registrar after the vital records are purged of confidential information pursuant to rule 641—95.11(144). The county registrar will allow the general public access to the electronic statewide vital records system to search as a public user as a right under Iowa Code chapter 22 for events that occurred in that county.

95.7(2) Information inspected and copied shall not be used to establish an official system for the registration of vital statistics except as authorized by Iowa Code chapter 144.

95.7(3) County registrars may issue uncertified copies of vital records held in the registrars' physical custody or accessible through the electronic statewide vital records system, except those records excluded by statute. Uncertified copies issued by the county registrar will be issued on plain white paper and clearly stamped "not for legal purposes." Security paper provided by the state registrar shall not be used to produce uncertified copies.

95.7(4) For records available in the electronic statewide vital records system, the state registrar will send to the county registrars a list of all records that have been modified. County registrars shall, as directed by the state registrar, remove all forms of any vital record in their physical custody from the county vital records system if the vital record appears on the list of modified records.

95.7(5) For records not available in the electronic statewide vital records system, the state registrar will send a copy of any modified vital record to the county of event and, if the record is a death record, to the county of residence.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.8(144) Direct tangible interest in and entitlement to a vital record. Certified copies of vital records may be issued by the state registrar or county registrar upon written application, payment of the required fee pursuant to paragraph 95.6(1)*"a,"* and demonstration of a verifiable, direct tangible interest and entitlement.

95.8(1) The following persons shall be considered to have a direct tangible interest and entitlement and are authorized to obtain a certified copy of a vital record:

a. The registrant, if the registrant is of legal age, has reached the age of majority, or is an emancipated minor.

b. A member of the registrant's immediate legal family, including:

(1) Current spouse or surviving spouse;

(2) Children;

(3) Mother or father if listed on the registrant's birth certificate;

(4) Sibling, if sibling has reached the age of majority;

(5) Maternal grandparents, or paternal grandparents if the father is listed on the birth certificate; or

(6) Step-parent or step-child if:

1. Legal parent and step-parent are currently married at the time of application; or

2. Step-parent is the surviving spouse of the legal parent and not remarried.

c. The documented legal representative of the registrant or the registrant's immediate legal family, including:

(1) An attorney;

(2) A court-appointed guardian;

(3) A foster parent;

(4) A funeral director, for up to one year following the decedent's date of death; or

(5) A legal executor.

d. Other persons who demonstrate a direct tangible interest and entitlement when it is shown that the certified copy is needed to determine or protect a personal or property interest and the interest is for the benefit of the registrant.

95.8(2) The following persons shall not be deemed to have direct tangible interest and entitlement or be authorized to secure vital records:

a. Biological parents of adopted persons in the absence of a court order from the court of competent jurisdiction;

b. Biological family members of adopted persons;

c. Adopted persons requesting biological family records; or

d. Commercial firms or agencies requesting lists of vital record events, or lists of names, or lists of addresses, or that are not legal representatives requesting records on behalf of entitled individuals.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.9(144) Search and issuance of a certified copy of a vital record. The search and issuance of a certified copy of a vital record shall be requested from the state registrar or county registrar.

95.9(1) Only entitled applicants as described in rule 641—95.8(144) may submit requests for certified copies of vital records.

95.9(2) A person requesting a search and issuance of a certified copy of a vital record shall provide in writing the following:

a. The name of the person or persons whose vital record is to be searched;

b. The purpose of such request;

c. The relationship to the registrant of the person making the request; and

d. The notarized signature and the address of the person making the request.

95.9(3) In addition to a completed written application, the applicant shall provide:

a. A current, legible government-issued photo identification of the applicant making the request or other identification documents acceptable to the state registrar; and

b. Payment of the required fee before the search is conducted.

95.9(4) The state registrar and county registrar will have the authority to mandate additional supporting documents to prove direct tangible interest and entitlement pursuant to rule 641—95.8(144).

95.9(5) If, after the search is conducted, no record is on file and the state registrar or county registrar issues a "notification of record search" on certified paper, the fee for the search will be retained pursuant to paragraph 95.6(1)*"a."*

95.9(6) If a certified copy of a vital record is issued and sent to the applicant using a mail service and the applicant does not receive the certified copy, the state registrar or the county registrar may replace the certified copy without an additional fee using an Affidavit of Non-Receipt. The applicant must contact the issuing registrar within 90 days of the date of request. A minimum of 30 days must have elapsed from the time the certified copy was mailed. The applicant shall read the instructions, complete the Affidavit of Non-Receipt and have the applicant's signature notarized. The original Affidavit of Non-Receipt and a photocopy of the applicant's driver's license must be reviewed by the issuing registrar before the certified copy can be replaced for no additional fee. The state registrar or county registrar may refuse any Affidavit of Non-Receipt when the state registrar or county registrar determines proof of receipt, fraud or misrepresentation. The state registrar will give to the registrant a notice in writing of the state registrar's reason and intention to refuse the Affidavit of Non-Receipt.

95.9(7) If printed from the electronic statewide vital records system by a county registrar, the certified copy of a vital record will be stamped by the issuing county registrar to reflect the county in which the certified copy was issued.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.10(144) Search and issuance for genealogy or family history. The search and issuance of a vital record for genealogy may be requested from the state registrar or county registrar upon written application and payment of the required fee pursuant to paragraph 95.6(1)*"a."*

95.10(1) The state registrar or county registrar may issue certified copies of a vital record for genealogy or family history to an applicant who can satisfactorily demonstrate a line of direct lineal consanguinity and to aunts, uncles, and cousins not past twice removed.

95.10(2) All certified copies issued for genealogy or family history will be clearly marked "for genealogical purposes only."

95.10(3) No certified copy will be issued for genealogy or family history if the registrant is known to be living.

95.10(4) If, after the search is conducted, no record is on file, the state registrar or county registrar will issue a "notification of record search" on certified paper, and the fee for the search will be retained pursuant to paragraph 95.6(1)*"a."*

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.11(144) Registrars' responsibility for maintenance of confidentiality.

95.11(1) The state registrar and county registrar will maintain the confidentiality of the following material, records, and information:

a. Entries indicated as confidential or statistical in nature on the face of the record or otherwise confidential by law;

b. Any record that is ordered sealed by the state registrar or pursuant to a court order.

95.11(2) The county registrar will take all necessary steps to ensure that confidential information reflected on vital records has been redacted from general public access. If confidential information is included with accessible information, only accessible information will be made available to the general public for examination.

95.11(3) The county registrar will employ at a minimum all of the following methods to ensure confidentiality:

a. Permanently cover or remove, by appropriate means, confidential information;

b. Promptly process the notice to seal a record as directed by the state registrar; and

c. Seal and not reproduce confidential information when copies of vital records are made.

95.11(4) The county registrar may charge reasonable administrative costs to reflect the expenses for efforts needed to allow general public access, examination and the assurance of confidentiality of this material and information pursuant to the authority of Iowa Code chapter 22.

a. The administrative cost is to be paid by persons who request the services provided by the county registrar, including supervising, copying or providing a suitable place for such work.

b. The county registrar will retain all administrative costs collected to allow general public access, examination, and the assurance of confidentiality of the vital record and information pursuant to the authority of Iowa Code chapter 22.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.12(144) Disclosure of data.

95.12(1) The state registrar may disclose data from the system of vital statistics to federal, state, county or municipal agencies of government that request such data in the conduct of their official duties, subject to conditions the state registrar may impose to ensure that the use of the data is limited to official purposes.

a. The aforementioned agencies shall not provide the certified copy or a copy of the vital record, or release information contained therein, to the person named on the certificate, a member of the person's legal family, or the person's legal representative.

b. Certified copies issued to the aforementioned agencies will be appropriately stamped, for example, "administrative purposes only" or "for veteran affairs purposes only."

95.12(2) Confidential verifications of the facts contained in vital records may be furnished by the state registrar to any federal, state, county or municipal government agency or other entity in the conduct of the agency's or entity's official duties, subject to conditions the state registrar may impose to ensure that the verification is limited to official purposes. Confidential verification of the facts contained in vital records may be furnished by a county registrar to another county office, within the county jurisdiction, in the conduct of the county's official duties, subject to conditions the state and county registrar may impose to ensure that the verification is limited to official purposes.

a. Such confidential verifications will be on forms prescribed and furnished by the state registrar or on forms furnished by the requesting agency or entity and acceptable to the state registrar, or the state registrar may authorize the verification in other ways.

b. The aforementioned agencies and entities shall not provide the original or a copy of the verified certificate, or release information contained therein, to the person named on the certificate, a member of the person's legal family, or the person's legal representative.

95.12(3) The state registrar may permit the use of data from vital statistics for research purposes subject to conditions the state registrar may impose to ensure the use of the data is limited to such research purposes. No data will be furnished from vital statistics for research purposes until the state registrar has prepared in writing the conditions under which the data may be used and has received an agreement signed by a responsible agent of the research organization agreeing to meet and conform to such conditions.

95.12(4) The state registrar may transmit to the county registrar data needed to produce certified copies of vital records pursuant to rule 641—95.8(144).

95.12(5) The state registrar may transmit to the statewide immunization registry information from birth certificates for the sole purpose of identifying those children in need of immunizations. The state registrar may impose conditions to ensure that the use of the information is limited to official purposes.

95.12(6) The state medical examiner or the county medical examiner may request an uncertified copy of a death certificate before the death certificate is accepted and filed at the county registrar's office.

a. The copy will be clearly stamped "administrative purposes only."

b. The death certificate shall be for the sole use of the state medical examiner or county medical examiner and shall not be used as a legal document, be distributed, be copied or be maintained other than to be made a part of the investigatory file.

c. If the state medical examiner or any county medical examiner determines the death does not warrant further investigation, the state medical examiner or county medical examiner shall destroy the uncertified copy of the death certificate.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.13(144) Preparation of certified copies. Certified copies of vital records may be prepared and issued by the state registrar or the county registrar pursuant to rules 641—95.3(144) and 641—95.9(144).

95.13(1) Certified copies of vital records may be made by mechanical, electronic, or other reproductive processes, except for confidential information. Certified copies will be issued using security paper that is prescribed by the state registrar.

95.13(2) When a certified copy is issued, each certification will contain a statement certifying that the facts are the true facts recorded in the issuing office, the date issued, the name of the issuing office, the registrar's signature or an authorized copy thereof, and the seal of the issuing office.

95.13(3) No person shall prepare or issue any certificate that purports to be an original, certified copy, or copy of a certificate of birth, death, fetal death, or marriage.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.14(144) Access to original certificate of birth prior to adoption. Notwithstanding any provision of law to the contrary, an adopted person who was born in this state and whose original certificate of birth was substituted with a new certificate of birth pursuant to Iowa Code section 144.24 based upon the adoption, or an entitled person, may apply for and obtain a noncertified copy of the original certificate of birth of the adopted person who is the subject of the original certificate of birth in accordance with this rule, including with any mandatory redaction of personally identifiable information pursuant to Iowa Code section 144.24A(2).

95.14(1) Entitlement.

a. If an adopted person who is the subject of the original certificate of birth is submitting the application, the adopted person shall be at least 18 years of age at the time the application is filed.

b. If an entitled person is submitting the application, the adopted person who is the subject of the original certificate of birth must be deceased at the time the application is filed.

95.14(2) The adopted person or the entitled person requesting a noncertified copy of the original certificate of birth shall file a written application with the state registrar on a form and in the manner prescribed by the state registrar.

95.14(3) Upon receipt of the written application, proof of identification pursuant to paragraph 95.9(3)*"a,"* and payment of a fee pursuant to paragraph 95.6(1)*"b,"* the state registrar will issue a noncertified copy of the original certificate of birth to the applicant in accordance with this rule, including with any mandatory redaction of personally identifiable information pursuant to Iowa Code section 144.24A(2). At the time of such issuance, the state registrar will also provide to the applicant any contact preference form or medical history form completed and submitted to the state registrar including with any mandatory redaction of personally identifiable information pursuant to Iowa Code section 144.24A(2).

a. A biological parent may file a contact preference form prescribed by the state registrar in accordance with the provisions outlined in Iowa Code section 144.24A(2) and state the biological parent's preference for contact by an adopted person or an entitled person following application for and issuance of the noncertified copy of the original certificate of birth under this rule. The contact preference form will be provided to the biological parent in accordance with Iowa Code section 600A.4. A contact preference form may be completed or updated by the biological parent at any time at the request of the biological parent.

b. A biological parent may file a medical history form prescribed by the state registrar in accordance with the provisions outlined in Iowa Code section 144.24A(3) and provide medical history of the biological parent and any blood relatives. The medical history form will be provided to the biological parent in accordance with Iowa Code section 600A.4. A medical history form may be completed or updated by the biological parent at any time at the request of the biological parent.

c. Upon receipt of a completed contact preference form or medical history form, the state registrar will attach any such completed form to the original certificate of birth.

d. For the purposes of this rule, "entitled person" means the spouse of the adopted person who is deceased or an adult related to the adopted person who is deceased within the second degree of consanguinity.

e. An application may be submitted under this rule by an adopted person or an entitled person to obtain a noncertified copy of an adopted person's original certificate of birth in accordance with this rule, if the adopted person who is the subject of the original certificate of birth was born before January 1, 1971.

f. An application may be submitted under this rule by an adopted person or an entitled person to obtain a noncertified copy of an adopted person's original certificate of birth in accordance with this rule, notwithstanding the date of birth of the adopted person who is the subject of the original certificate of birth prescribed under paragraph 95.14(3)*"b."*

This rule is intended to implement Iowa Code sections 144.24A and 600A.4.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.15(144) Certificate of nonviable birth.

95.15(1) A health care provider who attends or diagnoses a nonviable birth or a hospital at which a nonviable birth occurs shall advise a patient who experiences a nonviable birth that the patient may request a certificate of nonviable birth as provided in this section and, upon request by the patient, shall provide a letter certifying the nonviable birth to the patient on the form prescribed by the state registrar.

95.15(2) The department will issue a certificate of nonviable birth to a patient within 60 days of receipt of a request and certification letter. The request shall be made on the form prescribed by the state registrar.

95.15(3) The certificate of nonviable birth will contain all of the following:

a. The date of the nonviable birth.

b. The name and sex of the baby, if known.

(1) If the name is not furnished by the patient, the department will complete the certificate with the name "baby boy" or "baby girl" and the last name of the patient.

(2) If the sex is unknown, the department will complete the certificate with the name "baby" and the last name of the patient.

c. The name of the patient and, if married, the patient's spouse.

d. The statement: "This certificate is not proof of live birth."

95.15(4) The fees collected will be remitted to the treasurer of state for deposit in the general fund of the state and the vital records fund in accordance with Iowa Code section 144.46A.

95.15(5) A certificate of nonviable birth shall not be filed or registered with the department. The department will not register the nonviable birth associated with a certificate issued under this section or use the nonviable birth in calculating live birth statistics.

95.15(6) A certificate of nonviable birth shall not be used to establish, bring, or support a civil cause of action seeking damages against any person for bodily injury, personal injury, or wrongful death for a nonviable birth.

95.15(7) This rule will only apply to, and a certificate of nonviable birth may be requested and issued for, nonviable births occurring on or after January 1, 2000.

This rule is intended to implement Iowa Code section 144.31B.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.16(144) Cancellation of fraudulent records.

95.16(1) When the state registrar determines that a certificate was registered through fraud or misrepresentation, the state registrar will give to the registrant a notice in writing of the state registrar's intention to cancel the certificate.

95.16(2) The notice of cancellation will give the registrant an opportunity to appear and show cause why the certificate should not be canceled.

a. The notice may be served on the registrant, or, in the case of a minor or incompetent person, on the parent or guardian, by the forwarding of the notice by certified mail to the last-known address on file in the office of the state registrar.

b. The certificate shall not be available for certification unless the registrant, parent or guardian within 30 days after the date of mailing the notice shows cause satisfactory to the state registrar why the certificate should not be canceled.

95.16(3) Upon presentation to the state registrar of a court order stating a marriage certificate was registered through fraud or misrepresentation, the state registrar will remove the record from the vital statistics system. The state registrar will order the county registrar to remove any record related to the marriage.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.17(144) Unlawful acts.

95.17(1) *Serious misdemeanors.* Any person who reports information required under Iowa Code chapter 144 and who commits any of the following acts is guilty of a serious misdemeanor:

a. Willfully and knowingly makes any false statement in a report, record, or certificate required to be filed or in an application for an amendment or willfully and knowingly supplies false information intending that such information be used in the preparation or amendment of any such report, record, or certificate.

b. Without lawful authority and with the intent to deceive, makes, alters, amends, or mutilates any report, record, or certificate required to be filed or a certified copy of such report, record, or certificate.

c. Willfully and knowingly uses or attempts to use or furnish to another for use for any purpose of deception any certificate, record, or report or certified copy thereof.

d. Willfully and knowingly alters, amends, or mutilates any copy, certified copy, record or report.

e. Willfully, with the intent to deceive, uses or attempts to use any certificate of birth or certified copy of a record of birth knowing that such certificate or certified copy was issued based upon a record that is false in whole or in part or that relates to the birth of another person.

f. Willfully and knowingly furnishes a certificate of birth or certified copy of a record of birth with the intention that it be used by a person other than the person to whose birth the record relates.

g. Disinterring a body in violation of Iowa Code section 144.34.

h. Knowingly violates a provision of Iowa Code section 144.29A.

95.17(2) *Simple misdemeanors.* Any person committing any of the following acts is guilty of a simple misdemeanor:

a. Knowingly transports or accepts for transportation, interment, or other disposition a dead body without an accompanying permit as provided in Iowa Code sections 144.32, 144.33, and 144.34.

b. Refuses to provide information required by Iowa Code chapter 144.

c. Willfully violates any of the provisions of Iowa Code chapter 144 or refuses to perform any of the duties imposed upon the person.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

641—95.18(144) Enforcement assistance.

95.18(1) The department will report cases of alleged violations to the proper county attorney, with a statement of the facts and circumstances, for such action as is appropriate.

95.18(2) Upon request of the department, the attorney general will assist in the enforcement of the provisions of Iowa Code chapter 144.

[**ARC 0142D**, IAB 3/18/26, effective 7/1/26]

These rules are intended to implement Iowa Code chapter 144.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
[Filed ARC 1074C (Notice ARC 0926C, IAB 8/7/13), IAB 10/2/13, effective 1/1/14][2]
[Filed ARC 1402C (Notice ARC 1294C, IAB 1/22/14), IAB 4/2/14, effective 5/7/14]
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[Filed ARC 6108C (Notice ARC 5926C, IAB 9/22/21), IAB 12/29/21, effective 2/2/22]
[Filed ARC 6849C (Notice ARC 6648C, IAB 11/16/22), IAB 2/8/23, effective 3/15/23]
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[Filed ARC 9617C (Notice ARC 9491C, IAB 8/20/25), IAB 10/15/25, effective 12/1/25]
[Filed ARC 0142D (Notice ARC 9948C, IAB 1/7/26), IAB 3/18/26, effective 7/1/26]

[Editorial change: IAC Supplement 6/10/26]

[1] January 16, 2013, effective date of the rescission of Chapter 95 and the adoption of new Chapter 95 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

[2] January 1, 2014, effective date of 95.6(2) [ARC 1074C, Item 2] delayed 70 days by the Administrative Rules Review Committee at its meeting held October 8, 2013.

[3] March 8, 2017, effective date of 95.2, 95.7 and 95.10 [ARC 2933C] delayed 70 days by the Administrative Rules Review Committee at its meeting held February 10, 2017.

CHAPTER 96
BIRTH REGISTRATION
[Prior to 12/12/12, see [641] 95.1 to 95.4, Ch 99, 100.3]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—96.1(144) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 apply.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.2(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand.

96.2(1) The forms supplied or approved for reporting birth events will be used for official purposes as provided for by law, rules and instructions of the state registrar.

96.2(2) No forms, except those furnished or approved by the state registrar, shall be used in the reporting of birth events or the making of copies of vital records.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.3(144) Standard birth registration—up to seven days.

96.3(1) A certificate of live birth for each live birth that occurs in this state shall be filed as directed by the state registrar within seven days after the birth.

96.3(2) The person responsible for registering the certificate of live birth pursuant to rules 641—96.5(144) through 641—96.7(144) shall:

a. Utilize the official birth worksheet to report all information and any additional documentation as needed to complete the standard form for a certificate of live birth; and

b. Submit all required fees and reports with the birth registration.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.4(144) Standard birth registration—seven days to one year.

96.4(1) After seven days but within one year, a certificate of live birth for each live birth that occurs in this state shall be filed as directed by the state registrar.

96.4(2) The person responsible for registering the certificate of live birth pursuant to rules 641—96.5(144) and 641—96.6(144) shall:

a. Utilize the official birth worksheet to report all information and any additional documentation as needed to complete the standard form for a certificate of live birth; and

b. Submit all required fees and reports with the birth registration.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.5(144) Birthing institutions.

96.5(1) When a live birth occurs in an institution or en route to an institution, the person in charge of the institution or the person's designated representative, utilizing the official birth worksheet, shall within seven days:

a. Obtain the personal data;

b. Obtain the signature of the mother or her legal spouse or other signature as directed by the state registrar;

c. Provide the medical information required;

d. Certify that the child was born alive at the place, date, and time stated; and

e. File the certificate using the electronic birth registration system or as directed by the state registrar.

96.5(2) The birthing institution shall submit the fee report and remit the fees to the state registrar pursuant to rule 641—96.16(144).

96.5(3) The birthing institution shall maintain the birth worksheet for a minimum of ten years.

96.5(4) Upon demand of the state registrar, the birth worksheet and other information about the birth event shall be made available for inspection by the state registrar.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.6(144) Non-birthing institutions.

96.6(1) Institutions that do not register birth records through the electronic birth registration system shall request instructions from the state registrar.

96.6(2) When a live birth occurs in a non-birthing institution or en route to a non-birthing institution, the person in charge of the institution or the person's designated representative, utilizing the official birth worksheet for birth other than at a delivering hospital, shall within seven days:

a. Obtain the personal data;

b. Obtain the signature of the mother or her legal spouse or other signature as directed by the state registrar;

c. Provide the medical information required;

d. Certify that the child was born alive at the place, date, and time stated; and

e. Contact the state registrar for instructions on how to submit the worksheet and arrange for payment of applicable fees.

[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.7(144) Non-institution birth.

96.7(1) In case of a non-institution Iowa live birth, the official birth worksheet for birth other than at a delivering hospital shall be completed and filed with the state registrar by one of the following in the indicated order of priority:

a. The physician in attendance at or immediately after the live birth.

b. Any other person, including a certified nurse midwife or any person providing assistance with the birth, in attendance at or immediately after the live birth.

c. The mother or her legal spouse.

d. The person in charge of the premises where the live birth occurred.

96.7(2) An Iowa-licensed certified nurse midwife may preregister with the state registrar by submitting a completed Iowa-Licensed CNM Pre-Registration Application For Home Births and a clear photocopy of that person's current government-issued photo identification.

a. To register a live birth, certified nurse midwives who are preregistered shall submit to the state registrar the following:

(1) A letter of certification that identifies the live birth submitted for registration, supports the facts of the live birth, and contains the original signature of the person responsible for registering the live birth;

(2) The original official birth worksheet for birth other than at a delivering hospital completed and signed pursuant to subrule 96.7(4) or as directed by the state registrar;

(3) Payment of fees, which shall be included with the birth worksheet; and

(4) Other evidence acceptable to the state registrar as requested.

b. It is the responsibility of the individual preregistering to update any information provided in the individual's original registration.

96.7(3) A certified nurse midwife, or any person providing assistance with the birth, who is not preregistered prior to submitting a certificate of live birth for registration shall follow subrules 96.7(1), 96.7(2) and 96.7(4) for all live births the person attends outside a birthing institution.

96.7(4) The official birth worksheet for birth other than at a delivering hospital shall include a notarized signature of the mother or her legal spouse and shall be accompanied by a clear photocopy of that person's current government-issued photo identification. If photo identification is unavailable, other identifying documentation may be acceptable to the state registrar.

[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.8(144) Gestational surrogate arrangement birth registration. Establishment of a certificate of live birth for a child born of a gestational surrogate arrangement shall conform to the process established pursuant to rule 641—99.15(144).

[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.9(144) Foundling birth registration.

96.9(1) The person assuming physical custody of a foundling shall, within one business day of finding the infant, contact the state registrar for specific directions and guidance for filing the certificate of live birth.

96.9(2) Foundling registration shall be completed in the standard manner by the state registrar pursuant to Iowa Code section 144.14. Within five days after assuming physical custody of the foundling, the custodian of the foundling shall provide on the official birth worksheet the following minimum birth data and other data required by the state registrar:

a. The date when and the place where the child was found;

b. The sex, color or race, and approximate age of the child;

c. The name and address of the person or institution that has assumed physical custody of the child;

d. The name given to the child by the custodian;

e. The name, title, and license number, if any, of the person acting as the certifier to the facts of the foundling registration;

f. Parentage information, if the parent is known;

g. Any additional supporting information known.

96.9(3) The place where the child was found will be entered as the place of birth, and the date of birth will be determined by approximation. The information provided on the official birth worksheet will constitute the certificate of live birth.

96.9(4) The record will be on file only at the state registrar's office, and all supporting documentation will be placed in a sealed file, which shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.

96.9(5) Pursuant to Iowa Code section 144.14, if the child is properly identified after the registration, the certificate of live birth will be reestablished as needed and all records pertaining to the foundling registration will be sealed along with the original supporting documentation that shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.

[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.10(144) Newborn safe haven registration.

96.10(1) Newborn safe haven registration procedures apply when a parent voluntarily relinquishes physical custody of a newborn infant pursuant to Iowa Code section 233.2.

96.10(2) The person assuming physical custody of the living infant pursuant to Iowa Code section 233.2(2)*"a"* shall, within one business day of assuming custody, contact the state registrar for specific directions and guidance for registering the birth.

96.10(3) If the name of the parent is unknown, newborn safe haven registration will be completed in the standard manner by the state registrar pursuant to Iowa Code section 144.14. Within five days after assuming physical custody of the infant, the custodian shall provide on the official birth worksheet the following minimum birth data and other data required by the state registrar:

a. The date when and the place where the child was found;

b. The sex, color or race, and approximate age of the child;

c. The name and address of the person or institution that has assumed physical custody of the child;

d. The name given to the child by the custodian;

e. The name, title, and license number, if any, of the person acting as the certifier to the facts of the newborn safe haven registration;

f. Any additional supporting information known.

96.10(4) If the name of the parent is disclosed to the facility where the newborn was relinquished, the facility shall file the certificate of live birth as required pursuant to Iowa Code sections 144.13 and 233.2(2)*"d."*

96.10(5) Pursuant to Iowa Code section 144.14, if the child is properly identified after the newborn safe haven registration, the birth record will be reestablished as needed and all records pertaining to the newborn safe haven registration will be sealed along with the original supporting documentation that shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.

96.10(6) The record will be on file only at the state registrar's office, and all supporting documentation will be placed in a sealed file that shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes. The confidentiality of the live birth certificate will be maintained pursuant to Iowa Code sections 233.2(2)*"d"* and 144.43.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.11(144) Birth registration following a foreign-born adoption.

96.11(1) A certificate of foreign birth will be established by the state registrar for a child born in a foreign nation upon the state registrar's receipt of a completed Certificate of Adoption Report form from an Iowa court of competent jurisdiction or upon request of the resident adoptive parent or parents and the state registrar's receipt of all of the following documents:

a. The authenticated adoption decree in both the foreign language and the English translation, which shall contain the official signature of the translator, or a certified copy of an adoption decree from an Iowa court of competent jurisdiction;

b. If the decree does not contain information to establish the certificate of foreign birth, the adoptee's authenticated birth certificate in both the foreign language and the English translation, which shall contain the official signature of the translator;

c. Evidence of the adoptee's permanent residence, such as a passport or citizenship papers;

d. A certified copy of the certificate of live birth of each adoptive parent; and

e. A notarized statement that is on letterhead from the licensed adoption agency or certified adoption investigator and that establishes the parent or parents were residents of Iowa at the time the adoption was final in the foreign nation. The statement will not be required if the parent's or parents' Iowa address is shown in the adoption documents.

96.11(2) The certificate of foreign birth shall not constitute U.S. citizenship.

96.11(3) The state registrar will charge the adoptive parent or parents the appropriate fee for the registration of a certificate of foreign birth for a foreign-born child adopted by a parent who resided in Iowa at the time of adoption pursuant to Iowa Code section 144.13A.

96.11(4) Administrative and certified copy fees shall be charged and remitted as provided in rule 641—95.6(144).

96.11(5) The evidence presented will be on file only at the state registrar's office, and all supporting documentation will be placed in a sealed file that shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.12(144) Birth registration fees. A fee is required for each birth registered pursuant to Iowa Code sections 144.13, 144.13A, 144.15, 144.18, 144.23, 144.25A, and 600.15.

96.12(1) The parents will be charged and the person responsible for filing the certificate of live birth shall remit to the state registrar the $20 fee for the standard registration of a certificate of live birth and the $20 fee for a certified copy of the birth certificate pursuant to Iowa Code section 144.13A.

96.12(2) The individual filing a delayed certificate of live birth will be charged and shall remit to the state registrar the $20 fee for the registration of a delayed certificate of live birth for a registrant 17 years of age or younger pursuant to Iowa Code sections 144.13A, 144.15, and 144.18.

96.12(3) The adoptive parents will be charged and shall remit to the state registrar the $20 fee for the registration of a certificate of foreign birth pursuant to Iowa Code sections 144.13A and 144.25A.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.13(144) Fee collection. If a person responsible for the registration of a certificate of live birth under Iowa Code section 144.13 is not the parent, the person shall collect the fees from the parent and remit the fees to the state registrar.

96.13(1) The person collecting the fee on behalf of the state registrar will not charge an administrative fee for collection of the registration and certified copy fees pursuant to Iowa Code section 144.13A(3).

96.13(2) A person is discharged from the duty to collect and remit the fees when the person has made a good-faith effort to collect the fees from the parent or has established that the fees are to be waived pursuant to Iowa Code section 144.13A(4).
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.14(144) Waivers. The registration fee and certified copy fee are waived if the expenses of the birth are reimbursed under the medical assistance program established by Iowa Code chapter 249A or if the parent is indigent and unable to pay the expenses of the birth and no other means of payment is available to the parent.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.15(144) Fee deposit. Birth registration and certified copy fees collected on behalf of the state registrar and forwarded to the state registrar will be remitted to the treasurer of state for deposit in the appropriate state fund.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.16(144) Responsibilities of institutions. Institutions responsible for filing certificates of live birth shall collect both the registration fee and the certified copy fee from the parent.

96.16(1) The institution shall complete the Summary of Fee Report for Birth Registration and Certified Copy form. The institution shall submit the completed form and the total fee amount by check or money order to the state registrar within seven days of the live birth or as directed by the state registrar. All live births shall be reported and indicate for each birth that:

a. The fee was collected for the registration and certified copy;

b. The fee was waived, as applicable, and the reason for waiver; or

c. No fee was collected after a good-faith effort was made.

96.16(2) If a late birth registration fee is received, it shall be noted on the original Summary of Fee Report for Birth Registration and Certified Copy form.

96.16(3) The institution shall maintain copies of the submitted Summary of Fee Report for Birth Registration and Certified Copy form for three state fiscal years.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.17(144) Responsibility for births occurring in non-institutions and non-birthing institutions.

96.17(1) The state registrar will collect the registration and certified copy fees and complete a Summary of Fee Report for Birth Registration and Certified Copy form.

96.17(2) If a late birth registration fee is received, it will be noted on the original Summary of Fee Report for Birth Registration and Certified Copy form.
[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

641—96.18(144) Delayed birth registration—one year or more after event. All Iowa births registered one year or more after the date of the birth shall be prepared on a Delayed Certificate of Live Birth form. The state registrar will require documentary evidence to prove the facts of the birth pursuant to subrule 96.18(2). The delayed birth record will be registered and maintained solely at the state registrar's office.

96.18(1) *Application—certificate form.* A completed Delayed Certificate of Live Birth form shall be signed before a notary and filed with the state registrar by the following applicants in the indicated order of priority:

a. The registrant, if 18 years of age or older, whose birth occurred in Iowa but was not recorded within one year of the birth;

b. The registrant's parent or current legal court-appointed guardian; or

c. If no parent or legal guardian exists, a member of the registrant's family who has direct tangible interest and entitlement and who is competent to affirm to the accuracy of the information.

96.18(2) *Facts to be established.*

a. The applicant shall submit a notification of record search certified by the state registrar that will indicate that no prior certificate of live birth is on file for the person whose delayed birth record is to be

filed. The notification of record search will be returned to the applicant and will not be exchanged for a certified copy of delayed certificate of live birth.

b. The applicant shall substantiate the following with documentary evidence:

(1) The full name of the registrant at the time of the birth, except that the delayed certificate may reflect the name established by adoption or legitimation when such evidence is submitted;

(2) The date and place of the birth;

(3) The full name of the mother prior to any marriage as it is listed on her birth certificate;

(4) The full name of the mother at the time of the birth; and

(5) The full name of the mother's legal spouse. However, if the mother was not married at the time of conception or birth or at any time during the period between conception and birth, the name of a second parent shall not be entered on the delayed certificate unless the child has been adopted or legitimated or parentage has been determined by a court of competent jurisdiction.

96.18(3) *Documentary evidence.*

a. To be acceptable for purposes of registration, the name of the registrant and the date and place of birth entered on a Delayed Certificate of Live Birth form shall be supported at a minimum by the following documentary evidence:

(1) Two pieces of dated documentary evidence if the Delayed Certificate of Live Birth form is filed within seven years after the registrant's date of birth; or

(2) Three pieces of dated documentary evidence if the Delayed Certificate of Live Birth form is filed seven years or more after the registrant's date of birth.

b. Each piece of documentary evidence must be from an independent source. Facts of parentage shall be supported by at least one of the documents.

c. Documentary evidence shall be in the form of the original record, a certified copy thereof, or a notarized statement from the custodian of the record or document on the custodian's letterhead.

d. All documentary evidence submitted shall consistently support the facts of birth to be established.

e. All documentary evidence shall have been executed at least five years prior to the date of filing or shall have been established prior to the registrant's seventh birthday.

f. Documents not acceptable to establish a delayed certificate of live birth include but are not limited to:

(1) Baptismal record,

(2) Confirmation record,

(3) Family bible entries,

(4) Hospital commemorative birth certificate,

(5) Crib card,

(6) Cradle roll,

(7) Baby book memento, and

(8) Personal affidavit.

96.18(4) *Abstraction and certification by the state registrar.* The state registrar will abstract on the Delayed Certificate of Live Birth form a description of each document submitted to support the facts of birth. This description will include:

a. The title or description of the document;

b. The name and address of the custodian who has attested to the fact on the original documents in the custodian's custody;

c. The date of the original filing of the document being abstracted; and

d. The information regarding the registrant's birth and parentage.

96.18(5) *Acceptance of documentary evidence for registration.*

a. The state registrar will by signature certify that:

(1) No prior certificate of live birth is on file for the person whose birth is to be recorded;

(2) The evidence has been reviewed and substantiates the alleged facts of the birth; and

(3) The abstract of the evidence appearing on the Delayed Certificate of Live Birth form accurately reflects the nature and content of the documents.

b. All documents submitted in support of the delayed registration of live birth will be returned to the applicant after review, abstraction, and registration.

96.18(6) *Denial of registration.*

a. When the applicant does not submit substantiating evidence or the state registrar finds reason to question the validity or adequacy of the evidence submitted to establish a delayed certificate of live birth, the state registrar will not register the delayed certificate of live birth. The written notice of refusal from the state registrar will include:

(1) The rejected form;

(2) The Delayed Birth Evidence Refusal form; and

(3) Information related to the applicant's right of appeal to the district court pursuant to Iowa Code sections 144.17 and 144.18.

b. The application to establish a delayed certificate of live birth will be dismissed if not actively pursued within six months of the date the notice of refusal was sent to the applicant.

96.18(7) *Duties of the county registrar.* The county registrar may assist the registrant, registrant's parent, or current court-appointed guardian in the completion and notarization of the delayed form, excluding the portion restricted for state use only. The county registrar may forward the form, documents and fees to the state registrar for final review and possible acceptance.

96.18(8) *Fees.* Administrative and certified copy fees will be charged as provided in rule 641—95.6(144).

[**ARC 0143D**, IAB 3/18/26, effective 7/1/26]

These rules are intended to implement Iowa Code sections 144.12, 144.13, 144.13A, 144.14, 144.15, 144.17, 144.18, 233.2(2)*"c"* and 600.15.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
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[Filed ARC 0143D (Notice ARC 9947C, IAB 1/7/26), IAB 3/18/26, effective 7/1/26]

[1] January 16, 2013, effective date of the rescission of Chapter 96 and the adoption of new Chapter 96 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 97
DEATH REGISTRATION AND DISPOSITION OF DEAD HUMAN BODIES
[Prior to 12/12/12, see [641] 98.2, Chs 99, 101]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—97.1(144) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 apply.
[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.2(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of death events are the property of the department and will be surrendered to the state registrar upon demand.

97.2(1) The forms supplied or approved for reporting death events will be used for official purposes as provided for by law, rules and instructions of the state registrar.

97.2(2) No forms, except those furnished or approved by the state registrar, can be used in the reporting of death events or the making of copies of vital records.
[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.3(144) Standard registration of death—up to one year. Iowa death records submitted for registration within one year from the date of death will be prepared on the standard Certificate of Death form.

97.3(1) The county in which the death occurs or in which the dead human body is found is the county of death.

97.3(2) If the death occurs in a moving conveyance, the county in which the dead human body is first removed from the conveyance is the county of death.

97.3(3) Each person with a duty related to death certificates shall participate in the electronic death record system. A person with a duty related to a death certificate includes but is not limited to a physician as defined in Iowa Code section 135.1, a physician associate, an advanced registered nurse practitioner, a funeral director and a county recorder.
[**ARC 0144D**, IAB 3/18/26, effective 7/1/26; Editorial change: IAC Supplement 6/10/26]

641—97.4(144) Standard registration of fetal death—up to one year. Iowa fetal death records submitted for registration within one year from the date of fetal death shall be prepared on the standard Certificate of Fetal Death form. A fetal death certificate shall not be filed after one year from the date of the event. A fetal death record shall not be entered into the electronic death record system.

97.4(1) When a fetal death occurs in an institution, the person in charge of the institution or the person's designee, the physician in attendance at or after delivery, or a medical examiner may assist in preparation of the Certificate of Fetal Death form as directed by the state registrar.

97.4(2) In cases in which a fetus has reached the gestation period of 20 completed weeks or more or a weight of 350 grams or more, a Certificate of Fetal Death form shall be:

a. Registered and maintained solely at the state registrar's office; and

b. Filed within three days after delivery and prior to final disposition of the fetus.

97.4(3) The county in which the dead human fetus is found is the county of death. The certificate of fetal death shall be filed within three days after the fetus is found.

97.4(4) If the fetal death occurs in a moving conveyance, the county in which the fetus is first removed from the conveyance is the county of death.

97.4(5) A blank Certificate of Fetal Death form shall be used only by the state registrar or authorized agents.
[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.5(144) Preparation of the certificate of death or fetal death.

97.5(1) The funeral director or person other than the funeral director who first assumes custody of a dead human body or fetus for the purposes of disposition shall:

a. Obtain the personal data from the next of kin or the best-qualified person or source available;

b. Obtain the medical certification of cause of death from the medical certifier; and

c. Within three days after the death and prior to final disposition of the dead human body, file the completed certificate of death using the electronic statewide vital records system or, within three days after delivery and prior to disposition of the fetus, file the completed certificate of fetal death with the state registrar.

97.5(2) The funeral director or person other than the funeral director who first assumes custody of the dead human body for the purposes of disposition shall prepare the certificate of death using the electronic statewide vital records system.

97.5(3) The funeral director or person other than the funeral director who first assumes custody of the dead fetus for the purposes of disposition shall prepare the certificate of fetal death on the official form and paper issued by the state registrar.

97.5(4) Unless otherwise directed by the state registrar, a certificate of fetal death will be accepted for filing and registration only when:

a. All names are documented in the spaces provided;

b. All items are completed as required;

c. No alterations or erasures are apparent;

d. All signatures are original and genuine and are in dark blue or black ink;

e. The certificate presented for registration is on the approved form and official paper prescribed by the state registrar;

f. Data are consistent with the facts of death; and

g. The form is prepared in conformity with these rules or instructions issued by the state registrar.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.6(144) Medical certification of death. The funeral director shall submit the completed fact of death portion of the certificate of death to the physician, physician associate, advanced registered nurse practitioner, or medical examiner for the completion of the medical portion.

97.6(1) For a natural cause of death, the physician, physician associate or advanced registered nurse practitioner in charge of the patient's care for the illness or condition that resulted in death shall complete and sign the medical certification within 72 hours after receipt of the death certificate from the funeral director or individual who initially assumed custody of the body.

97.6(2) If there is a non-natural cause of death, the state medical examiner or county medical examiner shall be notified and shall conduct an investigation.

97.6(3) If the decedent was an infant or child and the cause of death is not known, a medical examiner shall conduct an investigation and an autopsy shall be performed as necessary to exclude a non-natural cause of death.

97.6(4) If upon investigation into a death, the state medical examiner or county medical examiner determines that a preexisting natural disease or condition was the likely cause of death and that the death does not affect the public interest as described in Iowa Code section 331.802(3), the state medical examiner or county medical examiner may elect to defer to the physician, physician associate or advanced registered nurse practitioner in charge of the patient's preexisting condition the certification of the cause of death.

97.6(5) When an investigation is required by the state medical examiner or county medical examiner, the state medical examiner or county medical examiner shall investigate the cause and manner of death and shall complete and sign the medical certification within 72 hours after determination of the cause and manner of death.

97.6(6) The medical certifier completing the medical certification of cause of death shall attest to the accuracy of the medical certification either by signature or by an electronic process approved by the state registrar.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26; Editorial change: IAC Supplement 6/10/26]

641—97.7(144) Medical certification of fetal death.

97.7(1) The medical certification for a fetal death shall be completed by the physician in attendance at or after delivery of the fetus within 72 hours after delivery, except when an investigation is required by a medical examiner.

97.7(2) When an investigation by a medical examiner is required, or when a fetal death occurs without medical attendance upon the mother at or after delivery, the medical examiner shall investigate the cause of fetal death and shall complete the medical certification of the fetal death within 72 hours after taking charge of the case.

97.7(3) The physician or medical examiner completing the medical certification of fetal death shall attest to the accuracy either by signature or by an electronic process approved by the state registrar.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.8(144) Medical certifier.

97.8(1) Only an Iowa-licensed physician, physician associate, advanced registered nurse practitioner, or medical examiner shall certify to the cause and manner of death.

97.8(2) If the medical certifier is unavailable, an alternate Iowa-licensed medical certifier may complete the cause and manner of death when:

a. The alternate medical certifier has access to the medical history of the case;

b. The alternate medical certifier views the deceased at the time of death or after death has occurred; and

c. The death is from natural causes.

97.8(3) In all other cases in which a medical certifier is unavailable, the medical examiner shall prepare the medical certification of cause of death.

97.8(4) The medical certifier who signs the medical certification on a certificate of death shall be entitled to view the death record through the electronic statewide vital records system for up to one year from the date of death.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26; Editorial change: IAC Supplement 6/10/26]

641—97.9(144) Report of autopsy findings.

97.9(1) In cases in which an autopsy is to be performed, it shall not be necessary to defer the entry of the cause of death pending a full report of microscopic or toxicological studies.

97.9(2) In any case in which the gross findings of an autopsy are inadequate to determine the cause of death, the medical certifier shall mark the cause of death as "pending investigation" on the certificate and sign the certificate. Immediately after the medical data necessary for determining the cause of death have been made known, the medical certifier shall provide to the state registrar a signed statement that identifies the decedent and the cause of death.

97.9(3) In any case in which the autopsy findings significantly change the medical diagnosis of cause of death, the medical certifier shall make a report of the cause of death and submit it to the state registrar as soon as the findings are available. Such report shall be a signed statement that identifies the decedent and the revised cause of death. Such report shall amend the original certificate, and the report shall be maintained in a sealed file.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.10(144) Extension of time. If the medical certifier is unable to complete the medical certification of cause of death or if the funeral director is unable to obtain the personal information about the deceased within the statutory time period, the funeral director shall file the certificate of death or fetal death with all available information.

97.10(1) Such certificate of death or fetal death shall be considered appropriate authority to issue a burial-transit permit.

97.10(2) As soon as possible, the person responsible for completing the information missing from the original certificate shall report the missing information to the state registrar.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.11(144) Removal of a dead human body or fetus.

97.11(1) A person assuming custody of a dead human body shall:

a. Contact the attending physician, physician associate, or advanced registered nurse practitioner and receive confirmation the death was from natural causes and that the physician, physician associate, or advanced registered nurse practitioner will assume responsibility for certifying the cause of death; or

b. Contact the medical examiner and receive authorization to remove the dead human body if the case is within the jurisdiction of the medical examiner.

97.11(2) A person assuming custody of a dead human fetus shall:

a. Contact the attending physician and receive confirmation the death was from natural causes and that the physician will assume responsibility for certifying to the cause of fetal death; or

b. Contact the medical examiner and receive authorization to remove the dead human fetus if the case is within the jurisdiction of the medical examiner.

97.11(3) A person other than a funeral director, medical examiner, or emergency medical service provider who assumes custody of a dead human body or fetus shall first contact the state registrar for instructions for registering the certificate of death or fetal death. After review and registration of the certificate of death or fetal death, the state registrar will issue a burial-transit permit pursuant to rule 641—97.12(144) prior to removal of the dead human body or fetus from the place of death.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26; Editorial change: IAC Supplement 6/10/26]

641—97.12(144) Burial-transit permit. If a person other than a funeral director, medical examiner, or emergency medical service assumes custody of a dead human body or fetus, the person is mandated to secure a burial-transit permit pursuant to rule 641—97.11(144) and Iowa Code section 144.32. Pursuant to Iowa Code chapter 144, an unlicensed employee of the funeral establishment shall be considered an agent of the funeral director.

97.12(1) The burial-transit permit will be issued upon a form prescribed by the state registrar and will state:

a. The name of the decedent;

b. The date and place of death;

c. If the death was from a communicable disease;

d. The name and location of the cemetery, crematory, or other location where final disposition of the remains is to be made;

e. The method of disposition;

f. That a certificate of death or fetal death has been filed; and

g. That permission is granted to inter, remove or otherwise dispose of the dead human body or fetus.

97.12(2) To be valid, a burial-transit permit will not be issued prior to the presentation of the completed and registered certificate of death or certificate of fetal death. The burial-transit permit must be issued by the county medical examiner, a funeral director, or the state registrar. The burial-transit permit shall be obtained prior to the removal of the dead human body or fetus from the place of death and shall accompany the body or fetus to the place of final disposition. The person responsible for obtaining the burial-transit permit shall provide the permit to the person in charge of the place of final disposition.

97.12(3) The person in charge of the place of final disposition shall ensure that all of the requirements of this chapter relative to the burial-transit permit have been complied with before the final disposition of the remains. Such person shall retain the burial-transit permit for a period of one year from the date of the final disposition.

97.12(4) A burial-transit permit will not be issued to a person other than a licensed funeral director if the death or fetal death was caused by a suspected or known "communicable disease" as defined by Iowa Code section 139A.2.

97.12(5) In cases in which a fetus has reached the gestation period of 20 completed weeks or more, or a weight of 350 grams or more, a burial-transit permit will be obtained prior to the final disposition of the fetus.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.13(144) Transportation and disposition of a dead human body or fetus.

97.13(1) A dead human body or fetus shall be transported only after enclosure in a container for transfer that will control odor and prevent leakage of body fluids unless the body or fetus has been embalmed or is being transported by a licensed funeral director, emergency medical service provider or medical examiner. The transport of a dead human body or fetus shall be in a manner that is respectful of the dead, the feelings of relatives, and the sensibilities of the community.

97.13(2) When a dead human body or fetus is transported from the state for final disposition, the burial-transit permit shall accompany the body or fetus. When a dead human body or fetus is brought into the state for final disposition, a burial-transit permit under the law of the state in which the death occurred shall accompany the body or fetus.

97.13(3) If the final disposition of a dead human body or fetus is cremation at a licensed cremation establishment, scattering of cremated remains shall be subject to the local ordinances of the political subdivision and any and all regulations of the cemetery, if applicable, in which the scattering site is located. However, such local ordinances and cemetery regulations shall not allow the scattering of cremated remains upon public property or upon private property without the property owner's consent. In the absence of an applicable local ordinance or cemetery regulation, the scattering of cremated remains shall not be allowed upon any public property or upon private property without the property owner's consent. Cremation shall be considered final disposition by the department, and no further burial-transit permit shall be needed.

97.13(4) If the final disposition of a dead human body or fetus is burial, interment, or entombment, local ordinances of the political subdivision in which the final disposition site is located and any and all regulations of the cemetery, if applicable, shall apply. In the absence of an applicable local ordinance, the depth of the grave at its shallowest point shall be at least three feet from the top of the burial container.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.14(144) Disinterment permits.

97.14(1) A disinterment permit may be issued as follows:

a. Disinterment of a dead human body or fetus, without a court order, shall be allowed for the purpose of autopsy or reburial only and then only if supervised by a funeral director.

b. Disinterment of cremated remains, without a court order, shall be allowed but only if supervised by a funeral director.

c. The state registrar, without a court order, will not issue a permit without the consent of the person authorized to control the decedent's remains under Iowa Code section 144C.5.

d. Disinterment of a dead body or fetus for the purpose of reburial may be allowed by court order only upon a showing of substantial benefit to the public and then only if supervised by a funeral director.

e. Disinterment of a dead body or fetus for the purpose of autopsy by court order shall be allowed only when reasonable cause is shown that someone is criminally or civilly responsible for such death, after hearing, upon reasonable notice prescribed by the court to the person authorized to control the decedent's remains under Iowa Code section 144C.5 and then only if supervised by a funeral director.

f. Disinterment of a dead body or fetus for the purpose of cremation may be allowed by court order if supervised by a funeral director. Subsequent to the disinterment, cremation of the body will only be allowed upon a determination by the state or county medical examiner that the death was due to natural causes.

97.14(2) A permit for disinterment will be issued by the state registrar according to rules adopted pursuant to Iowa Code chapter 17A or when ordered by the district court of the county in which such body is buried. A person authorized to control final disposition of a decedent's remains under Iowa Code section 144C.5 is an interested person and shall be entitled to notice prior to the obtaining of a court order.

97.14(3) Disinterment permits are mandated for any relocation above ground or below ground of remains from the original site of interment. Disinterment permits will be valid for 30 days after the date the permit is signed by the state registrar. Disinterment permits are issued on a form as prescribed by the state registrar with copies to be distributed as follows:

a. One copy filed with the sexton or person in charge of the cemetery in which disinterment is to be made;

b. One copy to be used during transportation of the remains;

c. One copy filed with the sexton or person in charge of the cemetery of reburial; and

d. One copy to be returned to the state registrar by the funeral director within ten days after the date of disinterment.

97.14(4) When removed from the vault for final burial, a dead human body or fetus, properly embalmed and placed in a receiving vault, shall not be considered a disinterment.

97.14(5) The following persons who are competent adults may acquire a disinterment permit without a court order pursuant to Iowa Code sections 144.34 and 144C.5 in the following descending order:

a. A designee, or alternate designee, acting pursuant to the decedent's declaration.

b. The surviving spouse of the decedent, if not legally separated from the decedent, whose whereabouts are reasonably ascertainable.

c. A surviving child of the decedent or, if there is more than one surviving child, a majority of the surviving children whose whereabouts are reasonably ascertainable.

d. The surviving parent or parents of the decedent whose whereabouts are reasonably ascertainable.

e. A surviving grandchild of the decedent or, if there is more than one surviving grandchild, a majority of the surviving grandchildren whose whereabouts are reasonably ascertainable.

f. A surviving sibling of the decedent or, if there is more than one surviving sibling, a majority of the surviving siblings whose whereabouts are reasonably ascertainable.

g. A surviving grandparent of the decedent or, if there is more than one surviving grandparent, a majority of the surviving grandparents whose whereabouts are reasonably ascertainable.

h. A person in the next degree of kinship to the decedent in the order named by law to inherit the estate of the decedent under the rules of inheritance for intestate succession or, if there is more than one such surviving person, a majority of such surviving persons whose whereabouts are reasonably ascertainable.

i. A person who knows the identity of the decedent and who signs an affidavit affirming the identity of the decedent and assuming the right to control final disposition of the decedent's remains and the responsibility to pay any expense associated with such final disposition. A person who affirms the identity of the decedent pursuant to this paragraph is liable for all damages that result, directly or indirectly, from that affirmation.

j. The county medical examiner, if responsible for the decedent's remains.

97.14(6) A funeral director may await a court order before proceeding with disinterment of a decedent's remains if the funeral director is aware of a dispute among:

a. Persons who are members of the same class of persons described in subrule 97.14(5); or

b. Persons who are authorized under subrule 97.14(5) and the executor named in the decedent's will or personal representative appointed by the court.

97.14(7) Due consideration under this rule shall be given to the public health, the preferences of a person authorized to control final disposition of a decedent's remains under Iowa Code section 144C.5, and any court order.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.15(144) Delayed death registration—one year or more after event. Iowa deaths registered one year or more after the date of death shall be prepared on a Delayed Certificate of Death form developed by the state registrar. The state registrar will require documentary evidence to prove the facts of the death pursuant to Iowa Code section 144.16. The delayed certificate of death will be registered and maintained solely at the state registrar's office.

97.15(1) *Application.* Registration of a delayed certificate of death may be requested by the surviving next of kin of the deceased, or the surviving next of kin's legal representative, in the following descending order:

a. Executor of the decedent's estate;

b. Spouse, if not legally separated from the decedent;

c. Child or legal guardian of the child if the child is under the age of majority;

d. Parent;

e. Grandchild or legal guardian of the grandchild if the grandchild is under the age of majority;

f. Sibling;

g. Grandparent; or

h. Funeral director responsible for the disposition of the decedent.

97.15(2) *Facts to be established.*

a. The applicant shall submit a notification of record search certified by the state registrar that will indicate that no prior certificate of death is on file for the person whose delayed death record is to be filed.

The notification of record search will be returned to the applicant and will not be exchanged for a certified copy of the delayed certificate of death.

b. The applicant shall substantiate the following with documentary evidence:

(1) The full legal name and sex of the deceased at the time of the death;

(2) The date and place of birth;

(3) The date and time of death;

(4) The place of death, including the type of place and location where the death occurred;

(5) The method and location of the final disposition;

(6) The full name and address of the person responsible for the final disposition;

(7) Cause and manner of death; and

(8) The full name, address, and relationship to the decedent of the person applying to register the delayed certificate of death.

97.15(3) *Documentary evidence.*

a. The application to register the delayed certificate of death shall be supported by a minimum of the following:

(1) An affidavit of the person filing the certificate attesting to the accuracy of the information on the certificate; and

(2) Three dated documents from independent sources that consistently support the information necessary pursuant to subrule 97.15(2). The documents shall be in the form of the original record, a certified copy thereof, or a notarized statement from the custodian of the record or document on the custodian's letterhead. Personal affidavits are not acceptable.

b. The state registrar may require additional documentary evidence to prove the facts of the death event.

97.15(4) *Abstraction and certification by the state registrar.* The state registrar will abstract on the Delayed Certificate of Death form a description of each document submitted to support the facts of death. This description will include:

a. The title or description of the document;

b. The name and address of the custodian who attested to the facts on the original documents in the custodian's custody;

c. The date of the original filing of the document being abstracted; and

d. The information regarding the death for delayed registration.

97.15(5) *Acceptance of documentary evidence for registration.* All documents submitted in support of the delayed registration will be returned to the applicant after review, abstraction, and registration. The state registrar will by signature certify that:

a. No prior certificate of death is on file for the decedent;

b. The evidence has been reviewed and substantiates the facts of death; and

c. The abstract of the evidence appearing on the delayed certificate of death accurately reflects the nature and content of the documents.

97.15(6) *Denial of registration.* In the absence of adequate substantiating evidence or if the state registrar finds reason to question the validity or adequacy of the evidence necessary to establish a delayed certificate of death, the state registrar will not register the delayed record.

a. The written notice of rejection from the state registrar will include:

(1) The Delayed Certificate of Death form stamped "rejected"; and

(2) The Delayed Evidence Refusal form.

b. Applications for a delayed certificate of death that have not been completed within one year from the date of application may be dismissed at the discretion of the state registrar. Upon dismissal, the state registrar will advise the applicant, and all documents submitted in support of such registration will be returned to the applicant.

97.15(7) *Duties of county registrar.* The county registrar may assist the applicant in the completion and notarization of the Delayed Certificate of Death form, excluding the portion restricted for state use only. The county registrar may forward the partially completed Delayed Certificate of Death form, documents and fees to the state registrar for final review and possible acceptance.

97.15(8) *Fees.* Administrative and certified copy fees will be charged as provided in rule 641—95.6(144).

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.16(144) Registration of presumptive death.

97.16(1) A petition shall be filed with the district court in the county where the presumptive death occurred and shall be supported with the completed Affidavit of Personal Knowledge of a Missing Person form. The form shall be completed by the surviving next of kin of the deceased, or the surviving next of kin's legal representative, in the following descending order:

a. Spouse, if not legally separated from the decedent;

b. Child or the child's legal guardian if the child is under the age of majority;

c. Parent;

d. Grandchild or the grandchild's legal guardian if the grandchild is under the age of majority;

e. Sibling;

f. Grandparent;

g. Aunt or uncle;

h. Niece or nephew; or

i. A person in the next degree of kinship to the decedent in the order named by law to inherit the estate of the decedent pursuant to Iowa Code sections 633.210 through 633.226.

97.16(2) In addition to the Affidavit of Personal Knowledge of a Missing Person form or in the absence of the next of kin, the petition may be supported by the following:

a. Affidavit by Employer for an Employee Who Was Working at Time of Disappearance form;

b. Affidavit by Government Official for a Government Employee Missing While Involved in Rescue Efforts form; or

c. Affidavit by Reliable Informant of Missing Person form.

97.16(3) The state registrar will provide the affidavit forms and the certificate of presumptive death. The affidavits and the certificate of presumptive death will be registered and maintained solely at the state registrar's office.

97.16(4) Upon presentation of a certified copy of a court order, the state registrar will file a certificate of presumptive death pursuant to Iowa Code sections 633.517 through 633.520. The order from the district court shall only establish the presumptive death record.

97.16(5) In cases under the jurisdiction of the medical examiner, the certified copy of the court order and the completed supporting affidavits listed in subrules 97.16(1) and 97.16(2) shall be delivered to the medical examiner. The medical examiner will complete the certificate of presumptive death and certify to the cause of death.

97.16(6) The certificate of presumptive death will be registered and maintained solely at the state registrar's office.

97.16(7) The certificate of presumptive death will be recorded based on the date of the court order and shall not be registered as a delayed certificate of death.

97.16(8) If the missing person is located and found to be alive, the certificate of presumptive death will be voided and removed from the vital records system of registration. Any issued certified copies shall be surrendered to the state registrar.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.17(144) Release or final disposition of a dead human body or fetus by an institution.

97.17(1) When a dead human body or fetus is released by an institution, the person in charge of the institution shall maintain a record showing:

a. Name of the deceased;

b. Date, time, and place of death;

c. Name, title, and license number of person who pronounced death;

d. Name and address of the medical certifier;

e. Name and address of the person to whom the dead human body or fetus is released; and

f. Date of removal of the dead human body or fetus from the institution.

97.17(2) When a dead human body or fetus is released or final disposition is completed by an institution, the person in charge of the institution shall keep a record showing the date, place, and manner of release or final disposition.

97.17(3) At the direction of the state registrar, the institution shall provide the information listed in subrule 97.17(1) to the funeral director or person acting as such who assumes custody of the dead human body for purposes of final disposition.

97.17(4) Records maintained under this rule will be retained for a period of not less than ten years and will be made available for inspection by the state registrar upon demand.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

641—97.18(144) Additional record by funeral director.

97.18(1) In addition to filing any certificate or other form required by Iowa Code chapter 144, a funeral director or other person who removes from the place of death or transports or completes final disposition of a dead human body or fetus shall maintain a record that shall identify the following:

a. Name of the deceased;

b. Date, time, and place of death;

c. Name and address of the person to whom the dead human body or fetus is released;

d. Name of institution or other place of death releasing the dead human body or fetus;

e. Date of removal from the place of death; and

f. Place and method of final disposition of the dead human body or fetus.

97.18(2) Records maintained under this rule shall be retained for a period of not less than ten years at the funeral establishment responsible for disposition and shall be made available for inspection by the state registrar upon demand.

[**ARC 0144D**, IAB 3/18/26, effective 7/1/26]

These rules are intended to implement Iowa Code sections 135.11(7), 144.12, 144.16 through 144.18, 144.26 through 144.29, 144.30 through 144.35, 144.47, 144.49 through 144.51, 144C.5, 331.802(3) and 633.517 through 633.520.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
[Filed ARC 2276C (Notice ARC 2156C, IAB 9/30/15), IAB 12/9/15, effective 1/13/16]
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[Editorial change: IAC Supplement 6/10/26]

[1] January 16, 2013, effective date of Chapter 97 [ARC 0483C] delayed until the adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 98
MARRIAGE REGISTRATION
[Prior to 12/12/12, see [641] Ch 96, 99.13]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—98.1(144,595) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 apply.
[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

641—98.2(144,595) Forms—property of department. All forms, certificates and reports pertaining to the registration of a marriage are the property of the department and shall be surrendered to the state registrar upon demand.

98.2(1) The forms supplied or approved for reporting a marriage will be used for official purposes as provided for by statute, rules and instructions of the state registrar.

98.2(2) No forms, except those furnished or approved by the state registrar, can be used in the reporting of a marriage or the making of copies of vital records.
[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

641—98.3(144,595) Standard registration of marriage—up to one year. A marriage event that takes place in Iowa shall be prepared on the standard Certificate of Marriage form and submitted for registration within one year from the date of marriage.

98.3(1) Prior to marriage, the applicants shall:

a. Obtain an Application for a License to Marry in Iowa form from the county registrar;

b. Submit to the county registrar the completed application and fee pursuant to Iowa Code section 331.605; and

c. Receive a license to marry in Iowa and a Certificate of Marriage form from the county registrar.

98.3(2) Once the marriage is solemnized, the completed certificate of marriage will be filed with the county registrar where the license to marry was issued. The county registrar will then forward the certificate of marriage to the state registrar for filing.
[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

641—98.4(144,595) Application for a license to marry in Iowa.

98.4(1) The Application for a License to Marry in Iowa form is available from any county registrar. The applicants are the parties to be married.

98.4(2) The application will not be processed until all items on the form, including the affidavit of a competent and disinterested person, have been completed. The affidavit shall be completed and signed in front of a notary public by an individual of legal age who is acquainted with both applicants who plan to marry. A family member may serve as the competent and disinterested person.

98.4(3) Each applicant shall verify the personal information by notarized signature.

98.4(4) If an applicant is 16 or 17 years of age, the Certificate of Consent of Underage Party to Marry form shall be completed in accordance with Iowa Code section 595.2(4) and shall be approved by a judge in the county's judicial district before the application for a marriage license may be accepted by the county registrar. Persons 15 years of age or younger may not marry in Iowa.

98.4(5) The Application for a License to Marry in Iowa form shall be signed in front of a notary public by both parties to be married and their competent and disinterested person. By signature, the applicants and their competent and disinterested person are attesting that the applicants are:

a. Eighteen years of age or older or, if either or both are 16 or 17 years of age, that they have provided a signed Certificate of Consent of Underage Party to Marry form;

b. Competent to enter into a civil contract pursuant to Iowa Code section 595.1A;

c. Not legally married to each other and that neither is legally married to someone else who is living; and

d. Acknowledging that they have provided accurate information on the application form.

98.4(6) An applicant is not required to be a U.S. citizen.

98.4(7) The Application for a License to Marry in Iowa form shall be submitted to the registrar in the county where the application and marriage certificate are to be filed. The marriage license is valid in any county in Iowa.

98.4(8) A fee is due upon the submittal of a completed Application for a License to Marry in Iowa form pursuant to Iowa Code section 331.605(1)*"g."*

98.4(9) At the time of completion of the Application for a License to Marry in Iowa form, the applicants shall indicate the adoption of the legal name to be used after marriage pursuant to Iowa Code section 595.5(1). When the application is filed, the county registrar will enter the legal name on the License to Marry in Iowa form and the original Certificate of Marriage form. Once the application is filed, any changes to the legal name to be adopted shall only be made prior to the marriage by reapplication and repayment of the application fee unless it can be proven that an obvious typographical error was made when the license or the certificate was prepared. An individual shall have only one legal name at any one time pursuant to Iowa Code section 595.5(2).

98.4(10) The original certificate of marriage will not later be modified to reflect a court-ordered legal change of name.

[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

641—98.5(144,595) License to marry.

98.5(1) Upon receipt and acceptance of a completed Application for a License to Marry in Iowa form, the county registrar may issue the license to marry. When the marriage license valid date is computed, the day of application will be excluded. The license will become valid after the expiration of three calendar days after the date of application to marry.

98.5(2) The three-day waiting period may be waived by a district judge in the county's judicial district pursuant to Iowa Code section 595.4. An Application for Waiver of 3-Day Waiting Period form is available from the county registrar. If the waiver is granted, the county registrar will collect the $5 fee for the waiver pursuant to Iowa Code section 595.4.

98.5(3) When a license is issued, the county registrar will provide the applicant the Certificate of Marriage form and provide instructions to ensure the return of a complete and accurate certificate of marriage for filing.

98.5(4) If the license to marry in Iowa is not retrieved from the county registrar within six months from the date of application, the application is void.

98.5(5) The license to marry is proof that proper application to marry in Iowa has been made. The parties to be married shall present the license to the person who will solemnize the marriage pursuant to Iowa Code section 595.10.

[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

641—98.6(144,595) Certificate of marriage.

98.6(1) At the time the license to marry in Iowa is issued, the county registrar will also prepare the original copy of the Certificate of Marriage form. The person solemnizing the marriage shall complete the blank items pertaining to the marriage ceremony and obtain the required signatures.

98.6(2) All participants in the marriage ceremony shall be present at the same time and location within the geographic boundaries of the state of Iowa, including the parties to be married, two witnesses and the officiant. Marriage ceremonies shall not occur by proxy, telephone, or other electronic means.

98.6(3) After the marriage ceremony:

a. The parties married shall sign, at a minimum, their first and last legal name on the Certificate of Marriage form as indicated on the Application for a License to Marry in Iowa form; and

b. Two witnesses present at the ceremony and the officiant shall sign and print their names on the Certificate of Marriage form in the spaces provided. If there is more than one officiant, the signature and name of only one of the officiants shall be on the Certificate of Marriage form.

98.6(4) Photocopies of the certificate of marriage are prohibited prior to registration of the certificate with the county registrar. The officiant shall not affix any kind of seal to the certificate of marriage.

98.6(5) Within 15 days after the marriage ceremony, the officiant who solemnized the marriage shall file for registration the certificate of marriage with the county registrar that issued the marriage license, except as directed pursuant to Iowa Code section 595.16.

98.6(6) Upon registration of the certificate of marriage, the completed Application for a License to Marry in Iowa form becomes part of the record of marriage, including the granted three-day waiver and accepted consent to marriage of a minor, if applicable.

98.6(7) Original certificates of marriage registered by the county registrar shall be forwarded to the state registrar weekly or as directed by the state registrar.

[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

641—98.7(144,595) Delayed registration of marriage—one year or more after date of event. All Iowa marriages registered one year or more after the date of the marriage shall be prepared on the Delayed Certificate of Marriage form. The state registrar will require documentary evidence to establish the facts of the marriage pursuant to Iowa Code section 144.16 and subrule 98.7(2). The delayed marriage record will be registered and maintained solely at the state registrar's office.

98.7(1) *Application.* A completed Delayed Certificate of Marriage form shall be signed before a notary by both parties to the marriage and filed with the state registrar.

98.7(2) *Facts to be established.*

a. The applicant shall submit a notification of record search certified by the state registrar that shall indicate that no prior certificate of marriage is on file for the persons whose delayed marriage record is to be filed. The notification of record search will be returned to the applicant and will not be exchanged for a certified copy of a delayed certificate of marriage.

b. The applicant shall substantiate the following with documentary evidence:

(1) The county in Iowa where the license to marry was issued;

(2) The full name of the registrants before and after the marriage;

(3) The date and place of the marriage in Iowa;

(4) The full names of the registrants' parents;

(5) The full names of the two witnesses present at the marriage ceremony; and

(6) The full name and address of the officiant who performed the marriage ceremony.

98.7(3) *Documentary evidence.*

a. To be acceptable for purposes of registration by the state registrar, the delayed certificate of marriage must be supported by:

(1) All of the following:

1. A copy of the issued license to marry in Iowa or the completed Application for a License to Marry in Iowa form secured from the county registrar in the county where the license to marry was issued;

2. A notarized affidavit from two witnesses to the wedding ceremony attesting to the facts of the marriage; and

3. A certified copy transcribed from the official records where the marriage was performed, including the date and place of such marriage as attested to by the custodian of such records; or

(2) An affidavit of the person who performed the ceremony documenting that there was a marriage and the date and place of such marriage.

b. The state registrar may require additional documentary evidence to prove the facts of the marriage event.

98.7(4) *Abstraction and certification by the state registrar.* The state registrar will abstract on the Delayed Certificate of Marriage form a description of each document submitted to support the facts of the marriage event. This abstract will include:

a. The title, description and signatory from each document presented;

b. The date of the original filing of the document being abstracted; and

c. The facts of the marriage event as established pursuant to paragraph 98.7(2)*"b."*

98.7(5) *Acceptance of documentary evidence for registration.* All documents submitted in support of the delayed registration will be returned to the applicant after review, abstraction, and registration. The state registrar will by signature certify that:

a. No prior certificate of marriage is on file for the registrants;

b. The evidence has been reviewed and substantiates the facts of the marriage event; and

c. The abstract of the evidence appearing on the delayed certificate of marriage accurately reflects the nature and content of the document.

98.7(6) *Denial of registration.* In the absence of adequate substantiating evidence or if the state registrar finds reason to question the validity or adequacy of the evidence required to establish a delayed certificate of marriage, the state registrar will not register the delayed record.

a. The written notice of rejection from the state registrar will include:

(1) The Delayed Certificate of Marriage form stamped "rejected"; and

(2) The Delayed Evidence Refusal form.

b. Applications for delayed certificates that have not been completed within one year from the date of application may be dismissed at the discretion of the state registrar. Upon dismissal, the state registrar will advise the applicant, and all documents submitted in support of such registration will be returned to the applicant. The state registrar will provide information related to the applicant's right of appeal to the district court.

c. If a request to establish a delayed certificate of marriage is rejected under the provisions of Iowa Code section 144.16, a petition may be filed with the district court for an order to establish a delayed certificate of marriage. The petition shall:

(1) Be made on a form prescribed and furnished by the state registrar.

(2) Allege that diligent efforts by the petitioner have failed to obtain the evidence required in accordance with Iowa Code section 144.16.

(3) Allege that the state registrar has refused to establish the delayed certificate of marriage.

(4) Include such other allegations as may be required.

(5) Be accompanied by a statement of the registration official made in accordance with Iowa Code section 144.16 and all documentary evidence that was submitted to the registration official in support of such registration.

(6) Be verified by the petitioner.

98.7(7) *Duties of county registrar.* The county registrar may assist the applicant in the completion and notarization of the delayed form, excluding the portion restricted for state use only. The county registrar may forward the partially completed delayed form, documents and fees to the state registrar for final review and possible acceptance.

98.7(8) *Fees.* Administrative and certified copy fees shall be charged as provided in rule 641—95.6(144).

[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

641—98.8(144,595) Dissolution of marriage or annulment.

98.8(1) The completed Report of Dissolution of Marriage or Annulment form shall be filed with the clerk of district court within one month from the date of the dissolution of marriage or annulment and be prepared on the official paper issued by the state registrar by one of the following means:

a. Use of a typewriter using a dark blue or black ribbon on the standard form of the report;

b. Use of a computer program that is preapproved by the state registrar;

c. Use of an electronic form prescribed by the state registrar; or

d. As directed by the state registrar.

98.8(2) If an attorney or clerk of district court uses a computer software program to generate a Report of Dissolution of Marriage or Annulment form, the form will be reviewed by the state registrar for approval. The state registrar will deny approval if the form does not conform to the standard Report of Dissolution of Marriage or Annulment form as prescribed.

98.8(3) Clerks of district court shall submit reports of dissolution of marriage or annulment to the state registrar weekly or as directed by the state registrar.

[**ARC 0145D**, IAB 3/18/26, effective 7/1/26]

These rules are intended to implement Iowa Code sections 144.12, 144.16, 331.605(1)*"f"* and *"g,"* 595.2(4), 595.4, 595.5, 595.10, and 595.16.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]

[Filed ARC 4398C (Notice ARC 4127C, IAB 11/21/18), IAB 4/10/19, effective 5/15/19]

[Filed ARC 0145D (Notice ARC 9945C, IAB 1/7/26), IAB 3/18/26, effective 7/1/26]

[1] January 16, 2013, effective date of the rescission of Chapter 98 and the adoption of new Chapter 98 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 99
VITAL RECORDS MODIFICATIONS
[Prior to 12/12/12, see [641] Chs 100, 102]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—99.1(144) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 apply.
[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.2(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand.

99.2(1) The forms supplied or approved for reporting vital events will be used for official purposes as provided for by law, rules and instructions of the state registrar.

99.2(2) No forms, except those furnished or approved by the state registrar, can be used in the reporting or modification of vital events or the making of copies of vital records.
[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.3(144) Forms used in the establishment of new records. The standard certificate form for reporting of live birth, death, fetal death, or marriage in use at the time of the event will be used to prepare a new certificate.
[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.4(144) Corrections of minor errors in vital record—within one year of event.

99.4(1) Corrections of minor errors may be made by the state registrar within one year and prior to the first anniversary of the date of the event upon observation, upon request of the data provider, upon query, or upon request from an entitled person. Minor errors include obvious errors, omissions, or transpositions of letters in words of common knowledge.

99.4(2) For a certificate of live birth, entitled persons include in the following descending order of priority:

a. Either parent as shown on the child's certificate of live birth; or

b. The legal guardian or agency having legal custody of the child.

99.4(3) For a certificate of death or fetal death other than the medical certification, entitled persons include in the following descending order of priority:

a. The surviving spouse as shown on the certificate of death;

b. A parent as shown on the certificate of death or fetal death;

c. The informant as shown on the certificate; or

d. The data provider in the case of a data entry error.

99.4(4) For a certificate of marriage, entitled persons include:

a. The county registrar that issued the license to marry; or

b. Either of the parties married.

99.4(5) Entitled persons requesting a correction shall submit to the state registrar:

a. A notarized statement and a legible copy of current government-issued photo identification or other identification documents acceptable to the state registrar; and

b. Supporting evidence if requested by the state registrar.

(1) The state registrar will determine a priority of best evidence and may, at the state registrar's discretion, require additional documentary evidence to support the requested correction.

(2) The state registrar will evaluate the evidence submitted in support of any correction, and when there is reason to question the validity or adequacy of the evidence, the state registrar may reject the request for correction and will advise the applicant of the reasons for this action.

99.4(6) Only the state registrar will make corrections on a vital record. The source of information and the date of correction will be documented on the record but will not appear on the certified copy.

99.4(7) There are no administrative fees required to correct a certificate pursuant to this rule.

99.4(8) Certificates corrected pursuant to this rule will not be marked "amended."

99.4(9) Any certified copies of the incorrect certificate shall be surrendered to the state registrar for replacement at no cost pursuant to 641—subrule 95.6(3). Additional certified copies of the corrected certificate may be obtained upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to 641—paragraph 95.6(1)*"a."*

99.4(10) The corrected certificate will be on file at the county registrar's office pursuant to rule 641—95.7(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.5(144) Amendment of certificate of live birth to add first or middle given name—within one year of event.

99.5(1) The first or middle given name for a child whose birth was reported without a first or middle given name may be amended to add the first or middle given name within one year and prior to the first anniversary of the date of the live birth based upon a completed and notarized Affidavit to Add Child's Given Name form as provided by the department pursuant to Iowa Code section 144.38. The affidavit shall be submitted to the state registrar by entitled persons in the following descending order of priority:

a. The single parent or both parents as shown on the child's certificate of live birth;

b. The mother, in the case of the death or incapacity of the second parent;

c. The second parent if listed on the birth certificate, in the case of the death or incapacity of the mother; or

d. The legal guardian or agency having legal custody of the child.

99.5(2) A first or middle given name may be added to the certificate of live birth once in this manner. Thereafter, a first or middle given name shall be changed only upon submission of a court order for a legal change of name from a court of competent jurisdiction pursuant to Iowa Code chapter 674.

99.5(3) An administrative fee shall be charged and remitted pursuant to 641—paragraph 95.6(1)*"b."*

99.5(4) The original certificate will be marked "amended" and will be endorsed on the certified copy. The date of amendment and a summary description of the evidence submitted in support of the amendment will be made a part of the record.

99.5(5) The certificate will be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.5(6) Any certified copies of the incorrect certificate shall be surrendered for replacement at no cost. Additional certified copies of the amended certificate may be obtained upon the state registrar's receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar, and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.6(144) Amendment of vital record—one year or more after the event.

99.6(1) Amendments of vital records may be made by the state registrar one year or more after the date of the event upon request from an entitled person or by an order to amend the record by a court of competent jurisdiction. Amendments include the correction of obvious errors, omissions, or transposition of letters in words of common knowledge.

99.6(2) For a certificate of live birth, entitled persons include in the following descending order of priority:

a. The registrant, if the registrant is of legal age, has reached the age of majority or is an emancipated minor;

b. Either parent as shown on the child's certificate of live birth; or

c. The legal guardian or agency having legal custody of the child.

99.6(3) For a certificate of death or fetal death other than the medical certification, entitled persons include:

a. The surviving spouse as shown on the certificate of death;

b. A parent as shown on the certificate of death or fetal death; or

c. The informant as shown on the certificate of death or fetal death.

99.6(4) Amendment of a medical certification of cause of death or fetal death shall be requested solely by the medical certifier listed on the certificate of death or fetal death.

99.6(5) For a certificate of marriage, entitled persons include either of the parties married.

99.6(6) Entitled persons requesting an amendment shall submit the following to the state registrar:

a. A completed and notarized amendment request on the applicable form as follows:

(1) Amendment to Certificate of Live Birth form.

(2) Amendment to Certificate of Death or Fetal Death form.

(3) Amendment to Certificate of Marriage form;

b. A legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar;

c. Certified copies of one or more pieces of documentary evidence supporting the amendment; and

d. The required fees pursuant to rule 641—95.6(144).

99.6(7) The documentary evidence shall have been established at least five years prior to the date of the application or within seven years of the date of the event.

a. The state registrar will determine a priority of best evidence and may, at the state registrar's discretion, require additional documentary evidence to support the requested amendment.

b. The state registrar will evaluate the evidence submitted in support of any amendment, and when there is reason to question the validity or adequacy of the evidence, the state registrar may reject the amendment and will advise the applicant of the reasons for this action and provide information related to the applicant's right of appeal to the district court pursuant to Iowa Code section 144.38.

c. If a request to amend a certificate of birth is rejected under the provisions of Iowa Code section 144.38, a petition may be filed with the district court for an order amending a vital record. The petition shall:

(1) Be made on a form prescribed and furnished by the state registrar.

(2) Allege that diligent efforts by the petitioner have failed to obtain the evidence required in accordance with Iowa Code section 144.38.

(3) Allege the state registrar has refused to amend the certificate of vital record.

(4) Include such other allegations as may be required.

(5) Be accompanied by a statement of the registration official made in accordance with Iowa Code section 144.38 and all documentary evidence that was submitted to the registration official in support of such registration.

(6) Be verified by the petitioner.

99.6(8) An administrative fee will be charged and remitted pursuant to rule 641—95.6(144).

99.6(9) The original certificate will be clearly marked "amended," and the date of the amendment will be endorsed on the certified copy. A summary description of the evidence submitted in support of the amendment will be made a part of the record.

99.6(10) The amended certificate will be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.6(11) Any certified copies of the incorrect certificate shall be surrendered for replacement at no cost. Additional certified copies of the amended certificate may be obtained upon the state registrar's receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.7(144) Method of amendment of vital records.

99.7(1) Records not on the electronic vital records system will be amended by drawing a single line through the incorrect item and inserting the correct or missing data immediately above or to the side of the item or by completing a blank item. In all cases in which a line must be drawn through an original entry, the line must not obliterate the original entry. The following will be endorsed on or made a part of the record:

a. The word "amended" and the date of the amendment action; and

b. A summary of the evidence submitted in support of the amendment.

99.7(2) Records on the electronic vital records system will be amended by correction of the incorrect item. The following will be endorsed on or made a part of the record:

a. The word "amended" and the date of the amendment action;

b. A statement identifying the amendment; and

c. A summary of the evidence submitted in support of the amendment.

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.8(144) Correction or amendment of same item more than once. After a correction or an amendment is made on a vital record, that entry will not be corrected again unless:

99.8(1) It can be proven that an error was made in processing the first correction or amendment; or

99.8(2) A court order is received from a court of competent jurisdiction to correct or amend the item. If a court order for a correction or an amendment is received, an administrative fee will be charged and remitted pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.9(144) Other amendments to certificate of live birth.

99.9(1) The parent's name or both parents' names as reported by the parent or parents on the birth worksheet used to establish the certificate of live birth shall only be amended if the amendment is supported by a certified copy of a vital record or amended by an order from a court of competent jurisdiction.

99.9(2) Certificates of live birth of deceased persons shall only be amended if the amendment is supported by a certified copy of a vital record or amended by an order from a court of competent jurisdiction.

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.10(144) Correction or substitution of medical certification of cause of death.

99.10(1) Corrections or substitutions of the medical certification of cause of death shall be requested solely by the medical certifier listed on the certificate of death or fetal death.

a. In the event the medical certifier listed on the certificate of death or fetal death is no longer licensed to practice in the state of Iowa, an authorized medical certifier may request correction or substitution of the medical certification of cause of death.

b. For the purposes of this rule, "authorized medical certifier" means an Iowa-licensed physician, physician associate, advanced registered nurse practitioner, or medical examiner who has knowledge of and access to the medical records associated with the decedent's care at the time of death.

99.10(2) The medical certifier may correct the medical certification of cause of death within 12 months of the date of death or fetal death. The request shall be submitted to the state registrar with supporting evidence on official letterhead signed and dated by the medical certifier listed on the certificate of death or fetal death or by an authorized medical certifier.

99.10(3) A correction to the medical certification of the cause of death and substitution of a death certificate requested solely by the medical certifier or by an authorized medical certifier after 12 months from the date of death or fetal death shall be made by order of a court of competent jurisdiction and considered an amendment. However, the medical certification of cause of death may be amended at any time upon submission of a report of autopsy or toxicological findings or additional findings by the county or state medical examiner.

99.10(4) No fee will be charged for correction, substitution or amendment made pursuant to this rule.

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26; Editorial change: IAC Supplement 6/10/26]

641—99.11(144) Correction or amendment to a certificate of marriage.

99.11(1) The request to correct a certificate of marriage during the first year may be made by the county registrar who issued the license to marry. The written request shall be submitted to the state registrar with supporting evidence.

99.11(2) The request to correct or amend a certificate of marriage may be made by either of the parties married. The written request shall be submitted to the state registrar with supporting evidence.

99.11(3) An order from a court of competent jurisdiction is required to correct or amend a legal name after marriage.

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.12(144) Correction to a report of dissolution of marriage or annulment.

99.12(1) A written notice to correct a report of dissolution of marriage or annulment may be submitted to the state registrar by the clerk of district court maintaining the record from which the original report was prepared. The notice shall state in what manner the report shall be corrected.

99.12(2) Those items appearing on the Report of Dissolution of Marriage or Annulment form that are not a part of the divorce decree may be corrected either by query or upon application of either party to the dissolution of marriage or annulment or the legal representative.

99.12(3) Corrections to the report of dissolution of marriage or annulment will be accepted only within the first year from the date of dissolution of marriage or annulment.

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.13(144) Minimum information required to establish a new certificate of live birth.

99.13(1) A request to establish a new certificate of live birth shall be submitted to the state registrar and include, at a minimum, the following information:

a. The full name of the child as stated on the original certificate of live birth;

b. The full name of the child to be listed on the new certificate of live birth;

c. The date and place of birth as stated on the original certificate of live birth;

d. The full name of the parent or parents as listed on the original certificate of live birth; and

e. The full name, place of birth, date of birth, and complete residential address of the parent or parents to be listed on the new certificate of live birth.

99.13(2) The new certificate of live birth will contain the same state file number and registration file date as were assigned to the original certificate of live birth.

99.13(3) The clerk of the court shall, within 30 days of issuance, deliver one certified copy of any adoption decree, any contact preference form or medical history form associated with the certified copy of any adoption decree for the purposes of Iowa Code section 144.24A, and the fee pursuant to rule 641—95.6(144) to the state registrar of vital statistics to prepare a certificate of birth as prescribed in Iowa Code section 144.19.

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.14(144) Establishment of new certificate of live birth following adoption.

99.14(1) Upon receipt of a completed Certificate of Adoption Report form or a certified copy of the decree of adoption from a court of competent jurisdiction and the information required pursuant to rule 641—99.13(144), the state registrar will establish a new certificate of live birth for a person who was born in Iowa and has been adopted.

99.14(2) The new certificate of live birth will not be marked "amended."

99.14(3) When a new certificate of live birth is established, the actual date and place of birth will be shown on the certificate.

99.14(4) The county registrar and state registrar will seal the original certificate of live birth. The state registrar will place the original certificate of live birth and all related adoption information in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24 or as provided in Iowa Code section 144.24A.

99.14(5) In accordance with Iowa Code section 144.23A, an adopted person may apply to the state registrar to have the adopted person's original certificate of birth prior to adoption reestablished to include the name of an omitted biological parent.

99.14(6) The new certificate of live birth after adoption shall not be on file at the county registrar's office.

99.14(7) The state registrar will reveal the date of the adoption and the name and address of the court that issued the adoption decree upon the receipt of a completed, notarized Revelation of County

of Adoption form from an adult adopted person, a biological parent, an adoptive parent, or the legal representative of the adult adopted person, the biological parent, or the adoptive parent pursuant to Iowa Code section 144.24.

99.14(8) Administrative and certified copy fees will be charged and remitted pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.15(144) Establishment of new certificate of live birth following a birth by gestational surrogate arrangement.

99.15(1) All live births shall be considered the product of the woman who delivered the live infant and shall be filed in the standard manner, with that woman named as the birth mother on the original record submitted for registration.

99.15(2) For the purpose of filing for registration the record of a live birth by a gestational surrogate, the institution's or non-institution's person responsible for filing the certificate of live birth shall:

a. Notify the state registrar of the birth of a child pursuant to a gestational surrogate arrangement;

b. Follow directives for completion of the official birth worksheet;

c. Submit the birth record for registration based on the birth mother's information; and

d. Notify the state registrar when the birth record has been submitted for registration.

99.15(3) In addition, the institution's or non-institution's person responsible for filing the record for registration shall:

a. Provide the prenatal and medical data on the medical portion of the birth worksheet pertinent to the pregnancy and the birth mother's prenatal care;

b. Waive all birth registration and copy fees as collected on behalf of the state registrar;

c. Indicate on the registration that the birth mother does not have custody of the infant;

d. Assist in advising the intended parents of the procedures required to file the original birth record for registration and to reestablish the record to reflect the intended parents' information; and

e. Advise the birth mother to complete the mother's portion of the birth worksheet and to mark "no" for the social security card for the child.

99.15(4) Two intended parents—both intended parents are biological parents to the child. If the intended mother is the egg donor and the intended father is the sperm donor to the child being carried by the gestational surrogate:

a. After the birth of the child, the intended parents shall petition a court of competent jurisdiction to establish legal paternity and maternity of the child.

b. The court shall enter an order requiring the state registrar to reestablish the certificate of live birth naming the intended mother and father as the legal mother and father and requiring the state registrar to seal the original birth certificate and all related documentation.

c. The court order shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full names of the birth mother and her legal spouse, if married;

(4) Disestablish the birth mother and her legal spouse, if married, as the legal parents of the child; and

(5) Identify the intended parents' full names prior to any marriage, full current legal names, dates of birth, birthplaces, social security numbers, and full current residential address, including county.

d. The intended parents or their legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(5) Two intended parents—intended mother is biological mother to the child; her legal spouse is not a biological parent. If the intended mother is the egg donor but her legal spouse is not the sperm donor, the intended mother shall petition a court of competent jurisdiction after the birth of the child to establish legal maternity.

a. The court shall enter an order requiring the state registrar to reestablish the certificate of live birth naming the intended mother as the legal mother and shall require the state registrar to seal the original certificate of live birth and all related documents.

b. The court order establishing legal maternity shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full names of the birth mother and her legal spouse, if married;

(4) Disestablish the birth mother and her legal spouse, if married, as the legal parents of the child; and

(5) Identify the intended mother's full name prior to any marriage, full current name, date of birth, birthplace, social security number, and full current residential address, including county.

c. The intended mother or her legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(6) Two intended parents—intended father is biological father to the child; his legal spouse is not a biological parent.

a. If the surrogate birth mother is unmarried and the intended father is the sperm donor, the unmarried surrogate birth mother and the intended father may complete a Voluntary Paternity Affidavit form after the child's birth to place the intended father's name and information on the certificate of live birth.

b. If the surrogate birth mother is married and the intended father is the sperm donor, the married surrogate birth mother and the intended father shall by court order disestablish the surrogate birth mother's legal spouse as the legal parent and may complete a Voluntary Paternity Affidavit form pursuant to Iowa Code section 144.13.

c. The court order that disestablishes the married surrogate birth mother's legal spouse and the completed Voluntary Paternity Affidavit form shall be submitted to the state registrar.

d. If a certified copy of the certificate of live birth is requested, a notarized written request shall also be submitted to the state registrar with the certified copy fee and mailing instructions.

e. There is no administrative fee to process the completed Voluntary Paternity Affidavit form.

f. Adoption laws shall be followed to reestablish the certificate of live birth by establishing the nonbiological parent on the certificate of live birth pursuant to Iowa Code chapter 600.

99.15(7) Two intended parents—neither biological parent to the child. If the intended parents are neither the egg donor nor sperm donor, adoption laws shall be followed to reestablish the certificate of live birth by disestablishing the birth mother and her legal spouse, if any, and establishing the nonbiological parents on the certificate of live birth pursuant to Iowa Code chapter 600.

99.15(8) One female intended parent—biological mother to the child. If the intended mother is the egg donor to the child being carried by the gestational surrogate:

a. After the birth of the child, the intended mother shall petition a court of competent jurisdiction to establish legal maternity of the child.

b. The court shall enter an order requiring the state registrar to reestablish the certificate of live birth naming the intended mother as the legal mother and requiring the state registrar to seal the original certificate of live birth and all related documentation.

c. The court order shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full names of the birth mother and her legal spouse, if married;

(4) Disestablish the birth mother and her legal spouse, if married, as the legal parents of the child; and

(5) Identify the intended parent's full name prior to any marriage, full current legal name, date of birth, birthplace, social security number, and full current residential address, including county.

d. The intended parent or her legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(9) One male intended parent—biological father to the child.

a. If the surrogate birth mother is unmarried and the intended father is the sperm donor, the unmarried surrogate birth mother and the intended father may complete a Voluntary Paternity Affidavit form after the child's birth to place the intended father's name and information on the certificate of live birth.

b. If the surrogate birth mother is married and the intended father is the sperm donor, the married surrogate birth mother and the intended father shall by court order disestablish the surrogate birth mother's legal spouse as the legal parent and may complete a Voluntary Paternity Affidavit form pursuant to Iowa Code section 144.13.

c. The court order that disestablishes the married surrogate birth mother's legal spouse and the completed Voluntary Paternity Affidavit form shall be submitted to the state registrar.

d. If a certified copy of the certificate of live birth is requested, a notarized written request shall also be submitted to the state registrar with the certified copy fee and mailing instructions.

e. There is no administrative fee to process the completed Voluntary Paternity Affidavit form.

f. If the intended father has been established as the legal father pursuant to paragraph 99.15(9)*"a"* or *"b"* and the surrogate birth mother and the intended father wish to remove the surrogate birth mother as the legal mother from the certificate of live birth, the parties shall seek a court order. The court order disestablishing legal maternity shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full name of the birth mother; and

(4) Disestablish the birth mother as the legal parent of the child.

g. The intended parent or his legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(10) One intended parent—not biological parent to the child. If the intended parent is neither the egg donor nor sperm donor, adoption laws shall be followed to reestablish the certificate of live birth by disestablishing the birth mother and her legal spouse, if any, and establishing the nonbiological parent on the certificate of live birth pursuant to Iowa Code chapter 600.

99.15(11) The state registrar will seal the original certificate of live birth. The state registrar will place the original certificate of live birth and all related documents in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.15(12) The new certificate of live birth will not be marked "amended."

99.15(13) The new certificate of live birth will not be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.15(14) A certified copy fee and an administrative fee to replace a parent's information on a certificate of live birth will be charged and remitted pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.16(144) Certificate of live birth following voluntary paternity affidavit.

99.16(1) If the birth mother was legally married at the time of conception or birth or at any time during the period between conception and birth, the name of her spouse shall be entered on the certificate of live birth as a parent pursuant to Iowa Code section 144.13.

99.16(2) If the birth mother was not legally married at the time of conception or birth or at any time during the period between conception and birth, the birth mother and the alleged biological father may:

a. Complete a Voluntary Paternity Affidavit form after the birth of the child; and

b. Submit the completed form to the state registrar.

99.16(3) If the birth mother was legally married at the time of conception or birth or at any time during the period between conception and birth, and her legal spouse is not the biological father, the birth mother and the alleged biological father may:

a. Complete a Voluntary Paternity Affidavit form after the birth of the child;

b. Obtain a court order that disestablishes her legal spouse as a parent; and

c. Submit the completed form and a certified copy of the court order to the state registrar.

99.16(4) If the birth mother and the biological father of an Iowa-born child subsequently marry each other after a voluntary affidavit of paternity has been processed, the parents may submit a second completed Voluntary Paternity Affidavit form with a certified copy of the parents' certificate of marriage to establish a new certificate changing the child's last name to that of the father.

99.16(5) If another man is shown as the father on the original certificate of live birth, a new certificate of live birth may be established only when a determination of paternity is made by a court of competent jurisdiction.

99.16(6) There is no age limitation and no fee for filing a completed Voluntary Paternity Affidavit form.

99.16(7) The county registrar and the state registrar will seal the original certificate of live birth. The state registrar will place the original certificate of live birth and all related documents in a sealed file, and the file will not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.16(8) A copy of the completed and processed Voluntary Paternity Affidavit form may be acquired by either parent or either parent's legal representative upon notarized application and payment of the fee pursuant to rule 641—95.6(144). The notarized application shall include, at a minimum, the following items:

a. The child's full name;

b. The child's date and place of birth;

c. The mother's full name prior to any marriage; and

d. The full name and mailing address of the applicant.

99.16(9) The new certificate of live birth will not be marked "amended."

99.16(10) The new certificate of live birth will be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.16(11) The birth mother and the biological father shall surrender any incorrect certified copies of the child's certificate of live birth for replacement at no cost. Additional certified copies of the new certificate of live birth shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.17(144) Certificate of live birth following court determination of paternity.

99.17(1) If the birth mother was married at the time of conception or birth or at any time during the period between conception and birth, the name of her spouse will be entered on the certificate of live birth as a parent unless paternity has been determined otherwise by a court of competent jurisdiction pursuant to Iowa Code section 144.13.

99.17(2) Upon receipt of a certified copy of the court determination of paternity order from a court of competent jurisdiction or the completed Abstract from Court Determination of Paternity form, the state registrar will establish a new certificate of live birth to be filed in place of the original certificate of live birth.

99.17(3) The new certificate of live birth will list the name of the child as stated in the court determination of paternity order.

99.17(4) Child support services may not change the child's name.

99.17(5) After a court determination of paternity has been completed, the parents as listed on the court order may submit a completed Voluntary Paternity Affidavit form to change the child's last name to that of the established father.

99.17(6) The county registrar and the state registrar will seal the original certificate of live birth. The state registrar will place the original certificate of live birth and all related documents in a sealed file, and the file will not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.17(7) The new certificate of live birth will not be marked "amended."

99.17(8) The new certificate of live birth will be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.17(9) There are no administrative fees required to establish a new certificate of live birth following a court determination of paternity.

99.17(10) Any incorrect certified copy of the child's certificate of live birth shall be surrendered for replacement at no cost. Additional certified copies of the new certificate of live birth shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.18(144) Certificate of live birth following rescission of paternity affidavit or disestablishment of paternity.

99.18(1) An application to rescind a voluntary paternity affidavit shall be made on the Rescission of Paternity Affidavit form by either the birth mother or the putative father who originally completed and signed the Voluntary Paternity Affidavit form pursuant to Iowa Code section 252A.3A.

a. The completed Rescission of Paternity Affidavit form shall be notarized and received by the state registrar within the earlier of either 60 days from the latest notarized parental signature on the original Voluntary Paternity Affidavit form or entry of a court order regarding the child by child support services pursuant to Iowa Code section 252A.3A.

b. Acceptance of the completed Rescission of Paternity Affidavit form shall remove the alleged biological father's information from the certificate of live birth and rescind the voluntary paternity affidavit.

c. The child's last name shall revert to the last name as it was listed on the certificate of live birth prior to the voluntary paternity affidavit.

d. The state registrar will send a written notice of the rescission to the last-known address of the signatory of the voluntary paternity affidavit who did not sign the Rescission of Paternity Affidavit form.

e. After the completed Rescission of Paternity Affidavit form has been accepted and processed, the state registrar will not accept any subsequent Voluntary Paternity Affidavit forms signed by the same mother and putative father relating to the same child pursuant to Iowa Code section 252A.3A.

99.18(2) Upon receipt of a court-ordered disestablishment of paternity, which shall include court-ordered language directing the state registrar to add or remove the father from the certificate of live birth, the father's information will be removed from the certificate of live birth. The child's last name shall revert to the last name as it was listed on the certificate of live birth prior to the establishment of paternity.

99.18(3) An administrative fee will be charged and remitted pursuant to rule 641—95.6(144).

99.18(4) The county registrar and the state registrar will seal the original certificate of live birth. The state registrar will place the rescission of paternity information in the same sealed file as the original certificate of live birth and all previous related documents. The file will not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.18(5) The new certificate of live birth will not be marked "amended."

99.18(6) The new certificate of live birth will be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.18(7) Any incorrect certified copies of the child's certificate of live birth shall be surrendered for replacement at no cost. Additional certified copies of the new certificate of live birth shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.19(144) Certificate of live birth following court-ordered change of name.

99.19(1) For a court-ordered name change, a certified copy of an order from a court of competent jurisdiction pursuant to Iowa Code chapter 674 or an Abstract to Change Registrant's Legal Name form completed by the clerk of district court changing the name shall be submitted to the state registrar.

99.19(2) Only the person named on the record, parent or parents if the registrant is a minor child, legal guardian, or legal representative may request a court-ordered change of name.

99.19(3) The court order or abstract shall contain:

a. The registrant's full name as it appears on the original certificate of live birth;

b. The registrant's date and place of birth;

c. The mother's full maiden name and father's full name as it appears on the original certificate of live birth;

d. The registrant's full new name; and

e. The certification of the clerk of district court.

99.19(4) The certified copy of a certificate of live birth after a legal change of name will be clearly marked "legal change of name" and note the following:

a. The registrant's full name as shown on the original certificate;

b. Any previous legal name changes;

c. The registrant's full new name according to the court order;

d. The date the legal change of name order was granted; and

e. The name of the court that ordered the name change pursuant to Iowa Code chapter 674.

99.19(5) A parent cannot be added to the certificate of live birth with a court-ordered change of name.

99.19(6) The county registrar and the state registrar will seal the original certificate of live birth. The state registrar will place the original certificate of live birth and all related documents in a sealed file, and the file will not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.19(7) After the court-ordered change of name, the certificate of live birth will not be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.19(8) An administrative fee will be charged and remitted pursuant to rule 641—95.6(144).

99.19(9) Any incorrect certified copies of the certificate of live birth shall be surrendered for replacement at no cost. Additional certified copies of the new certificate shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

641—99.20(144) Disestablishment of parentage.

99.20(1) To disestablish parentage of a mother, father, or both on a certificate of live birth, the court will submit an abstract from court determination to disestablish parentage to the state registrar.

99.20(2) Upon receipt of a court-ordered abstract from court determination to disestablish parentage, which shall include court-ordered language directing the state registrar to remove the parent or parents from the certificate of live birth, the parent's or parents' information will be removed from the certificate of live birth.

99.20(3) The state registrar will prepare a new certificate of live birth to be filed in place of the original birth certificate.

99.20(4) The new birth certificate will bear the name of the child after the judgment and disestablish the parent's or parents' information as determined by the court.

[**ARC 0146D**, IAB 3/18/26, effective 7/1/26]

These rules are intended to implement Iowa Code sections 144.19 through 144.21, 144.23, 144.24, 144.25A, 144.38 through 144.41, 252A.3A, 600.15, 600.16A, 674.2, 674.7 and 674.9.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]

[Filed ARC 1075C (Notice ARC 0925C, IAB 8/7/13), IAB 10/2/13, effective 11/6/13]

[Filed ARC 4398C (Notice ARC 4127C, IAB 11/21/18), IAB 4/10/19, effective 5/15/19]
[Filed ARC 6108C (Notice ARC 5926C, IAB 9/22/21), IAB 12/29/21, effective 2/2/22]
[Filed ARC 8043C (Notice ARC 7507C, IAB 1/24/24), IAB 5/29/24, effective 7/3/24]
[Filed ARC 9175C (Notice ARC 8563C, IAB 12/25/24), IAB 4/30/25, effective 7/1/25]
[Filed ARC 9617C (Notice ARC 9491C, IAB 8/20/25), IAB 10/15/25, effective 12/1/25]
[Filed ARC 0146D (Notice ARC 9944C, IAB 1/7/26), IAB 3/18/26, effective 7/1/26]
[Editorial change: IAC Supplement 6/10/26]

[1] January 16, 2013, effective date of the rescission of Chapter 99 and the adoption of new Chapter 99 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 100
VITAL RECORDS REGISTRIES AND REPORTS
[Prior to 12/12/12, see [641] Chs 105 to 107]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—100.1(144) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 shall apply. In addition, the following definitions shall apply solely to this chapter:

"Abortion" means the same as defined in Iowa Code section 146B.1.

"Adult," when used in reference to the mutual consent voluntary adoption registry, means an individual who has reached the age of 18 years at the time application is made.

"Aggregate form" means the same as defined in Iowa Code section 144.29A.

"Attempt to perform an abortion" means the same as defined in Iowa Code section 146B.1.

"Child," when used in reference to the declaration of paternity registry, means a person under 18 years of age for whom paternity has not been established.

"Court" means the juvenile court when used in reference to the declaration of paternity registry.

"Father" means the male, biological parent of a child when used in reference to the declaration of paternity registry.

"Fertilization" means the same as defined in Iowa Code section 146B.1.

"Health care provider" means the same as defined in Iowa Code section 144.29A.

"Inducing a termination of pregnancy" means the same as defined in Iowa Code section 144.29A. "Inducing a termination of pregnancy" includes abortion.

"Major bodily function" means the same as defined in Iowa Code section 146B.1.

"Medical emergency" means the same as defined in Iowa Code section 146B.1.

"Medical facility" means the same as defined in Iowa Code section 146B.1.

"Perform," "performed," or *"performing"* means the same as defined in Iowa Code section 146B.1.

"Physician" means a person licensed under Iowa Code chapter 148.

"Postfertilization age" means the same as defined in Iowa Code section 146B.1.

"Probable postfertilization age" means the same as defined in Iowa Code section 146B.1.

"Registry" means the declaration of paternity registry or the mutual consent voluntary adoption registry.

"Sibling" means one of two or more persons who are born of the same parents or, sometimes, who have at least one parent in common. "Sibling" also means brother or sister when used in reference to the mutual consent voluntary adoption registry.

"Spontaneous termination of pregnancy" means the same as defined in Iowa Code section 144.29A.

"Unborn child" means the same as defined in Iowa Code section 146B.1.

[**ARC 0147D**, IAB 3/18/26, effective 7/1/26]

641—100.2(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand.

100.2(1) The forms supplied or approved for reporting vital events will be used for official purposes as provided for by law, rules and instructions of the state registrar.

100.2(2) No forms, except those furnished or approved by the state registrar, will be used in the reporting of vital events or the making of copies of vital records.

[**ARC 0147D**, IAB 3/18/26, effective 7/1/26]

641—100.3(144) Declaration of paternity registry established. Pursuant to Iowa Code section 144.12A, there is established in the department a registry for the declaration of paternity of a putative father who wishes to register prior to the birth of a child and no later than the date of the filing of the petition for termination of parental rights.

100.3(1) The putative father who files a Declaration of Paternity Registry form with the state registrar shall provide the following:

a. Registrant's name, current address, social security number, and notarized signature and date signed;

b. The name, last-known address, and social security number, if known, of the mother of the child; and

c. The name of the child, if known, and the date and location of the birth of the child, if known.

100.3(2) The putative father who files the Declaration of Paternity Registry form shall be responsible to notify the state registrar in writing of any change in address.

100.3(3) The state registrar will forward a copy of the declaration of paternity to the mother as notification the person has registered, if the mother's name and address have been provided.

100.3(4) There will be no fee required to file the declaration of paternity.

100.3(5) A fee as established pursuant to rule 641—95.6(144) will be charged and remitted for conducting a search of the registry. The fee will be retained for the search.

100.3(6) Upon written request and remittance of the required fee, the department will conduct a search of the registry. Written requests may be submitted by only:

a. The biological mother of the child;

b. A court;

c. Child support services for an action to establish paternity or support; or

d. The attorney of any party to an adoption, termination of parental rights, or establishment of paternity or support action.

100.3(7) If a declaration of paternity is on file, the department will provide the name, address, and social security number of a registrant to the following:

a. The biological mother of the child;

b. A court;

c. Child support services for an action to establish paternity or support; or

d. The attorney of any party to an adoption, termination of parental rights, or establishment of paternity or support action.

100.3(8) If no declaration of paternity is on file, a written statement to that effect will be provided to the person making the inquiry.

100.3(9) Information from the declaration of paternity registry will not be released to any person other than those listed in subrule 100.3(6) and will be considered a confidential record as to any other person, except upon order of the court.

100.3(10) Information provided to the registry may be revoked by the registrant by the submission of a written statement, signed and acknowledged by the registrant before a notary public.

a. The statement shall include a declaration that to the best of the registrant's knowledge:

(1) The registrant is not the father of the named child; or

(2) The paternity of the true father has been established.

b. Revocation will nullify the registration, and the information provided by the registrant will be expunged.

c. Revocation is effective only following the birth of the child.

100.3(11) The Declaration of Paternity Registry form is available from the state registrar of vital records or the county registrar.

100.3(12) The declaration of paternity registry does not constitute an affidavit of paternity filed pursuant to Iowa Code section 252A.3A. Declarations filed will be maintained in a registry separate and distinct from the affidavit of paternity registry.

100.3(13) A declaration of paternity filed with the registry may be used as evidence of paternity in an action to establish paternity or to determine a support obligation with respect to the putative father.

100.3(14) Failure or refusal to file a declaration of paternity shall not be used as evidence to avoid a legally established obligation of financial support for a child.

[**ARC 0147D**, IAB 3/18/26, effective 7/1/26]

641—100.4(144) Mutual consent voluntary adoption registry established. There is established in the department a mutual consent voluntary adoption registry. Adult adopted children, adult siblings, and the

biological parents of adult adoptees may register with the mutual consent voluntary adoption registry to obtain identifying birth information.

100.4(1) All identifying information maintained in the registry is confidential.

100.4(2) All requests shall be completed on the Mutual Consent Voluntary Adoption Registry Application form available from the state registrar of vital records or the county registrar.

100.4(3) Pursuant to rule 641—95.6(144), a fee will be charged and remitted for the filing of a completed application for the registry, and a fee will be charged and remitted for updating applicant information maintained in the registry.

100.4(4) The state registrar will reveal the identity of the biological parent to the adult adopted child or reveal the identity of the adult adopted child to the biological parent if the conditions of Iowa Code section 144.43A(2) are met.

100.4(5) The state registrar will reveal the identity of the adult adopted child to an adult sibling or will reveal the identity of an adult sibling to the adult adopted child if the conditions of Iowa Code section 144.43A(4) are met.

100.4(6) A person who has filed a request or provided consent may withdraw the consent at any time prior to the release of any information by submitting a written withdrawal of consent statement with the state registrar.

100.4(7) The adult adoptee, adult sibling, and biological parent completing an application shall be responsible for updating the contact information.

100.4(8) The state registrar will verify the address information and provide written notice to the parties.

[**ARC 0147D**, IAB 3/18/26, effective 7/1/26]

641—100.5(144) Statistical report of termination of pregnancy report. A health care provider who initially identifies and diagnoses a spontaneous termination of pregnancy or who induces a termination of pregnancy shall file with the department a Statistical Report of Termination of Pregnancy form for each termination.

100.5(1) The health care provider shall make a good-faith effort to obtain all the information outlined in Iowa Code section 144.29A(1) that is available with respect to each termination, as well as whether the termination was spontaneous or induced.

100.5(2) In addition, a physician who performs or attempts to perform an abortion shall report to the department all of the following:

a. If a determination of probable postfertilization age of the unborn child was made, the probable postfertilization age determined and the method and basis of the determination.

b. If a determination of probable postfertilization age of the unborn child was not made, the basis of the determination that a medical emergency existed.

c. If the probable postfertilization age of the unborn child was determined to be 20 or more weeks:

(1) The basis of the determination of a medical emergency, or

(2) The basis of the determination that the abortion was necessary to preserve the life of an unborn child.

d. The method used for the abortion.

(1) In the case of an abortion performed when the probable postfertilization age was determined to be 20 or more weeks, whether the method of abortion used was one that, in the physician's reasonable medical judgment, provided the best opportunity for an unborn child to survive, or

(2) If such a method was not used, the basis of the determination that termination of the human pregnancy in that manner would pose a greater risk than would any other available method of the death of the pregnant woman or of the substantial and irreversible physical impairment of a major bodily function.

100.5(3) The health care provider who identifies a spontaneous termination or performs an induced termination shall prepare the report on the standard form and forward to the state registrar on or before the tenth day of each calendar month all records for the preceding month. Reports may be sent by mail to the state registrar. Termination reports shall be submitted within 30 days of the date of the occurrence.

100.5(4) The department will provide the forms, or the provider may use the master copy of the form provided by the department to make copies for reporting.

100.5(5) The information will be collected, reproduced, released, and disclosed in a manner that meets the requirements of Iowa Code section 144.29A(2).

100.5(6) The department may share information with federal public health officials as outlined in Iowa Code section 144.29A(2).

100.5(7) By June 30, annually, the department will publish a demographic summary of the statistics for the previous calendar year pursuant to Iowa Code section 144.29A(2).

The department will establish and use a methodology to provide a statistically verifiable basis for any determination of the aggregate form at which information may be released pursuant to Iowa Code section 144.29A(2)*"c."* The methodology will consider both the counts of the events for each item of information and the population that could be represented.

100.5(8) A health care provider shall assign a report tracking number pursuant to Iowa Code section 144.29A(5). The report tracking number shall be maintained by the provider for a period of six months after the end of the calendar year.

100.5(9) For reporting of spontaneous terminations of pregnancy, a health care provider who practices within a hospital, clinic, or other health facility may file the required reporting forms with the department or may authorize one staff person to fulfill the reporting requirements. For reporting of induced terminations of pregnancy, the physician performing the termination shall file the required reporting forms with the department.

100.5(10) Reporting penalties.

a. A physician who fails to submit a report in accordance with Iowa Code section 146B.2 and these rules by the end of 30 days following the due date shall be subject to a late fee of $500 for each additional 30-day period or portion of a 30-day period the report is overdue. The fee will be collected by the department.

b. A physician required to report in accordance with Iowa Code section 146B.2 who has not submitted a report or who has submitted only an incomplete report more than one year following the due date may, in an action brought by the board of medicine in the manner in which actions are brought to enforce Iowa Code chapter 148, be directed by a court of competent jurisdiction to submit a complete report within a time period stated by court order or be subject to contempt of court.

c. A physician who intentionally or recklessly falsifies a report required under Iowa Code section 146B.2 is subject to a civil penalty of $100. The civil penalty will be collected by the department pursuant to Iowa Code chapter 17A.

100.5(11) Any person who knowingly violates a provision of these rules is guilty of a serious misdemeanor pursuant to Iowa Code section 144.52.

[**ARC 0147D**, IAB 3/18/26, effective 7/1/26]

These rules are intended to implement Iowa Code sections 144.29A, 144.43A, 144.52, 146B.2 and 252A.3A.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
[Filed ARC 3394C (Notice ARC 3211C, IAB 7/19/17), IAB 10/11/17, effective 11/15/17]
[Filed ARC 0147D (Notice ARC 9943C, IAB 1/7/26), IAB 3/18/26, effective 7/1/26]

[1] January 16, 2013, effective date of the rescission of Chapter 100 and the adoption of new Chapter 100 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 101
DEATH CERTIFICATION, AUTOPSY AND DISINTERMENT
[Prior to 7/29/87, Health Department[470] Ch 101]
Rescinded **ARC 0483C**, IAB 12/12/12, effective 1/16/13

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CHAPTER 102
CORRECTION AND AMENDMENT OF VITAL RECORDS
[Prior to 7/29/87, Health Department[470] Ch 102]
Rescinded **ARC 0483C**, IAB 12/12/12, effective 1/16/13

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CHAPTER 103
CONFIDENTIALITY OF RECORDS
[Prior to 7/29/87, Health Department[470] Ch 103]
Rescinded **ARC 0483C**, IAB 12/12/12, effective 1/16/13

January 16, 2013, effective date of the rescission of Chapter 103 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 104
COPIES OF VITAL RECORDS
[Prior to 7/29/87, Health Department[470] Ch 104]
Rescinded **ARC 0483C**, IAB 12/12/12, effective 1/16/13

January 16, 2013, effective date of the rescission of Chapter 104 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 105
DECLARATION OF PATERNITY REGISTRY
Rescinded **ARC 0483C**, IAB 12/12/12, effective 1/16/13

January 16, 2013, effective date of the rescission of Chapter 105 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 106
STATE-FUNDED FAMILY MEDICINE OBSTETRICS FELLOWSHIP PROGRAM
Rescinded **ARC 0467D**, IAB 8/5/26, effective 10/1/26

CHAPTER 107
BOARD-CERTIFIED BEHAVIOR ANALYST AND BOARD-CERTIFIED ASSISTANT BEHAVIOR ANALYST (BCBA/BCaBA) GRANTS PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 3/1/31

641—107.1(135) Definitions. For the purposes of these rules, the following definitions will apply:

"Board-certified assistant behavior analyst" or *"BCaBA"* means a person who has a bachelor's degree from an accredited university, has completed approved coursework as defined by the international Behavior Analyst Certification Board, has completed a defined period of supervised practical experience, and has passed the BCaBA examination.

"Board-certified behavior analyst" or *"BCBA"* means a person who has an acceptable graduate degree from an accredited university as defined by the international Behavior Analyst Certification Board, has completed acceptable graduate coursework in behavior analysis, has completed a defined period of supervised practical experience, and has passed the BCBA examination.

"Full-time enrollment" means the applicant is enrolled in a program to be eligible for board certification as a behavior analyst or assistant behavior analyst with the appropriate number of semester credit hours as defined by the educational institution.

"Nonresident" means a person who is not a resident.

"Part-time enrollment" means the applicant is enrolled in a program to be eligible for board certification as a behavior analyst or assistant behavior analyst with the appropriate number of semester credit hours as defined by the educational institution.

"Resident" means a natural person who physically resides in Iowa as the person's principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,
7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child's school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

[**ARC 9957C**, IAB 1/7/26, effective 3/1/26]

641—107.2(135) Eligibility criteria. To be eligible for a grant, the applicant shall:

107.2(1) Be an Iowa resident or nonresident.

107.2(2) Be accepted for admission to or be attending a university, a community college, or an accredited private institution, within or outside the state of Iowa; be enrolled in a program, offered at a physical location or online, that is accredited and meets coursework requirements to prepare the applicant to be eligible for board certification as a behavior analyst or assistant behavior analyst; and demonstrate financial need.

107.2(3) Have on file with the college student aid commission a current Free Application for Federal Student Aid (FAFSA) and Iowa Financial Aid Application or similar financial aid documentation from another state and submit documentation of financial need as described in the department's request for proposal process.

107.2(4) Agree to practice in the state of Iowa for a period of time, not to exceed four years, as specified in the contract entered into between the applicant and the department at the time the grant is awarded.

107.2(5) Agree, as specified in the contract between the applicant and the department at the time the grant is awarded, that during the contract period, the applicant will assist in supervising an individual working toward board certification as a behavior analyst or assistant behavior analyst or to consult with schools and service providers that provide services and supports to individuals with autism.
[**ARC 9957C**, IAB 1/7/26, effective 3/1/26]

641—107.3(135) Priority in grant awards. Priority in the awarding of a grant will be given to resident applicants.
[**ARC 9957C**, IAB 1/7/26, effective 3/1/26]

641—107.4(135) Amount of a grant. The department will award funds based upon the amount set aside in the special fund as identified in Iowa Code section 135.181. Moneys appropriated to, and all other moneys specified for deposit in, the fund will be dedicated to the BCBA/BCaBA grants program as established in Iowa Code section 135.181. These rules will be implemented only to the extent that funding is available. The amount of funding awarded to each applicant will be based on the applicant's enrollment status (full-time enrollment or part-time enrollment), the number of applicants, and the total amount of available funds. The total amount of funds awarded to an individual applicant will not exceed 50 percent of the total costs attributable to program tuition and fees, annually. Awarded grant funds will be payable to the student and prorated on the number of semesters or other terms of study to complete the program.
[**ARC 9957C**, IAB 1/7/26, effective 3/1/26]

641—107.5(135) Use of funds. Funds awarded may be used to offset the costs attributable to tuition and fees for the accredited behavior analyst or assistant behavior analyst program.
[**ARC 9957C**, IAB 1/7/26, effective 3/1/26]

641—107.6(135) Review process.

107.6(1) An applicant shall complete and submit an application to the program in the manner specified by the department. An applicant, if awarded a grant, shall enter into a contract with the department. The department will follow the requirements for competitive bid appeals contained in 441—Chapter 2506.

107.6(2) The department will establish an application process for applicants eligible to receive funding. The application review process and review criteria for preference in awarding the grants will be described in a request for proposals.

107.6(3) An applicant may appeal the denial of a properly submitted grant application. Appeals will be governed by the provisions set forth in 441—Chapter 2506.
[**ARC 9957C**, IAB 1/7/26, effective 3/1/26; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code section 135.181.

[Filed ARC 2765C (Notice ARC 2460C, IAB 3/16/16; Amended Notice ARC 2621C, IAB 7/20/16), IAB 10/12/16, effective 11/16/16]
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[Filed ARC 9957C (Notice ARC 9665C, IAB 11/12/25), IAB 1/7/26, effective 3/1/26]
[Editorial change: IAC Supplement 6/10/26]

CHAPTER 108
MEDICAL RESIDENCY TRAINING STATE MATCHING GRANTS PROGRAM

Rescinded **ARC 0467D**, IAB 8/5/26, effective 10/1/26

CHAPTER 109
PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 1/1/31

641—109.1(135M) Definitions. For purposes of this chapter, the following definitions apply:

"Centralized repository" means an entity approved by the contractor and licensed pursuant to applicable regulations of the board of pharmacy that accepts donated drugs, conducts a safety inspection of the drugs, and ships the donated drugs to a local repository to be dispensed in compliance with this chapter and federal and state laws, rules and regulations.

"Contractor" means the third party approved by the department to implement and administer the prescription drug donation repository program.

"Controlled substance" means the same as defined in Iowa Code section 124.101.

"Indigent" means the same as defined in Iowa Code section 135M.2.

"Local repository" means a pharmacy or medical facility that elects to accept and dispense donated drugs and that meets the eligibility requirements of rule 641—109.2(135M).

"Medical facility" means the same as defined in Iowa Code section 135M.2.

"NDC #" means the unique national drug code number that identifies a specific approved drug.

"Nurse practitioner" means an advanced registered nurse practitioner as defined in 481—Chapter 621.

"Pharmacist" means the same as defined in Iowa Code section 155A.3.

"Pharmacy" means the same as defined in Iowa Code section 155A.3.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Physician associate" means an individual licensed under Iowa Code chapter 148C.

"Prescription drug" means the same as defined in Iowa Code section 155A.3 and includes cancer drugs and antirejection drugs but does not include controlled substances.

"Supplies" means the same as defined in Iowa Code section 135M.2.

"USP" means United States Pharmacopoeia.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26; Editorial change: IAC Supplement 6/10/26]

641—109.2(135M) Eligibility criteria for program participation by medical facilities and pharmacies.

109.2(1) To be eligible for participation in the prescription drug donation repository program, a medical facility or pharmacy shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and the appropriate licensure standards, and shall hold active, nonrestricted, state-issued licenses or registrations in good standing.

109.2(2) Participation in the prescription drug donation repository program is voluntary.

109.2(3) A pharmacy or medical facility may elect to participate in the prescription drug donation repository program by providing, on a form prescribed by the department and available on the department's website, written notification to the centralized repository of all of the following:

a. The name, street address, and telephone number of the pharmacy or medical facility and any state-issued license or registration number issued to the pharmacy or medical facility, including the name of the issuing agency.

b. The name and telephone number of the responsible pharmacist, physician, physician associate or nurse practitioner who is employed by or under contract with the pharmacy or medical facility.

c. A statement, signed and dated by the responsible pharmacist, physician, physician associate or nurse practitioner, indicating that the pharmacy or medical facility meets the eligibility requirements under this rule and shall comply with the requirements of this chapter.

109.2(4) A pharmacy or medical facility may withdraw from participation in the prescription drug donation repository program at any time by providing written notice to the centralized repository on a form prescribed by the department and available on the department's website.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26; Editorial change: IAC Supplement 6/10/26]

641—109.3(135M) Standards and procedures for accepting donated prescription drugs and supplies.

109.3(1) Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to the centralized repository or a local repository if the drugs or supplies meet the requirements of this rule as determined by a pharmacist who is employed by or under contract with a drug repository.

109.3(2) No drugs that need storage temperatures other than normal room temperature as specified by the manufacturer or USP shall be donated or accepted as part of the prescription drug donation repository program. Drugs that need storage temperatures other than normal room temperature as specified by the manufacturer or USP shall not be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer.

109.3(3) Controlled substances shall not be donated or accepted. Pursuant to federal and state laws, a controlled substance cannot be returned or reused once the drug has been dispensed to a patient.

109.3(4) The centralized repository or a local repository may accept a prescription drug only if all of the following requirements are met:

a. The drug is in its original sealed and tamper-evident packaging. However, a drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging is undisturbed;

b. The drug has been stored according to manufacturer or USP storage requirements;

c. The packaging contains the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications will be destroyed in the event of a recall, pursuant to board of pharmacy rules;

d. The drug has an expiration date that is more than six months after the date that the drug was donated. However, a donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and distributed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date;

e. The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;

f. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity or adulteration; and

g. All drugs shall be inventoried at the centralized repository or a local repository. The inventory shall include the name of the drug, strength of the drug, quantity of the drug, and the date of donation if the drug has been continually under the control of a health care professional. If the drug has not been continually under the control of a health care professional, the repository shall collect a donation form provided by the prescription drug donation repository program that is signed by the person making the donation or that person's authorized representative.

109.3(5) A repository may accept supplies necessary to administer the prescription drugs donated only if all of the following requirements are met:

a. The supplies are in their original, unopened, sealed packaging;

b. The supplies are not adulterated or misbranded; and

c. The supplies are inventoried at the centralized repository or a local repository. The inventory shall include a description of the supplies and the date donated. Such inventory shall be recorded on a form provided by the department.

109.3(6) Drugs and supplies may be donated on the premises of a participating centralized repository or a local repository to a person designated by the repository. A drop box will not be used to deliver or accept donations.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26]

641—109.4(135M) Standards and procedures for inspecting and storing donated prescription drugs and supplies.

109.4(1) A licensed pharmacist employed by or under contract with the centralized repository or a local repository shall inspect donated prescription drugs and supplies to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects

the drugs shall sign an inspection record stating the above and attach it to the copy of the inventory or donor record provided with the drugs. If a local repository receives drugs and supplies from the centralized repository, the local repository does not need to reinspect the drugs and supplies.

109.4(2) The centralized repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies will not be stored with nondonated inventory. When donated drugs are not inspected immediately upon receipt, a repository shall quarantine the donated drugs separately from all dispensing stock until the donated drugs have been inspected and approved for dispensing under the program.

109.4(3) Repositories shall destroy donated noncontrolled substances that are not suitable for dispensing and make a record of such destruction according to rules of the board of pharmacy. The destruction record shall be made in the same manner as prescribed for the record of return or destruction of a controlled substance in subrule 109.4(4).

109.4(4) Controlled substances shall not be accepted for donation.

a. Controlled substances submitted for donation shall be documented and returned immediately to the donor or the donor's representative that provided the drugs.

b. In the event controlled substances enter the centralized repository or a local repository and it is not possible or practicable to return the controlled substances to the donor or the donor's representative due to inability to identify the donor or the donor's representative or due to refusal by the donor or the donor's representative to receive them, abandoned controlled substances shall be documented and destroyed beyond reclamation pursuant to rules of the board of pharmacy. Such destruction shall be performed by a pharmacist or other person who has authority to dispense controlled substances and shall be witnessed by another responsible adult employee of the repository.

109.4(5) If a repository receives a recall notification, the repository shall perform a uniform destruction of all of the recalled prescription drugs in the repository and complete the destruction information form for all donated drugs destroyed. If a recalled drug has been dispensed, the repository shall immediately notify the recipient of the recalled drug pursuant to established drug recall procedures.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26]

641—109.5(135M) Standards and procedures for dispensing donated prescription drugs and supplies.

109.5(1) Donated drugs and supplies may be dispensed only if the drugs or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a licensed pharmacist, physician, physician associate or nurse practitioner.

109.5(2) A repository shall prioritize dispensing to an individual requesting drugs through the program as follows:

a. First, to an indigent individual;

b. Second, to an individual who has no active third-party prescription drug reimbursement coverage for the drug prescribed; and

c. Third, to any other individual if an indigent or uninsured individual is unavailable.

109.5(3) A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, recordkeeping, drug utilization review, and patient counseling.

109.5(4) The centralized repository and a local repository shall remove the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drugs or supplies.

109.5(5) The centralized repository and a local repository shall be responsible for drug recalls and shall have an established mechanism to notify recipients in the event of a drug recall.

109.5(6) Prescription drugs or supplies donated under this program shall not be resold.

109.5(7) The participating centralized repository and local repositories may distribute drugs and supplies donated under this program to other participating repositories for use pursuant to the program. The repository distributing the drugs or supplies shall complete a transfer form.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26; Editorial change: IAC Supplement 6/10/26]

641—109.6(135M) Eligibility criteria for individuals to receive donated prescription drugs and supplies.

109.6(1) An individual who requests drugs from the prescription drug donation repository program shall certify to the repository that the individual is a resident of Iowa and meets one or both of the following criteria:

a. Is indigent; and

b. Has no active third-party prescription drug reimbursement coverage for the drug prescribed.

109.6(2) The local repository shall collect from each individual recipient a signed intake collection form provided by the department or its contractor.

a. The intake collection form shall attest that:

(1) The individual is a resident of the state of Iowa;

(2) The individual's income does not exceed 200 percent of the federal poverty level (FPL);

(3) The individual is uninsured and has no prescription coverage or is underinsured and has no prescription coverage;

(4) The individual acknowledges that the drugs may have been donated; and

(5) The individual consents to a waiver of the requirement for child resistant packaging of the Poison Prevention Packaging Act (as amended to August 1, 2025).

b. The intake collection form will include an identification card to be given to the recipient for continued use for one year.

109.6(3) The identification card is valid for one year or until the new federal poverty guidelines have been published for all prescriptions and supplies.

109.6(4) A summary of data taken from the intake collection form is to be sent via regular mail, email or facsimile to the centralized repository for data collection.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26]

641—109.7(135M) Forms and recordkeeping.

109.7(1) The following forms developed for the administration of this program shall be utilized by participants of the program and are available on the department's website:

a. Prescription drug donation repository program notice of participation or withdrawal.

b. Prescription drug donation repository program donation, transfer, inventory or destruction record.

c. A record of medications dispensed.

109.7(2) The prescription drug donation repository program recipient data collection form and identification card are given to the recipient by the local repository, and the completed data collection form is collected from the recipient by the local repository.

109.7(3) Recordkeeping requirements.

a. All records required to be maintained as a part of the prescription drug donation repository program shall be maintained for a minimum of five years by participating pharmacies and medical facilities.

b. Records required as part of this program shall be maintained pursuant to all current applicable practice acts.

c. Data collected by the prescription drug donation repository program from all participating repositories shall be submitted quarterly or upon request to the centralized repository.

d. The centralized repository and the contractor shall submit reports to the department as required by the contract or upon request of the department.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26]

641—109.8(135M) Handling fee. A repository may charge the recipient of a donated drug a handling fee, not to exceed a maximum of 200 percent of the Medicaid professional dispensing fee as established by rule. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

[**ARC 9765C**, IAB 11/26/25, effective 1/1/26]

641—109.9(135M) List of drugs and supplies program will accept. All prescription drugs, excluding controlled substances, that have been approved for medical use in the United States, that are listed in the USP or National Formulary (USP/NF), and that meet the criteria for donation established by these rules may be accepted for donation under the prescription drug donation repository program.
[**ARC 9765C**, IAB 11/26/25, effective 1/1/26]

641—109.10(135M) Prescription drug donation repository in disaster emergencies. The following are the requirements for the department to receive and distribute prescription drugs and supplies in preparation for a disaster emergency proclaimed by the governor or in preparation for a public health disaster.

109.10(1) The department may receive prescription drugs and supplies directly from the prescription drug donation repository contractor and dispense prescription drugs and supplies through licensed personnel during or in preparation for a disaster emergency proclaimed by the governor pursuant to Iowa Code section 29C.6 or during or in preparation for a public health disaster as defined in Iowa Code section 135.140(5).

109.10(2) The department may receive and distribute prescription drugs and supplies as outlined in Iowa Code section 135.142 to any Iowan who has been a victim of a disaster emergency proclaimed by the governor.
[**ARC 9765C**, IAB 11/26/25, effective 1/1/26]

These rules are intended to implement Iowa Code chapter 135M.

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[Editorial change: IAC Supplement 6/10/26]

CHAPTER 110
CENTER FOR RURAL HEALTH
AND PRIMARY CARE
Rescinded **ARC 0467D**, IAB 8/5/26, effective 10/1/26

CHAPTER 111
IOWA NEEDS NURSES NOW INFRASTRUCTURE ACCOUNT
Rescinded **ARC 0467D**, IAB 8/5/26, effective 10/1/26

CHAPTER 112
BIOLOGICAL AGENT RISK ASSESSMENT
Rescinded **ARC 3395C**, IAB 10/11/17, effective 11/15/17

CHAPTER 113
PUBLIC HEALTH RESPONSE TEAMS

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/1/30

641—113.1(135) Definitions. For purposes of this chapter, the following definitions apply:

"Defend" means that the office of the Iowa attorney general shall provide a public health response team member with legal representation at no cost to the public health response team member.

"Disaster medical assistance team" or *"DMAT"* means a public health response team that is sponsored and approved by the department to provide medical assistance in the event of a disaster or threatened disaster or other incident as defined in Iowa Code section 135.143.

"Environmental health response team" or *"EHRT"* means a public health response team that is sponsored and approved by the department to provide environmental health expertise and assistance in the event of a disaster or threatened disaster or other incident defined in Iowa Code section 135.143.

"Indemnify" means the state of Iowa will pay all sums that a public health response team member is legally obligated to pay as damages because of any claim made against the public health response team member that arises out of the provision of direct medical care or other support services rendered or that should have been rendered during a disaster, threatened disaster, or other incident defined in Iowa Code section 135.143, or arising out of a training exercise to prepare for a disaster or other incident defined in Iowa Code section 135.143.

"Iowa mortuary operational response team" or *"IMORT"* means a public health response team that is sponsored and approved by the department to provide decedent care in the event of a mass fatality disaster or threatened disaster or other incident defined in Iowa Code section 135.143.

"Logistical support response team" or *"LSRT"* means a public health response team that is sponsored and approved by the department to provide logistical support and assistance in the event of a disaster or threatened disaster or other incident defined in Iowa Code section 135.143.

"Public health response team" or *"PHRT"* means a team of professionals, including licensed health care providers, nonmedical professionals skilled and trained in disaster or emergency response, and public health practitioners, that is sponsored and approved by the department to provide assistance in the event of a disaster or threatened disaster or other incident defined in Iowa Code section 135.143. "Public health response team" includes a disaster medical assistance team, an environmental health response team, a logistical support response team, the Iowa mortuary operational response team, and other teams established and approved upon written order of the director to supplement and support disrupted or overburdened local medical and public health personnel, hospitals, and resources.

"Public health response team member" or *"PHRT member"* means an individual who has registered with the department and has received approval from the department to serve on a public health response team.

[**ARC 9323C**, IAB 5/28/25, effective 8/1/25]

641—113.2(135) Public health response team members.

113.2(1) *Registration and approval.* An individual may apply to the department to be a public health response team member. The applicant shall apply on the Iowa statewide registry of volunteers (iSERV) website or on a form approved by the department and shall provide all requested information. The department will register and approve an individual to serve as a PHRT member when the department is satisfied that the individual satisfies the requirements of this chapter and will perform on a PHRT in compliance with Iowa Code section 135.143 and this chapter. Upon registration and approval of an individual, the department will provide the individual with written notification that the individual is registered with the department and has been approved to serve on a PHRT. The written notification will also include the effective date of the approval and the terms and conditions of approval.

113.2(2) *Denial and revocation.* The department may deny approval to an individual or may revoke an individual's approval if the department determines the individual has violated or failed to comply with Iowa Code section 135.143 or this chapter, any term or condition contained in the written approval notification from the department, any operational procedure, or state or federal law or has exposed or

may expose the state to undue risk. The department will notify the individual of the department's decision in writing by certified mail, return receipt requested. In the event an individual is dissatisfied with the department's decision, the individual may submit a request for reconsideration to the department. Such request shall be delivered by certified mail, return receipt requested, within 20 days of the date of the denial or revocation notification, to the department. The department will review the matter and issue a written decision within 20 days of receipt of the request. The department's decision shall be final agency action. This appeal process does not constitute a contested case proceeding as defined in Iowa Code chapter 17A.

113.2(3) *Effect of revocation.* If the department revokes a public health response team member's approval, the action may preclude future eligibility but shall not negate defense and indemnification coverage or other protection for covered acts or omissions that occurred during the effective date of approval.

[**ARC 9323C**, IAB 5/28/25, effective 8/1/25]

641—113.3(135) Public health response team.

113.3(1) *General requirements.*

a. An individual may make application to be a member of a PHRT pursuant to subrule 113.2(1).

b. The department established the Iowa Volunteer Public Health Response Team Operational Procedures Manual as amended to August 1, 2024. The operational procedures will be in writing and will be provided to each PHRT member. All PHRT members shall follow the PHRT operational procedures as established by the department. The Iowa Volunteer Public Health Response Team Operational Procedures Manual, as amended to August 1, 2024, is available from the department.

c. If the department notifies a PHRT member of a violation of Iowa Code section 135.143, this chapter, or an operational procedure, the PHRT member shall correct the deficiency or violation identified by the department within a time frame determined by the department. If a PHRT member fails to correct a deficiency or violation within the time frame identified by the department, or if the deficiency or violation constitutes an immediate danger to public health, safety, or welfare, the department may initiate action to revoke approval pursuant to subrule 113.2(2).

113.3(2) *Team composition.*

a. A PHRT shall be comprised of health care professionals and administrative personnel as identified in the Iowa Volunteer Public Health Response Team Operational Procedures Manual.

b. The department is responsible for maintaining adequate staffing.

113.3(3) *Licensure and educational requirements.*

a. Each PHRT member shall hold and maintain an active unrestricted license, registration, or certification to practice in Iowa (if applicable) in the member's respective medical or health care profession.

b. Each PHRT member shall complete required training as listed in the Iowa Volunteer Public Health Response Team Operational Procedures Manual, as amended to August 1, 2024, including training specified in respective team annexes.

c. The department may provide specific position training to PHRT members as determined to be necessary.

d. The department will develop and implement training exercises to test the team's notification process, deployment readiness, and response capabilities.

e. The department is responsible for documenting each PHRT member's completion of required training.

113.3(4) *Deployment and standdown.*

a. PHRTs shall prepare to deploy within two to four hours of notification by the department. PHRTs shall not self-deploy and shall not be covered by the provisions of Iowa Code section 135.143 and this chapter if the PHRTs self-deploy or are deployed by another agency or entity.

b. Deployment and standdown procedures are outlined in the Iowa Volunteer Public Health Response Team Operational Procedures Manual, as amended to August 1, 2024, and shall be followed by all PHRT members.

[**ARC 9323C**, IAB 5/28/25, effective 8/1/25]

641—113.4(135) Legal and other protections. A PHRT member acting pursuant to Iowa Code section 135.143 and this chapter shall be considered an employee of the state under Iowa Code section 29C.21 and chapter 669; shall be afforded protection as an employee of the state under Iowa Code section 669.21 whom the state shall defend and indemnify; and shall be considered an employee of the state for purposes of workers' compensation, disability, and death benefits, provided that the member has done all of the following:

1. Registered with and received approval from the department pursuant to subrule 113.2(1) to serve on a PHRT.

2. Provided direct medical care or other support services during a disaster, threatened disaster, or other incident described in Iowa Code section 135.143(1); or participated in a training exercise to prepare for a disaster or other incident described in Iowa Code section 135.143(1).

[**ARC 9323C**, IAB 5/28/25, effective 8/1/25]

641—113.5(135) Reporting requirements and duties.

113.5(1) Upon obtaining knowledge or becoming aware of any injury allegedly arising out of the negligent rendering of, or the negligent failure to render, medical or other services as a PHRT member, the member shall provide written notice to the department, as soon as practicable, containing to the extent obtainable the circumstance of the alleged injury, the name and address of the injured, and any other relevant information.

113.5(2) Upon obtaining knowledge or becoming aware of any injury as described in subrule 113.5(1), a PHRT member shall promptly take all reasonable steps to prevent further or additional injury from the same or similar circumstances, situations, or conditions.

113.5(3) A PHRT member shall immediately notify the office of the Iowa attorney general of service or receipt of an original petition, suit, or claim seeking damage from the PHRT member related to participation on a PHRT.

113.5(4) Each PHRT member shall fully cooperate with the state in the defense of any claim or suit related to participation on a PHRT, including attending hearings, depositions, and trials and assisting in securing and giving evidence, responding to discovery, and ensuring the attendance of witnesses.

113.5(5) Each PHRT member shall accept financial responsibility for personal expenses and costs incurred in the defense of any claim or suit related to participation on a PHRT, including travel, meals, and compensation for time and lost practice.

[**ARC 9323C**, IAB 5/28/25, effective 8/1/25]

These rules are intended to implement Iowa Code section 135.143.

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[Filed ARC 9323C (Notice ARC 8460C, IAB 12/25/24), IAB 5/28/25, effective 8/1/25]

CHAPTER 114
PREPAREDNESS ADVISORY COMMITTEE
Rescinded **ARC 9176C**, IAB 4/30/25, effective 7/1/25

CHAPTERS 115 to 120
Reserved

CHAPTER 121
STANDARD FOR IMPACT RESISTANCE AND METHOD OF TESTING
[Prior to 7/29/87, Health Department[470] Ch 121]
Rescinded IAB 6/3/09, effective 7/8/09

CHAPTER 122
ANATOMICAL GIFT PUBLIC AWARENESS AND TRANSPLANTATION FUND
Rescinded **ARC 9324C**, IAB 5/28/25, effective 8/1/25

CHAPTER 123
Reserved

CHAPTER 124
INTERAGENCY COORDINATING COUNCIL
FOR THE STATE MEDICAL EXAMINER
Rescinded **ARC 8974C**, IAB 2/19/25, effective 4/1/25

CHAPTER 125
ADVISORY COUNCIL FOR THE STATE MEDICAL EXAMINER
Rescinded **ARC 4705C**, IAB 10/9/19, effective 11/13/19

CHAPTER 126
STATE MEDICAL EXAMINER

[Prior to 4/20/88, see Medical Examiner, State[566] Ch 1]
[Prior to 6/30/99, see Public Safety Department[661] Ch 21]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/31

641—126.1(144,331,691) Definitions.

"Autopsy" means the external and internal postmortem examination of a deceased person.

"County of appointment" means the county that requests a medical examiner to conduct an investigation, perform or order an autopsy, or prepare a report or reports in a death investigation case. The request may be authorized by the county attorney or the county medical examiner. The county of appointment shall be the county in which the death occurred.

[**ARC 0148D**, IAB 3/18/26, effective 7/1/26]

641—126.2(691) Fees for autopsies and related services and reimbursement for related expenses. Autopsies performed by the state medical examiner are provided on a fee-for-service basis. Costs of autopsies and related services and expenses are the responsibility of the county of appointment. The county of residence of the deceased shall reimburse the county of appointment.

126.2(1) *Fee schedule.* The following fees apply as specified in this subrule.

a. The following fees apply to autopsies conducted by the state medical examiner:

Autopsy.	$2,100*
	Pursuant to 126.2(1)"a"*(2), this amount will increase annually by 2 percent beginning July 1, 2027.
Copies of reports.	$20

(1) Exceptions: A copy of the autopsy report is automatically sent to the county medical examiner and to the county attorney without fee. A single copy of an autopsy report may be provided to the immediate next of kin of the deceased without fee. Copies of autopsy reports may be provided to public officials and physicians of record for official purposes without fee.

(2) Beginning with the fiscal year starting July 1, 2027, the amount of the autopsy fee will increase annually by 2 percent each July 1.

b. The following fee is for time spent reviewing case materials, preparing for deposition or court, testifying in deposition or court, and travel time.

State, deputy, or associate medical examiner(s) time for all court cases	$450 per hour with a one-hour minimum

c. A cremation permit fee of $75 will be assessed for each permit investigated and authorized by the state medical examiner's office.

126.2(2) *Expense reimbursement.* Other laboratory services associated with an autopsy, which include but are not limited to photography, toxicology, radiology, microbiology, and morgue fees, will be billed by the department to the county of appointment. Moneys collected pursuant to this subrule will be paid by the department to the laboratory or other entity providing the service.

126.2(3) *State medical examiner acting as county medical examiner.* When the state medical examiner acts in the capacity of county medical examiner, the state medical examiner receives from the county of appointment a fee of $100 per hour, with a one-hour minimum, for each report prepared plus the state medical examiner's actual expenses. Counties should not depend on the state medical examiner for full-time coverage.

[**ARC 0148D**, IAB 3/18/26, effective 7/1/26]

641—126.3(691) Fees for tissue recovery. When the tissue recovery room located within the office of the state medical examiner is utilized by an authorized tissue recovery agency, a fee of $400 per case will be

assessed. The tissue recovery agency is responsible for this fee, payable to the office of the state medical examiner.

[**ARC 0148D**, IAB 3/18/26, effective 7/1/26]

These rules are intended to implement Iowa Code section 691.6.

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CHAPTER 127
COUNTY MEDICAL EXAMINERS
[Prior to 7/29/87, Health Department [470] Ch 127]

Chapter rescission date pursuant to Iowa Code section 17A.7: 4/1/31

641—127.1(144,331,691) Definitions.

"Autopsy" means the external and internal postmortem examination of a deceased person.

"Cause of death" means the disease or injury that sets in motion the chain of events that eventually results in the death of a person. The physician shall consider "but for" this injury or disease the person would still be living.

"County medical examiner" or *"CME"* means a medical or osteopathic physician or surgeon licensed in the state of Iowa and appointed by the board of supervisors to serve in this capacity.

"County medical examiner investigator" or *"CME-I"* means an individual appointed by a county medical examiner, with approval by the board of supervisors and the state medical examiner, to serve under the supervision of a county medical examiner to assist in death investigations.

"County of appointment" means the county that requests a medical examiner to conduct an investigation, perform or order an autopsy, or prepare a report(s) in a death investigation case. The request may be authorized by the county attorney or the county medical examiner. The county of appointment shall be the county in which the death occurred.

"Cremation" means the technical process, using heat and flame, that reduces human remains to bone fragments.

"Cremation permit" means an electronic cremation permit approved by the medical examiner.

"Day" means calendar day.

"Death" means the condition as described in Iowa Code section 702.8.

"Death affecting the public interest" means any death of a human being in which the circumstances are sudden, unexpected, violent, suspicious, or unattended, including but not limited to those deaths listed in Iowa Code sections 331.802(3) and 144.29.

"Deputy county medical examiner" or *"DCME"* means an individual appointed by a county medical examiner, with approval by the board of supervisors and the state medical examiner, to assist the county medical examiner in the performance of the county medical examiner's duties.

"EMER" means the electronic medical examiner report.

"External examination" means a close inspection of the exterior of a deceased human body for the purpose of locating, describing, and delineating any and all injuries or other abnormalities. External examination of a body does not constitute an autopsy, even if toxicology samples are obtained.

"Fee" means an amount to be paid to a county medical examiner's office as determined by the board of supervisors of the county of appointment for completion of an investigation, autopsy, or report(s). Fees for services provided by the state medical examiner's office are established in rule 641—126.3(691).

"Manner of death" means the circumstances under which the cause of death occurred and may be specified as follows: natural, accident, suicide, homicide, undetermined, or pending.

"Medical care provider" means an individual licensed or certified in any medical profession, including but not limited to a physician, physician associate, nurse, emergency medical care provider, certified nurse's aide, pharmacist, physical therapist, and medical technologist.

"Medical examiner" means the state medical examiner, deputy state medical examiner, county medical examiner, or deputy county medical examiner.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26; Editorial change: IAC Supplement 6/10/26]

641—127.2(331,691) Duties of medical examiners—jurisdiction over deaths that affect the public interest.

127.2(1) *Jurisdiction.* Upon receiving notification of a death that affects the public interest, a medical examiner shall notify any appropriate law enforcement agency not otherwise notified and take charge of the body of the decedent. The body shall not be disturbed or removed from the position in which it was found without authorization from the medical examiner except for the purpose of preserving the body from loss

or destruction or permitting the passage of traffic on a highway, railroad, or airport, or unless the failure to remove the body might endanger life, safety, or health.

127.2(2) *Investigation.* A county medical examiner shall conduct a preliminary investigation of the cause and manner of death and utilize the investigative protocol outlined in the County Medical Examiner's Handbook as amended to August 1, 2025, available from the state medical examiner's office. A medical examiner may perform or authorize performance of any scientific study to assist in identifying the cause, circumstances, and manner of death. A medical examiner shall cooperate with other investigating officials and agencies involved and share reports, information, and conclusions with these officials and agencies.

127.2(3) *Reports required.*

a. EMER.

(1) Preparation and filing. A county medical examiner shall electronically enter the examiner's findings in the Preliminary Medical Examiner Report in the EMER system. A county medical examiner must complete and submit the EMER within 14 days of the date of death and file a copy of the EMER with the county attorney within 14 days of the date of the death and retain a copy for the county medical examiner's records.

(2) Content. The EMER shall be completed as fully as possible in light of all available information and may be signed by either a county medical examiner or a county medical examiner investigator acting under the supervision of a county medical examiner. If the cause or manner of death, identity of the decedent, or other information is unknown or pending at the time of filing, "unknown" or "pending" may be written in the appropriate area of the form. If additional information becomes available, this information shall be forwarded to the state medical examiner in written form at such time as it becomes available to be added as a supplement to the file.

b. Jurisdiction declined or terminated. An EMER with designated, abbreviated, or minimal information shall be completed and submitted in accordance with subparagraphs 127.2(3)*"a"*(1) and *"a"*(2) in cases reported to the county medical examiner where jurisdiction is terminated or declined.

127.2(4) *Disposition of body.* After an investigation, including an autopsy if one was performed, the body of the decedent shall be made available to the funeral home designated by a relative or friend of the decedent for burial or appropriate disposition. A medical examiner cannot use influence in favor of a particular funeral director or funeral home. If no one claims a body, it shall be disposed of as provided in Iowa Code chapter 142.

127.2(5) *Coverage.*

a. When an individual is required to report a death to a medical examiner and the county medical examiner cannot be located or is not available, the individual must contact a county medical examiner from any adjacent Iowa county to perform those duties outlined in this chapter. The responding medical examiner has full authority to conduct any procedures necessary to the investigation of the cause and manner of death. If an adjacent county medical examiner is not available, the state medical examiner shall be contacted and may act in the capacity of a county medical examiner.

b. The responding county medical examiner will be reimbursed by the county for which the service is provided for all fees and expenses at the rate that is customarily paid by the county for which the service is provided or at a rate agreed upon by the medical examiner and the board of supervisors of the county for which the service is provided.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.3(331,691) Autopsies.

127.3(1) *Autopsy required.* A county medical examiner shall order that an autopsy be performed in the following cases:

a. All cases of homicide or suspected homicide, irrespective of the period of survival following injury.

b. All cases in which the manner of death is undetermined.

c. All cases involving unidentified bodies.

d. All deaths of children under the age of two when there is not a clear cause of death, including suspected cases of unexpected or unexplained death.

e. All work- and farm-related deaths unless there is an obvious natural cause of death.

f. All drowning deaths.

g. All deaths of commercial vehicle drivers that occur during the performance of their job duties.

h. Deaths due to poisoning.

i. Deaths of airplane pilots who die as a result of an airplane crash. The National Transportation Safety Board and the Federal Aviation Administration should be contacted prior to the autopsy to request specimen kit(s).

j. Deaths due to a natural disaster, including tornadoes and floods.

k. Deaths in a prison, jail or correctional institution or under police custody, where there is not a natural disease process that accounts for the death.

127.3(2) *Autopsy recommended.* It is recommended that a county medical examiner should perform an autopsy or order that an autopsy be performed in the following cases:

a. Deaths of adolescents less than 18 years of age when there is not a natural cause of death.

b. All cases that involve a motor vehicle crash.

c. Deaths from suicide.

d. All pedestrian, bicycle, motorcycle, snowmobile, boating, watercraft, three- or four-wheeler or all-terrain vehicle fatalities.

e. Deaths due to failure of a consumer product.

f. Deaths due to a possible public health hazard.

g. Deaths due to drug or alcohol abuse or overdose.

h. Electrical- and lightning-related deaths.

i. Deaths from burns or smoke or soot inhalation.

j. All deaths related to exposure, such as hypothermia and hyperthermia.

k. All sport-related deaths, including but not limited to deaths from auto racing and deaths resulting from injuries sustained in football, basketball, baseball, softball, soccer, or other games or sports.

127.3(3) *Other deaths.* For those deaths not listed in subrule 127.3(1) or 127.3(2), a county medical examiner will determine whether the public interest requires an autopsy and order that an autopsy be performed. A county medical examiner may consult with the state medical examiner to assist in determining the need for an autopsy.

127.3(4) *Performance of autopsy.*

a. Who may authorize. Autopsies may be authorized by the state medical examiner, the county medical examiner for the county in which the death occurred or the county where any injury contributing to or causing the death was sustained, or the county attorney who would have jurisdiction in any criminal proceeding related to the death.

b. Who may perform. An autopsy must be performed by a pathologist trained or with experience in forensic pathology, licensed to practice medicine and surgery or osteopathic medicine and surgery in the state of Iowa and board-certified by the American Board of Pathology, or under the direct supervision of a physician with these qualifications. The following types of deaths shall be transported to the office of the state medical examiner for autopsy unless otherwise approved by the state medical examiner:

(1) Deaths of adolescents through 18 years of age when there is not a known or preexisting natural cause of death.

(2) All cases of homicide or suspected homicide, irrespective of the period of survival following injury.

(3) Deaths of children under the age of two years if death results from an unknown cause or is unexpected.

(4) All suspicious suicides.

(5) All high-profile deaths, including but not limited to deaths of elected officials in municipal, state or federal government.

(6) All deaths of inmates occurring in any institutions under the department of corrections as outlined in Iowa Code section 904.102, excluding those deaths that result from a pre-existing medical condition.

c. Permit required—EMER. A medical examiner must complete the EMER. All reasonable efforts must be made to complete the EMER prior to the performance of an autopsy.

127.3(5) *Autopsy report.* A complete record of the findings of the autopsy shall be submitted to the state medical examiner's office, the county attorney of the county where the death occurred and the county attorney of the county where the injury contributing to or causing the death was sustained within 90 days following the date of death unless unusual circumstances requiring further investigation or testing exist. The report filed shall include transcriptions of the autopsy observations and opinions and toxicology reports.

127.3(6) *Out-of-state autopsy.* The body of a decedent may be sent out of state for an autopsy or postmortem examination only if the county medical examiner certifies in writing that the out-of-state autopsy or examination is necessary for any of the following reasons:

a. A forensic pathologist practicing in the state of Iowa is unavailable;

b. Requiring an in-state autopsy would cause financial hardship; or

c. Requiring an in-state autopsy would delay the funeral or burial more than three days.

127.3(7) *Retention and disposal of tissues, organs, and bodily fluids.* The office of the state medical examiner will retain tissues, organs, and bodily fluids as necessary to determine the cause and manner of death or as deemed advisable by the state medical examiner for medical or public health investigation, teaching, or research. Tissues, organs, and bodily fluids will be retained at a minimum for the time periods established by the National Association of Medical Examiners and may be retained for a longer time period at the discretion of the state medical examiner. Tissues, organs, and bodily fluids retained under this subrule will be disposed of without the specific consent or notification of the legal next of kin and in accordance with applicable federal and state regulations, including but not limited to OSHA-recommended biohazard and blood-borne pathogen standards. The anatomical material must be removed from the laboratory premises through use of a contracted, licensed, and bonded medical waste removal service to a medical waste processing center for final disposition.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.4(331,691) Fees.

127.4(1) *Payment of fee and expenses.*

a. A medical examiner receives from the county of appointment or the county of the decedent's residence a fee for each preliminary investigation and report submitted in a case in which a death affects the public interest. A county medical examiner shall also receive from the county of appointment or the county of the decedent's residence the examiner's actual expenses. The fee and expenses are submitted by the county medical examiner to the county of appointment, which may immediately pay the invoice or forward the invoice to the county of the decedent's residence for payment to the county medical examiner. If the county medical examiner does not receive payment from the county of the decedent's residence within 60 days of receiving the invoice, the county of appointment shall pay the invoice.

b. A pathologist or other physician who performs an autopsy under medical examiner authorization shall be paid for the services by the county of appointment.

c. Invoices produced for services performed by a county medical examiner, deputy county medical examiner or county medical examiner investigator must be submitted as a joint invoice to the county of appointment when services were rendered in a case by multiple county medical examiner staff.

127.4(2) *Reimbursement.*

a. County of residence different from county of appointment—Iowa resident. The county of the decedent's residence shall reimburse the county of appointment for the fee and expenses paid by the county of appointment.

b. Death caused by criminal defendant. If the person's death is caused by a criminal defendant who has been convicted and sentenced for murder, voluntary manslaughter, involuntary manslaughter, or homicide by vehicle, the county of the person's residence may recover from the defendant the fee and expenses.

c. Out-of-state resident—law enforcement involvement. The fee and expenses of a county medical examiner who performs an investigation or autopsy of a person who dies after being brought into the state for emergency medical treatment by or at the direction of an out-of-state law enforcement officer or public authority will be paid by the state. A claim for payment shall be filed with the state appeal board.

d. Out-of-state resident—no law enforcement involvement. The fee and expenses of a county medical examiner who performs an investigation or autopsy of an out-of-state resident shall be paid by the county of appointment.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.5(144,331,691) Death certificates—deaths affecting the public interest.

127.5(1) *Completion.* The funeral director to whom the body is released shall complete the personal data on the death certificate. The medical examiner must complete the manner of death and cause of death sections of the death certificate within 72 hours after determination of the cause and manner of death. If an autopsy is performed by the state medical examiner, the death certificate medical certifier sections will be completed by the state medical examiner's office.

127.5(2) *Filing.* The funeral director shall file the certificate with the county registrar in the county in which the death occurred. A death certificate shall be filed prior to the issuance of a burial transit permit and prior to disposal of the body.

127.5(3) *Extension of time.* If a medical examiner is unable to complete the manner of death and cause of death sections of the death certificate within the 24-hour time period, the funeral director must file a death certificate form completed with all available information. Such certificate is authority for the issuance of a burial transit permit. Within 15 days, a supplemental report shall be filed with the local registrar that provides the information missing from the original certificate.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.6(331,691) Cremation.

127.6(1) *Permit obtained prior to cremation—cremation permit.* A permit for cremation must be obtained from a county medical examiner or state medical examiner prior to cremation of a body of a decedent. Cremation permits must be completed in the electronic death registry system. For the purposes of this requirement, a hard copy or facsimile of a hard copy shall only be utilized if the electronic death registry system is off-line for four or more hours.

127.6(2) *Requirements for issuance of permit.* A county medical examiner shall direct an inquiry into the cause and manner of death and determine whether the death is one that affects the public interest prior to issuing a cremation permit.

a. Death that affects the public interest. If the death occurred in a manner specified in Iowa Code section 331.802(3) or if reasonable suspicion that the death occurred in such a manner exists, a medical examiner shall view the body, make a personal inquiry into the cause and manner of death, and complete or cause to be completed all necessary autopsy or postmortem examinations prior to issuing a cremation permit.

b. Death that does not affect the public interest. If, following an inquiry into the cause and manner of death, the county medical examiner determines that the death did not occur in a manner specified in Iowa Code section 331.802(3), a medical examiner is not required to view the body prior to issuing a cremation permit. A county medical examiner must certify on the Cremation Permit in the electronic death registry system that the medical examiner's inquiry into the cause and manner of death did not disclose evidence that the death occurred in a manner specified in Iowa Code section 331.802(3).

127.6(3) *Fee.* A fee for the Cremation Permit by Medical Examiner shall be paid by the family, next of kin, guardian of the decedent, or other person authorized to act on behalf of the decedent.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.7(331,691) County medical examiner investigators.

127.7(1) *Appointment.* A county medical examiner may appoint one or more county medical examiner investigators upon approval by the board of supervisors and the state medical examiner.

127.7(2) *Qualifications.*

a. Prior to appointment, a CME-I should possess a minimum of two years of experience as a licensed or certified nurse or medical care provider. A certified peace officer may be appointed to the position of CME-I if a nurse or medical care provider is not available.

b. A CME-I shall satisfy the following criteria:

(1) Prior to or within two years of appointment, attend the St. Louis University School of Medicine Basic Medicolegal Death Investigation Course or its state medical examiner-approved equivalent; and

(2) Prior to or within five years of appointment, obtain certification at the registry level as a death investigator by the American Board of Medicolegal Death Investigators.

c. A CME-I is not required to meet the requirements of paragraph 127.7(2)*"a"* or *"b"* if the individual has functioned in the capacity of a CME-I for a period of five years.

d. If a CME is unable to appoint a CME-I who possesses the qualifications required by paragraph 127.7(2)*"a," "b,"* or *"c,"* the CME may request a waiver. Waiver requests must be submitted in writing to the state medical examiner and include the efforts undertaken by the CME to locate a CME-I who meets the above qualifications; the qualifications of the individual willing to serve in the capacity of a CME-I; and the period of time for which the waiver is requested, not to exceed two years. The state medical examiner has sole discretion to waive the requirements of this rule and may withdraw or modify a waiver request upon a finding that the CME-I has failed to adequately perform the duties of the position or for other good cause.

e. If a CME-I is unable to meet the eligibility requirements for obtaining registry certification due to the small number of cases requiring investigation in the county of appointment, then a waiver must be obtained from the state medical examiner in order for the investigator to continue the investigator's duties. The county medical examiner must submit a request for a waiver in writing with documentation of the number of deaths occurring in the county of appointment that require death investigation. The waiver must be renewed every five years if the required number of investigations has still not been achieved.

127.7(3) *Duties.* A CME-I shall assist in death investigations. A CME-I acting under the supervision of a county medical examiner may sign the EMER. A CME-I cannot sign a certificate of death or a cremation permit.

127.7(4) *Supervision.* A CME-I shall serve under the supervision of a county medical examiner. A CME-I provides services under the direction of a county medical examiner or state medical examiner's office. A CME-I can perform services in a manner that is consistent with the protocol outlined in this chapter.

127.7(5) *Fees.* Fees for the services provided by a CME-I shall be paid by the county of appointment or by the county of the decedent's residence. A CME-I shall receive from the county of appointment or the county of the decedent's residence reimbursement for actual expenses. The fee and expenses must be submitted by the CME-I to the county of appointment, which may immediately pay the invoice or forward the invoice to the county of the decedent's residence for payment to the CME-I. If the CME-I does not receive payment from the county of the decedent's residence within 60 days of receiving the invoice, the county of appointment shall pay the invoice.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.8(331,691) Deputy county medical examiners.

127.8(1) *Appointment.* A county medical examiner may appoint one or more DCMEs upon approval by the board of supervisors and the state medical examiner.

127.8(2) *Qualifications.* A DCME must be licensed in the state of Iowa as a medical or osteopathic physician or surgeon.

127.8(3) *Duties.* A DCME serves at the direction of the county medical examiner and may perform any duty of a county medical examiner that is delegated by the county medical examiner to the DCME.

127.8(4) *Fees.* Fees for the services provided by a DCME are paid by the county of appointment or by the county of the decedent's residence. A DCME receives from the county of appointment or the county of the decedent's residence reimbursement for actual expenses. The fee and expenses will be submitted by the DCME to the county of appointment, which may immediately pay the invoice or forward the invoice to the county of the decedent's residence for payment to the DCME. If the DCME does not receive payment from the county of the decedent's residence within 60 days of receiving the invoice, the county of appointment pays the invoice.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.9(331,691) Failure to comply with rules. If a county medical examiner, deputy county medical examiner, county medical examiner investigator, pathologist, or other physician fails to comply with these rules, the state medical examiner may provide written notice of the failure to comply to that individual, the appropriate county medical examiner, and the appropriate county board of supervisors. Within 30 days of the date of the notice, the individual to whom the notice was provided shall submit a written response to the state medical examiner, outlining a proposed corrective action plan. If no response is received within the 30 days or if the proposed corrective action plan is unacceptable, the state medical examiner will forward copies of the notice and all pertinent correspondence and information to the board of supervisors for the county that appointed the individual, notifying the board of the individual's failure to comply with these rules.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.10(331,691,22) Confidentiality. Records and reports of a medical examiner may be confidential records pursuant to Iowa Code section 22.7(2), 22.7(5), and 22.7(41) and other provisions of Iowa law. Prior to releasing a medical examiner record or report to a member of the public, a county medical examiner may inform the appropriate law enforcement agency, the county attorney, and the state medical examiner to determine whether release is authorized under Iowa law.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

641—127.11(331,691,670) Indemnification. A board of supervisors shall defend, hold harmless, and indemnify a county medical examiner and any properly appointed staff members to the extent provided in Iowa Code chapter 670.

[**ARC 0076D**, IAB 2/18/26, effective 4/1/26]

These rules are intended to implement Iowa Code chapters 331 and 691.

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CHAPTER 128
DOGS FOR SCIENTIFIC RESEARCH
Rescinded IAB 7/30/08, effective 9/3/08.

CHAPTER 129
Reserved

CHAPTER 130
EMERGENCY MEDICAL SERVICES ADVISORY COUNCIL
Rescinded **ARC 9325C**, IAB 5/28/25, effective 8/1/25

CHAPTER 131
EMERGENCY MEDICAL SERVICES—PROVIDERS—INITIAL CERTIFICATION—RENEWAL AND REACTIVATION—AUTHORITY—COMPLAINTS AND INVESTIGATIONS

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—131.1(147A,147D,272C) Definitions. For the purpose of these rules, the following definitions apply:

"Advanced emergency medical technician" or *"AEMT"* means an individual who has successfully completed a course of study based on the U.S. Department of Transportation's National Emergency Medical Services Education Standards (December 2021), has passed the Department or NREMT testing requirements for the AEMT, and is currently certified by the department as an AEMT.

"CAPCE" means the Commission on Accreditation for Prehospital Continuing Education, the accrediting body charged with the review and accreditation of EMS continuing education.

"CEH" means continuing education hour, which is based upon 50 minutes of training per hour. Fifty minutes equals one CEH, and 30 minutes equals one-half CEH.

"Certification" or *"certificate"* means a document issued by the department authorizing a person to practice as an emergency medical care provider in Iowa.

"Certification period" means the length of time an emergency medical care provider certificate is valid. The certification period is two years from initial issuance or from renewal unless otherwise specified on the certificate or unless sooner suspended or revoked.

"Certification status" means the status of an individual EMS certificate holder.

1. "Active" means the holder of the certification has the authority to function as an emergency medical care provider at the level certified in accordance with subrule 131.4(1).
2. "Probation," which is an active certification, means the holder of the certification has the authority to function as an emergency medical care provider at the level certified in accordance with subrule 131.4(1) and under the conditions of probation.
3. "Denied" means the certificate is inactive and the holder of the certification has no authority to function as an emergency medical care provider.
4. "Inactive" means the certificate is inactive and the holder of the certification has no authority to function as an emergency medical care provider.
5. "Revoked" means the certification is inactive and the holder of the certification has no authority to function as an emergency medical care provider.
6. "Surrendered" means the certification is inactive and the holder of the certification has no authority to function as an emergency medical care provider.
7. "Suspended" means the certification is inactive and the holder of the certification has no authority to function as an emergency medical care provider.

"Certified" means being officially recognized as meeting department-approved testing and training standards and being issued a certificate by the department in accordance with Iowa Code chapters 272C and 147A to practice as an emergency medical care provider in the state of Iowa.

"Compact" means the emergency medical services personnel licensure interstate compact according to Iowa Code chapter 147D.

"Complete criminal record" includes the complaint and judgment of conviction for each offense of which the applicant has been convicted, regardless of whether the offense is classified as a felony or a misdemeanor, and regardless of the jurisdiction in which the offense occurred.

"Conviction" means a finding, plea, or verdict of guilt made or returned in a criminal proceeding, even if the adjudication of guilt is deferred, withheld, or not entered. "Conviction" includes Alford pleas and pleas of nolo contendere.

"Core continuing education" means education obtained during a certification period to renew certification. Core continuing education will have an assigned sponsor number from CAPCE, an authorized EMS training program, or the department.

"Critical care paramedic" or *"CCP"* means a currently certified paramedic who has successfully completed a critical care course of instruction approved by the department and has received endorsement from the department as a critical care paramedic.

"Disqualifying offense" means a conviction directly related to the duties and responsibilities of the profession. A conviction is directly related to the duties and responsibilities of the profession if either (1) the actions taken in furtherance of an offense are actions customarily performed within the scope of practice of a certified profession, or (2) the circumstances under which an offense was committed are circumstances customary to a certified profession.

"Emergency medical care" means any medical procedure authorized by Iowa Code chapter 147A and these rules.

"Emergency medical care provider" means the same as defined in Iowa Code section 147A.1.

"Emergency medical care student" means an individual registered with the department and enrolled in an EMS training program with an active EMS student registration.

"Emergency medical responder" or *"EMR"* means an individual who has successfully completed a course of study based on the U.S. Department of Transportation's National Emergency Medical Services Education Standards (December 2021), has passed the department or NREMT testing requirements for the EMR, and is currently certified by the department as an EMR.

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

"Emergency medical technician" or *"EMT"* means an individual who has successfully completed a course of study based on the U.S. Department of Transportation's National Emergency Medical Services Education Standards (December 2021), has passed the department or NREMT testing requirements for the EMT, and is currently certified by the department as an EMT.

"Emergency medical technician-defibrillation" or *"EMT-D"* means an individual who has successfully completed an approved program and is currently certified by the department as an EMT-D.

"EMS clinical guidelines" or *"minimum EMS clinical guidelines"* means a minimum clinical standard approved by the department upon which a service program's medical director will base service program protocols.

"EMS instructor" or *"EMS-I"* means an individual who has successfully completed an EMS instructor curriculum approved by the department and is currently endorsed by the department as an EMS-I.

"Endorsement" or *"endorsed"* means an approval granted by the department authorizing an individual to serve as an EMS-I or CCP.

"Fees" means those fees received pursuant to Iowa Code chapters 147A and 147D.

"First responder" or *"FR"* means an individual who has successfully completed an approved program and is currently certified by the department as an FR.

"First responder-defibrillation" or *"FR-D"* means an individual who has successfully completed an approved program and is currently certified by the department as an FR-D.

"NREMT" means the National Registry of Emergency Medical Technicians. The NREMT provides a valid, uniform process to assess the knowledge and skills required for competent practice by EMS professionals.

"Paramedic" or *"PM"* means an individual who has successfully completed a course of study based on the U.S. Department of Transportation's National Emergency Medical Services Education Standards (December 2021), has passed the department or NREMT testing requirements for the paramedic, and is currently certified by the department as a paramedic.

"Patient" means an individual who is sick, injured, or otherwise incapacitated and has been evaluated or provided treatment by an emergency medical care provider.

"Patient abandonment" means a termination of the provider/patient relationship at a time when a continuous level of care is needed. Patient abandonment does not occur when a scene is unsecured, deteriorates or becomes too dangerous for the emergency medical care provider to safely function. Patient abandonment does not occur when patient care is transferred to another emergency medical care provider following assessment or triage.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Physician associate" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Protocols" means written directions and orders approved by a service program's medical director utilizing the EMS clinical guidelines.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Service program" or *"service"* means any transport service or nontransport service, inclusive of associated satellites and service program affiliates, that has received full or conditional authorization from the department.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0597D**, IAB 9/16/26, effective 11/1/26]

641—131.2(147A,272C) Initial certification.

131.2(1) An individual who has successfully completed the training program requirements at the EMR, EMT, AEMT or paramedic level and has a valid certification with NREMT shall submit the following to the department for initial Iowa emergency medical care provider certification:

a. A completed EMS certification application.

b. An NREMT active certification number.

c. Payment of the initial application fee.

d. A completed background check.

131.2(2) The individual seeking an Iowa emergency medical provider care certification shall submit all application materials within two years from the Iowa training program course completion date.

131.2(3) If the individual is unable to complete the requirements within two years due to medical reasons or military obligation, an extension may be granted upon submission of a signed statement from an appropriate medical or military authority and approval by the department.

131.2(4) Fees may be waived in accordance with provisions in Iowa Code chapter 272C.

131.2(5) Use of criminal convictions in eligibility determinations and initial licensing decisions.

a. License application. Unless an applicant for licensure petitions the department for an eligibility determination pursuant to paragraph 131.2(7)*"b,"* the applicant's convictions will be reviewed when the department receives a completed license application.

(1) An applicant must disclose all convictions on a license application. Failure to disclose all convictions is grounds for license denial or disciplinary action following license issuance.

(2) An applicant with one or more convictions shall submit the complete criminal record for each conviction and a personal statement regarding whether each conviction directly relates to the practice of the profession in order for the license application to be considered complete.

(3) An applicant must submit as a part of the license application all evidence of rehabilitation that the applicant wishes to be considered by the department.

(4) The board may deny a license if the applicant has a disqualifying offense unless the applicant demonstrates by clear and convincing evidence that the applicant is rehabilitated pursuant to Iowa Code section 272C.15.

(5) An applicant with one or more disqualifying offenses who has been found rehabilitated must still satisfy all other requirements for licensure.

(6) Any application fees paid will not be refunded if the license is denied.

b. Eligibility determination. An individual who has not yet submitted a completed license application may petition the department for a determination of whether one or more of the individual's convictions are disqualifying offenses that would render the individual ineligible for licensure. An individual with a conviction is not required to petition the department for an eligibility determination prior to applying for licensure. To petition the department for an eligibility determination of whether one or more of the petitioner's convictions are disqualifying offenses, a petitioner shall submit all of the following:

(1) A completed petition for eligibility determination form;

(2) The complete criminal record for each of the petitioner's convictions;

(3) A personal statement regarding whether each conviction directly relates to the duties and responsibilities of the profession and why the department should find the petitioner rehabilitated;

(4) All evidence of rehabilitation that the petitioner wishes to be considered by the department; and

(5) Payment of a nonrefundable fee of $25.

c. Appeal. A petitioner deemed ineligible or an applicant denied a license because of a disqualifying offense may appeal the decision in accordance with 441—Chapter 2506.

d. Future petitions or applications. If a final order determines a petitioner is ineligible, the petitioner may not submit a subsequent petition for eligibility determination or a license application prior to the date specified in the final order. If a final order denies a license application, the applicant may not submit a subsequent license application or a petition for eligibility determination prior to the date specified in the final order.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0597D**, IAB 9/16/26, effective 11/1/26]

641—131.3(147A) Background check results. All criminal history records are confidential and will only be used in accordance with this policy to determine eligibility. All background check records will be stored in a secure location. Background check records will not be redisseminated by the department.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25]

641—131.4(147A) Authority.

131.4(1) *Authority of emergency medical care provider.* An emergency medical care provider who holds an active Iowa certification issued by the department or has permission to practice in Iowa pursuant to Iowa Code chapter 147D may:

a. As a member of a responding authorized service program, render emergency medical care and perform emergency medical care without contacting medical direction if written protocols have been approved by the service program medical director.

b. Function in any hospital or any other entity in which health care is ordinarily provided only when:

(1) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided when under the direct supervision of a physician as a member of an authorized service program, or in an individual capacity, by rendering lifesaving services in the facility in which employed or assigned pursuant to the emergency medical care provider's certification and under direct supervision of a physician, physician associate, or registered nurse. An emergency medical care provider shall not routinely function without the direct supervision of a physician, physician associate, or registered nurse. However, when the physician, physician associate, or registered nurse cannot directly assume emergency care of the patient, the emergency medical care provider may perform, without direct supervision, emergency medical care procedures for which certified, if the life of the patient is in immediate danger and such care is required to preserve the patient's life;

(2) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided when under the direct supervision of a physician, as a member of an authorized service program, or in an individual capacity, to perform nonlifesaving procedures for which certified and designated in a written job description. Such procedures may be performed after the patient is observed by and when the emergency medical care provider is under the supervision of the physician, physician associate, or registered nurse and where the procedure may be immediately abandoned without risk to the patient.

131.4(2) *Scope of practice.*

a. Emergency medical care providers shall perform only those skills and procedures that are authorized within the scope of practice for which an emergency medical care provider is certified.

b. The Iowa Emergency Medical Care Provider Scope of Practice as amended to September 1, 2026, is hereby incorporated and adopted by reference for emergency medical care providers. For any differences that may occur between the scope of practice adopted by reference and these rules, the rules prevail. The Iowa Emergency Medical Care Provider Scope of Practice as amended to September 1, 2026, is available on the department's website.

c. The department may grant a waiver for changes to the scope of practice that have not yet been adopted by reference in these rules pursuant to 441—Chapter 2504.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0597D**, IAB 9/16/26, effective 11/1/26]

641—131.5(147A) Renewal standards, reactivation procedures, fees, and continuing education.

131.5(1) *Renewal of certification.*

a. An emergency medical care provider shall submit an application for renewal of an active Iowa EMS certification within 90 days prior to the certification expiration date.

b. The renewal application and process are completed online via an individual Iowa EMS provider account. The electronic portal to access individual accounts may be accessed through the department's website.

c. Renewal notifications will be sent to Iowa emergency medical care providers who have an active certification set to expire in 90 days. The notification will be sent by email to the address on file in the emergency medical care provider's electronic profile.

d. It is the emergency medical care provider's responsibility to ensure the electronic profile information, including the email address, is updated and correct within 30 days of any change.

e. A renewal certificate is valid for two years from the current expiration date unless sooner surrendered, suspended or revoked.

f. A lower-level certificate may be renewed if the individual voluntarily chooses to move from a higher level to a lower level by completing all applicable continuing education requirements for the lower level during the certification period and submitting a change of status request, available from the department upon request.

g. A certification status becomes inactive if the certificate has not been renewed by the certification expiration date unless the emergency medical care provider is granted an extension as described in subrule 131.5(3).

h. An emergency medical care provider may request an inactive status. The request must be made by submitting a change of status request, available from the department upon request. A request for inactive status, when accepted in connection with a disciplinary investigation or proceeding, has the same effect as an order of revocation.

131.5(2) *Late renewal of certification.*

a. An emergency medical care provider who has completed the required continuing education during the certification period but fails to submit the EMS renewal of certification application and applicable fees prior to the certification expiration date is eligible for late renewal of the inactive certification.

b. The emergency medical care provider shall complete the EMS renewal of certification application, submit a late fee in addition to the applicable renewal fee and submit an audit report form provided by the department. The fee and audit report form shall be submitted before the last day of the month following the certification expiration date. If the late renewal submission is not completed by the last day of the month following the certification expiration date, the certification remains inactive.

c. An emergency medical care provider who has not completed the required continuing education during the certification period is not eligible for late renewal. The certification is inactive.

131.5(3) *Extension of certification.*

a. An emergency medical care provider who is unable to attain all continuing education requirements within the certification period may request a 45-day extension. To complete the extension process, the provider shall:

(1) Submit a request for extension application, available from the department upon request, at least 7 days prior to the certification expiration date, but no more than 90 days prior to the certification expiration date, and payment of the extension fee.

(2) Complete the continuing education requirements.

(3) Complete and submit the EMS affirmative renewal of certification application, with all applicable renewal fees, to the department prior to the extended expiration date.

(4) Submit an audit report form provided by the department.

b. If an emergency medical care provider fails to submit any of the items required in subparagraphs 131.5(3)*"a"*(2) and (3) by the 45th day of the extended certification period, the certification will be inactive.

c. The emergency medical care provider may not use continuing education completed during the extension period in the subsequent renewal period.

131.5(4) *Reactivation of an inactive certification.*

a. Certification inactive up to 24 months. An emergency medical care provider may apply to reactivate an inactive certification up to 24 months after the certification became inactive.

(1) An individual will submit to the department an EMS certification reactivation application, which is available from the department upon request.

(2) If the department approves the application, the individual must submit core continuing education hours based upon the table in paragraph 131.5(7)*"a"* for the level of EMS certification requested for reactivation, a completed background check, and the reactivation fee. The core CEHs and the background check shall be completed after the department receives and approves the reactivation application.

(3) Upon receipt and approval of the items required in subparagraphs 131.5(4)*"a"*(1) and (2), the department may issue a new certification.

(4) An emergency medical care provider who fails to complete the reactivation process within 12 months from the date of application will not be eligible for reactivation.

b. Certification inactive for more than 24 months. An emergency medical care provider cannot apply to reactivate a certification that has been inactive for more than 24 months. An emergency medical care provider who has been inactive for more than 24 months may complete the NREMT reentry requirements and apply for certification in accordance with subrule 131.2(1).

131.5(5) *Reactivation of revoked or suspended certification.*

a. Any person whose certification to practice has been revoked or suspended may apply to the department for reactivation in accordance with the terms and conditions of the order of revocation or suspension, unless the order of revocation provides that the certification is permanently revoked.

b. If the order of revocation or suspension did not establish terms and conditions upon which reactivation might occur or if the certification was voluntarily surrendered, an initial application for reactivation may not be made until one year has elapsed from the date of the order or the date of the voluntary surrender.

c. All proceedings for reactivation shall be initiated by the person whose certification has been revoked or suspended in accordance with subrule 131.5(4). An application for reactivation shall allege facts that, if established, will be sufficient to enable the department to determine that the basis for the revocation or suspension of the person's certification no longer exists and that it will be in the public interest for the certification to be reinstated. The burden of proof to establish such facts is on the person whose certification has been suspended or revoked.

d. An order denying or granting reactivation shall be based upon a decision that incorporates findings of facts and conclusions of law.

131.5(6) *Fees.* The nonrefundable fees are as follows:

a. Application for initial Iowa certification at all certification levels: $30.

b. Reactivation of a certification to practice: $30.

c. Renewal of a certification to practice as a first responder, EMR: no fee.

d. Renewal of a certification to practice as an EMT: no fee.

e. Renewal of a certification to practice as an AEMT: $10.

f. Renewal of a certification to practice as a paramedic: $25.

g. Late renewal of a certification to practice: $30.

h. Returned payment due to insufficient funds: $40.

i. Extension of certification: $50.

131.5(7) *Continuing education renewal.*

a. The table below illustrates the minimum number of core CEHs by topic area for each level of emergency medical care provider to renew an Iowa EMS certification.

Core Topics	EMR/FR	EMT/EMT-D	AEMT	PM
Airway, Respirations, Ventilations	1.5	4	5	6
Cardiology	2	5	6	7
Trauma	1	3	4	5
Medical	2.5	6	7	8

Operations	1	2	3	4
Pediatric	1	2	3	4
Totals	**9**	**22**	**28**	**34**

b. All core continuing education hours issued by an Iowa EMS training program, the department, or CAPCE used to renew an Iowa EMS certification must have a sponsor number before the emergency medical care provider attends the offering.

c. An emergency medical care provider who is registered with the NREMT may renew the provider's Iowa EMS certification by meeting the NREMT's requirements. The emergency medical care provider must submit the Iowa affirmative renewal of certification application and all appropriate fees.

d. An emergency medical care provider is deemed to have complied with the continuing education requirements during periods in which the provider serves honorably on active duty in the military services or for periods in which the provider is a government employee working as an emergency medical care provider and assigned to duty outside the United States. The emergency medical care provider must submit the Iowa affirmative renewal of certification application, all appropriate fees and documentation of assignment.

e. The emergency medical care provider must maintain a file containing documentation of CEHs accrued during each certification period for four years from the end of each certification period.

f. A group of emergency medical care providers will be audited for each certification period. Emergency medical care providers to be audited will be chosen in a random manner or at the discretion of the department. Falsifying reports or failure to comply with the audit request may result in formal disciplinary action. If audited, within 30 days from the date of request for audit, the emergency medical care provider must provide a copy of the course completion certification or other verifying documentation that contains the following information at a minimum:

(1) Date of program.
(2) Program sponsor number (if applicable).
(3) Title of program.
(4) Number of approved hours.

131.5(8) *Continuing education approval.* The following standards apply for approval of continuing education:

a. CEHs issued by CAPCE, an authorized EMS training program, or the department will have an assigned sponsor number before the emergency medical care provider attends the offering.

b. Human health-related college courses may be approved in advance by the department at one quarter credit equal to 10 CEHs, one semester credit equal to 15 CEHs.

c. Courses must be, at a minimum, 30 minutes in duration (one-half CEH). Multi-hour courses are granted credit in half-hour increments (e.g., one hour and 30 minutes = one and one-half CEHs).

d. Continuing education courses that are accepted by the board of nursing and the board of medicine that are directly related to EMS patient care and apply to the core continuing education topics will be accepted.

131.5(9) *Out-of-state continuing education.* Out-of-state continuing education courses will be accepted for CEHs if all criteria in subrule 131.5(7) are met and if the courses have been approved for emergency medical care personnel in the state in which the courses were held. A copy of course completion certificates (or other verifying documentation) shall, upon request, be submitted to the department.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25; **ARC 0597D**, IAB 9/16/26, effective 11/1/26]

641—131.6(147A,272C) Discipline—denial, citation and warning, probation, suspension, or revocation of certificates or renewal.

131.6(1) This rule is not subject to waiver pursuant to 441—Chapter 2504 or any other provision of law.

131.6(2) Prohibited grounds for discipline. The department will not suspend or revoke the certification of a person who is in default or is delinquent on repayment or a service obligation under federal or state postsecondary educational loans or public or private services-conditional postsecondary tuition assistance solely on the basis of such default or delinquency.

131.6(3) Methods of discipline.

a. The department has the authority to impose the following disciplinary sanctions against an emergency medical care provider:

(1) Issue a citation and warning.

(2) Impose a civil penalty not to exceed $1,000.

(3) Require reexamination.

(4) Require additional education or training.

(5) Impose a period of probation under specific conditions.

(6) Prohibit permanently, until further order of the department, or for a specific period, a provider's ability to engage in specific procedures, methods, acts or activities incident to the practice of the profession.

(7) Suspend a certificate until further order of the department or for a specific period.

(8) Deny an application for certification.

(9) Revoke a certification.

(10) Impose such other sanctions as allowed by law and as may be appropriate.

b. A request for inactive status in connection with a disciplinary investigation or proceeding has the same effect as an order of revocation.

c. A citation and warning, denial, probation, restriction, suspension, revocation, or civil penalty imposed upon an individual certificate holder by the department will be considered applicable to all certificates and endorsements issued to that individual by the department.

d. An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days.

131.6(4) The department may deny an application for issuance or renewal of an emergency medical care provider certificate, including endorsement, or may impose any of the disciplinary sanctions provided in subrule 131.6(3) when it finds that the individual or certificate holder has committed any of the following acts or offenses:

a. Negligence in performing emergency medical care.

b. Failure to follow the directions of supervising physicians or their designees.

c. Rendering treatment not authorized under Iowa Code chapter 147A.

d. Patient abandonment.

e. Misrepresentation in procuring certification or renewal, including but not limited to:

(1) A perversion of the truth in making application for a certification to practice in this state;

(2) False representations of a material fact, whether by word or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application for a certification in this state; or

(3) Attempting to file or filing with the department or training program any false or forged diploma or certificate or affidavit or identification or qualification in making an application for a certification in this state.

f. Professional incompetency. Professional incompetency includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of practice.

(2) A substantial deviation from the standards of learning or skill ordinarily possessed and applied by other emergency medical care providers in the state of Iowa acting in the same or similar circumstances.

(3) A failure to exercise the degree of care that is ordinarily exercised by the average emergency medical care provider acting in the same or similar circumstances.

(4) Failure to conform to the minimal standard of acceptable and prevailing practice of certified emergency medical care providers in this state.

(5) A substantial lack of knowledge or ability to discharge professional obligations within the minimum clinical standards approved by the department.

g. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of the profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of

actual injury need not be established. Acts that may constitute unethical conduct include but are not limited to:

(1) Verbally or physically abusing a patient, coworker or any other individual encountered while a certified emergency medical care provider.

(2) Improper sexual contact with or making suggestive, lewd, lascivious or improper remarks or advances to a patient, coworker or any other individual encountered while certified as an emergency medical care provider in the state of Iowa.

(3) Betrayal of a professional confidence.

(4) Engaging in a professional conflict of interest.

(5) Falsification of medical records, official documents or other writings or records.

h. Engaging in any conduct that subverts or attempts to subvert a department investigation.

i. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

j. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

k. Failure to report another emergency medical care provider to the department for any violations listed in these rules pursuant to Iowa Code chapter 147A.

l. Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

m. Representing oneself as an emergency medical care provider when one's certification has been suspended or revoked or when one's certification is lapsed or has been placed on inactive status.

n. Permitting the use of a certification by a noncertified person for any purpose.

o. Mental or physical inability reasonably related to and adversely affecting the emergency medical care provider's ability to practice in a safe and competent manner as determined by an evaluation from a licensed evaluator of the provider's mental or physical status.

p. Being adjudged mentally incompetent by a court of competent jurisdiction.

q. Sexual harassment of a patient, student, coworker or any other individual encountered while certified as an emergency medical care provider in the state of Iowa. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal or physical conduct of a sexual nature communicated in person, in writing, via a third person or through electronic communication.

r. Habitual intoxication or addiction to drugs.

(1) The inability of an emergency medical care provider to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

(2) The excessive use of drugs that may impair an emergency medical care provider's ability to practice with reasonable skill or safety.

(3) Obtaining, possessing, attempting to obtain or possess, or administering controlled substances without lawful authority.

s. Fraud in representation as to skill, ability or certification.

t. Willful or repeated violations of Iowa Code chapter 147A or these rules.

u. Conviction of a disqualifying offense. A copy of the guilty plea or order of conviction constitutes conclusive evidence of conviction.

v. Having certification to practice emergency medical care suspended or revoked or having other disciplinary action taken by a licensing or certifying authority of this state or another state, territory or country. A copy of the record or order of suspension, revocation or disciplinary action is conclusive or prima facie evidence.

w. Falsifying certification renewal reports or failure to comply with the renewal audit request.

x. Acceptance of any fee by fraud or misrepresentation.

y. Repeated failure to comply with standard precautions for preventing transmission of infectious diseases as issued by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

z. Violating privacy and confidentiality. An emergency medical care provider shall not disclose or be compelled to disclose patient information unless disclosure is required or authorized by law.

aa. Discrimination. An emergency medical care provider shall not practice, condone, or facilitate discrimination against a patient, student, or any other individual encountered while acting as certified as an emergency medical care provider in the state of Iowa on the basis of race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability, diagnosis, or social or economic status.

ab. Practicing emergency medical services or using a designation of certification or otherwise holding oneself out as practicing emergency medical services at a certain level of certification when the emergency medical care provider is not certified at such level.

ac. Failure to respond within 30 days of receipt, unless otherwise specified, to communication from the department that was sent by registered or certified mail.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0597D**, IAB 9/16/26, effective 11/1/26]

641—131.7(147A) Certification denial. An individual who has been denied certification by the department may appeal the denial and request a hearing on the issues related to the licensure denial pursuant to 441—Chapter 2506.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—131.8(147A) Emergency adjudicative proceedings. To the extent necessary to prevent or avoid immediate danger to the public health, safety or welfare and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend a certificate in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

131.8(1) Before issuing an emergency adjudicative order, the department will consider factors, including but not limited to the following:

a. Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

b. Whether the specific circumstances that pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

c. Whether the individual required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

e. Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

131.8(2) Issuance of order.

a. An emergency adjudicative order will contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

b. The written emergency adjudicative order will be immediately delivered to the individual who is required to comply with the order. Delivery will be made by one or more of the following procedures:

(1) Personal delivery.

(2) Certified mail, return receipt requested, to the last address on file with the department.

(3) Fax. Fax may be used as the sole method of delivery if the individual required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

c. To the degree practicable, the department will select the procedure for providing written notice that best ensures prompt, reliable delivery.

d. Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department will make reasonable immediate efforts to contact by telephone the individual who is required to comply with the order.

e. After the issuance of an emergency adjudicative order, the department will proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

f. Issuance of a written emergency adjudicative order will include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the individual who is required to comply with the order is the party requesting the continuance.

[**ARC 9123C**, IAB 4/16/25, effective 6/1/25]

641—131.9(147A) Complaints, investigations and appeals.

131.9(1) This rule is not subject to waiver pursuant to 441—Chapter 2504 or any other provision of law.

131.9(2) All complaints regarding emergency medical care personnel, training programs or continuing education providers, or those purporting to be or operating as the same shall be reported to the department in writing.

131.9(3) An emergency medical care provider who has knowledge of an emergency medical care provider or service program that has violated Iowa Code chapter 147A, 641—Chapter 132 or these rules shall report such information to the department.

131.9(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

131.9(5) A determination of mental incompetence by a court of competent jurisdiction automatically suspends a certificate for the duration of the certificate unless the department orders otherwise.

131.9(6) Notice of denial, issuance of a citation and warning, probation, suspension or revocation shall be effected in accordance with the requirements of 441—Chapter 16 and may be appealed pursuant to 441—Chapter 2506.

131.9(7) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, the news media or employer.

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These rules are intended to implement Iowa Code chapters 147A and 147D and section 272C.4.

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CHAPTER 132
EMERGENCY MEDICAL SERVICES—SERVICE PROGRAM AUTHORIZATION
[Joint Rules pursuant to 147A.4]
[Prior to 7/29/87, Health Department[470] Ch 132]

Chapter rescission date pursuant to Iowa Code section 17A.7: 5/21/30

641—132.1(147A) Definitions. For the purpose of these rules, the following definitions apply:

"Advanced emergency medical technician level service" or *"AEMT level service"* means a service program that provides emergency medical care that does not exceed the scope of practice of a certified AEMT provider as outlined in 641—subrule 131.5(2).

"Advanced registered nurse practitioner" or *"ARNP"* means a nurse licensed pursuant to 655—7.1(152) with current licensure as a registered nurse in Iowa who is registered in Iowa to practice in an advanced role.

"Ambulance" means any privately or publicly owned ground, fixed-wing or rotor-wing vehicle equipped with life-support systems and specifically designed to transport the sick or injured who require emergency medical care.

"Applicant" means an owner of a transport or nontransport program or service program that is applying to the department for authorization as a service program or renewal of current authorization as a service program.

"Biomedical hazardous waste" means waste product that may be contaminated with a biological material that is an infectious disease transmission risk.

"Communication system" means but is not limited to a telecommunication system, radio communication system, or mobile data communication system.

"Conditional service level authorization" means an enhanced service program authorization under which a service program may provide an advanced level of service from that routinely provided under the service program's full authorization level, on an intermittent basis with department and medical director approval.

"Continuous quality improvement" or *"CQI"* means a program that is an ongoing process to monitor standards at all EMS operational levels.

"Credentialing" means a clinical determination that is the responsibility of a physician medical director. It is the employer or affiliating organization's responsibility to act on the clinical credentialing status of EMS personnel in making employment or deployment decisions.

"Critical care transport" or *"CCT"* means a paramedic level service program that has received an endorsement from the department to provide specialty care patient transportation and that is staffed by one or more paramedics with a critical care paramedic endorsement from the department or that is staffed by other health care professionals in an appropriate specialty area.

"Deficiency" means noncompliance with Iowa Code chapter 147A or these administrative rules.

"Emergency medical care" means any medical procedure authorized by Iowa Code chapter 147A and 641—Chapter 131.

"Emergency medical care provider" means the same as defined in Iowa Code section 147A.1.

"Emergency medical responder level service" or *"EMR level service"* means a nontransport service program that provides emergency medical care that does not exceed the scope of practice of a certified EMR provider as outlined in 641—subrule 131.5(2).

"Emergency medical services" or *"EMS"* means the same as defined in Iowa Code section 147A.1.

"Emergency medical technician" or *"EMT"* means the same as defined in 641—Chapter 131.

"Emergency medical technician level service" or *"EMT level service"* means a service program that provides emergency medical care that does not exceed the scope of practice of a certified EMT provider as outlined in 641—subrule 131.5(2).

"Emergency medical transportation" means transportation of a patient by an ambulance.

"Emergency vehicle driver" or *"driver"* means a currently licensed driver rostered with the service program or other emergency response personnel with emergency vehicle driving training.

"EMS clinical guidelines" or *"minimum EMS clinical guidelines"* means a minimum clinical standard approved by the department upon which a service program's medical director will base service program protocols.

"Endorsement" means an approval granted by the department authorizing a paramedic level service program to provide critical care transport (CCT).

"FAA" means Federal Aviation Administration.

"Fixed-wing ambulance" means any privately or publicly owned fixed-wing aircraft specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

"First response vehicle" means any privately or publicly owned vehicle that is not an ambulance and that is used solely for the transportation of personnel and equipment to and from the scene of an emergency.

"Full authorization" means a service program authorization under which a service is authorized to provide and routinely provides a specific level of emergency medical care for initial 911 or emergency calls 24 hours per day, seven days per week.

"Hospital" means any hospital licensed under the provisions of Iowa Code chapter 135B.

"Medical direction" means direction, advice, or orders provided by a medical director, supervising physician, PA, or ARNP to emergency medical care personnel.

"Medical director" means a physician designated by the service program and responsible for providing medical direction and overall supervision of the medical aspects of the service program.

"Nontransport service" means any privately or publicly owned service program that does not provide patient transportation and provides emergency medical care at the scene of an emergency.

"Paramedic" or *"PM"* means the same as defined in 641—Chapter 131.

"Paramedic level service" or *"PM level service"* means a service program that provides emergency medical care that does not exceed the scope of practice of a certified paramedic provider as outlined in 641—subrule 131.4(2).

"Patient" means any individual who is sick, injured, or otherwise incapacitated.

"Patient care report" or *"PCR"* means a report that documents the assessment and management of the patient by the emergency care provider.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Physician associate" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Primary response ambulance" means any ambulance utilized by a service program and dispatched as the initial ambulance response to a 911 or emergency call.

"Protocols" means written directions and orders approved by a service program's medical director utilizing the EMS clinical guidelines.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Rotorcraft ambulance" means any privately or publicly owned rotorcraft specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

"Service director" means an individual designated by the service program who is responsible for the operation and administration of a service program.

"Service program" or *"service"* means any ground or air medical transport service or nontransport service, inclusive of associated satellites, that has received full or conditional authorization from the department.

"Service program affiliate" or *"affiliate"* means an independently owned service program affiliated with one or more service programs or a separate management entity.

"Service program affiliate agreement" or *"affiliate agreement"* means a written agreement executed between one or more service programs or one or more management entities and filed with the department that clearly defines the responsibilities of each service program to ensure compliance with these rules.

"Service program base of operation" means the physical location from which a service program responds and at which the service program houses emergency medical care personnel and equipment.

"Service program ownership" means the legal owner of the service program responsible for providing emergency medical care and compliance with Iowa Code chapter 147A and these rules.

"Service program satellite" or *"satellite"* means one or more additional service program locations owned by the same service program.

"Student" means any individual enrolled in a training program and participating in the didactic, clinical, or field experience portions.

"Tiered response" means a rendezvous between service programs to allow the transfer, continuation, or enhancement of patient care.

"Transport agreement" means a written agreement executed between two or more service programs and filed with the department that ensures response and transportation for initial 911 or emergency calls. A transport agreement may be a component of an affiliate agreement.

"Transport service" means any privately or publicly owned service program that utilizes ambulances in order to provide patient transportation.

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641—132.2(147A) Service program—authorization and renewal procedures and inspections.

132.2(1) *Requirements for initial service program authorization.*

a. An entity that desires to provide emergency medical care services in the out-of-hospital setting in this state shall apply to the department for service program full authorization.

b. Information for initial authorization can be found on the department's website or upon request.

c. Transport service—full authorization. An entity seeking authorization as a transport service program shall apply for full authorization at a minimum of the EMT level or the level of care that will be provided by the service program or through a transport agreement for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMT.
(2) AEMT.
(3) Paramedic.

d. Transport service—conditional service level authorization. An entity seeking authorization as a transport service that is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) AEMT.
(2) Paramedic.

e. Nontransport service—full authorization. An entity seeking authorization as a nontransport service program shall apply for full authorization at a minimum of the EMR level or at the level of care that will be provided for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMR.
(2) EMT.
(3) AEMT.
(4) Paramedic.

The nontransport service program shall have an executed written transport agreement ensuring simultaneous dispatch with an authorized transport service program for all 911 or emergency calls.

f. Nontransport service—conditional service level authorization. An entity seeking authorization as a nontransport service program that has an executed written transport agreement ensuring simultaneous dispatch with an authorized transport service program for all 911 or emergency calls and is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) EMT.
(2) AEMT.
(3) Paramedic.

g. Conditional service level authorization requirements.

(1) A service program that has been granted conditional service level authorization shall only advertise or otherwise hold itself out to the public as an authorized service program at the level of full authorization.

(2) A service program authorized to operate at a conditional service level shall operate at such level only when an emergency medical care provider certified at the advanced certification level is listed on the service roster, physically present and directly responsible for patient care.

h. Initial service program authorization is valid for a period of one year from its effective date unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked or surrendered.

i. An applicant shall provide evidence of liability insurance coverage for the service program and emergency medical care provider staff. Any change in insurance status must be reported to the department no later than 30 days from the change.

j. An applicant seeking endorsement must submit a department-approved application.

132.2(2) *Requirements for renewal of service program authorization.*

a. A service program seeking renewal of current authorization shall submit all required documentation to the department at least 90 days prior to the current authorization expiration date.

b. Transport service—full authorization. An entity seeking renewal authorization as a transport service program shall apply for full authorization at a minimum of the EMT level or the level of care that will be provided by the service program or through a transport agreement for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMT.

(2) AEMT.

(3) Paramedic.

c. Transport service—conditional service level authorization. An entity seeking renewal authorization as a transport service that is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) AEMT.

(2) Paramedic.

d. Nontransport service—full authorization. An entity seeking renewal authorization as a nontransport service program shall apply for full authorization at a minimum of the EMR level or at the level of care that will be provided for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMR.

(2) EMT.

(3) AEMT.

(4) Paramedic.

e. Nontransport service—conditional service level authorization. An entity seeking renewal authorization as a nontransport service program that is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) EMT.

(2) AEMT.

(3) Paramedic.

f. Air medical requirements.

(1) Staff fixed-wing ambulances, at a minimum on each flight request, with the following staff while a patient is being transported:

1. One health care clinician who is certified or licensed in the state from which the aircraft launches and is certified as an EMT or higher level; and

2. One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

(2) Staff rotorcraft ambulances, at a minimum on each flight request, with the following staff while a patient is being transported:

1. Two health care clinicians who are certified or licensed in the state from which the aircraft launches, one of whom must at a minimum be certified as a paramedic; and

2. One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

(3) Medical crew members trained in the following areas:

1. Patient care limitations in flight.
2. Altitude physiology.
3. Appropriate utilization of air medical services.
4. Air medical communication systems.
5. Aircraft operations and safety.
6. Emergency safety and survival.
7. Prehospital scene response and safety.
8. Crew resource management.
9. Program flight risk assessment procedures.

g. Conditional service level authorization requirements.

(1) A service program that has been granted conditional service level authorization shall only advertise or otherwise hold itself out to the public as an authorized service program at the level of full authorization.

(2) A service program authorized to operate at a conditional service level shall operate at such level only when an emergency medical care provider certified at the advanced certification level is listed on the service roster, physically present and directly responsible for patient care.

h. A service program that has submitted to the department fewer than 100 data reports per year for each of the previous two consecutive calendar years shall only be eligible for renewal of current authorization as an affiliate. The department will provide technical assistance in developing affiliations.

i. A service program shall be fully operational upon the effective date specified on the certificate of authorization and shall ensure compliance with Iowa Code chapter 147A and these rules.

j. A service program renewal authorization is valid for a period not to exceed three years from its effective date unless otherwise specified on the certificate of authorization or unless sooner revoked or suspended or surrendered.

132.2(3) *Reinstatement of service program authorization.*

a. A service program whose full authorization or conditional service level authorization has been revoked or suspended or surrendered may apply to the department for reinstatement in accordance with the terms and conditions of the order of revocation or suspension, unless the order of revocation provides that the authorization is permanently revoked.

b. If the authorization was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the order or the date of the voluntary surrender.

132.2(4) *Out-of-state service programs.*

a. An emergency medical service program authorized and based in another state shall provide the department with verification of current state authorization upon request and may provide emergency medical care to patients in Iowa.

b. A service program authorized and based in another state shall meet all requirements of Iowa Code chapter 147A and these rules and must be authorized by the department to respond to 911 requests in Iowa to transport patients in Iowa to locations within Iowa.

132.2(5) *Service program inspections.*

a. The department, at a minimum, will complete an inspection of each base of operations, all associated satellites, and all affiliate locations prior to initial authorization or renewal of current full authorization or conditional service level to ensure compliance with Iowa Code chapter 147A and these rules.

b. The department without prior notification may make additional inspections at times, at places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

c. Service program inspection forms are available on the department's website.

d. A service program shall correct deficiencies identified during a service program inspection within the time period specified by the department on the inspection form. Failure to correct identified deficiencies within the specified time period may result in disciplinary action.

e. The department may request additional information from or may inspect the records of any service program or associated satellite or associated affiliate that is currently authorized or that is seeking authorization to ensure continued compliance or to verify the validity of any information presented on the application for initial service program authorization or renewal of current authorization.

f. The department may inspect the patient care records of a service program to verify compliance with Iowa Code chapter 147A and these rules.

g. No person shall interfere with the inspection activities of the department or its agents pursuant to Iowa Code section 135.36.

h. Interference with or failure to allow an inspection by the department or its agents may be cause for disciplinary action.

[**ARC 9124C**, IAB 4/16/25, effective 5/21/25]

641—132.3(147A) Service program operations.

132.3(1) *Ownership.*

a. Each service program will have a unique authorization number assigned by the department.

b. A service program with satellites will have a single authorization number assigned by the department for all locations.

c. A service program owner shall ensure compliance with Iowa Code chapter 147A and these rules.

d. A service program shall report any change in ownership to the department at least seven days prior to the change.

e. A service program changing ownership shall apply to the department at least seven days prior to the change in ownership for initial authorization in accordance with 132.2(1).

132.3(2) *Medical director.*

a. Each service program shall have a designated medical director at all times.

b. A medical director shall:

(1) Be accessible for medical direction 24 hours per day, seven days per week or ensure accessibility to alternate medical direction.

(2) Ensure that all duties and responsibilities of the medical director are not relinquished before a new or temporary replacement is functioning in that capacity.

(3) Complete a department-sponsored medical director training within one year of assuming duties as a medical director and at a minimum once every three years thereafter.

(4) Develop, approve, and update service program protocols that meet or exceed the minimum EMS clinical guidelines approved by the department.

(5) Ensure that the emergency medical care providers rostered with the service program are credentialed in the emergency medical skills to be provided and the duties of the emergency medical care provider do not exceed the provider's scope of practice as referenced in 641—subrule 131.4(2) and the service program's EMS service level of authorization.

(6) Be available for individual evaluation and consultation with service program personnel.

(7) Have authority to restrict a service program's authorized functional EMS service level.

(8) Have the authority to permanently or temporarily restrict a service program member to function within a lower level scope of practice or prohibit a service program member from providing patient care.

(9) Approve the service program's CQI program.

(10) Perform or complete, or appoint a designee to perform or complete, the medical audits in the service program's established CQI policy.

(11) Randomly audit (on at least a quarterly basis) documentation of calls where emergency medical care was provided.

(12) Randomly review audits performed by the qualified appointee.

c. A medical director may:

(1) Make additions to the department-approved EMS clinical guidelines when developing service protocols, provided the additions are within the service program's level of authorization, the EMS provider's scope of practice, and acceptable medical practice.

(2) Request that service program providers provide additional emergency medical care skills on a limited pilot project basis. The pilot project applications are available from the department upon request.

(3) Approve the physician, PA and RN exception form identifying the level of EMS provider equivalency not to exceed the service program's EMS service level authorization for each physician, PA and RN who will be providing emergency medical care as part of the service program.

d. A medical director who receives no compensation for the performance of the director's volunteer duties under this chapter is considered a state volunteer as provided in Iowa Code section 669.24 while performing volunteer duties as an emergency medical services medical director. Compensation does not include payments for reimbursement of expenses.

e. A medical director, supervising physician, PA, or ARNP who gives orders to an emergency medical care provider is not subject to criminal liability by reason of having issued the orders and is not liable for civil damages for acts or omissions relating to the issuance of the orders unless the acts or omissions constitute recklessness.

f. Nothing in these rules requires or obligates a medical director, supervising physician, PA, or ARNP to approve requests for orders received from an emergency medical care provider.

g. A service program medical director who fails to comply with Iowa Code chapter 147A or these rules may be referred to the Iowa board of medicine.

132.3(3) *Service director.*

a. Each service program shall have a designated service director at all times.

b. A service director shall:

(1) Be accessible 24 hours per day, seven days per week or ensure accessibility to a service director designee.

(2) Be responsible for providing direction and overall supervision of the administrative and operational aspects of the service program.

(3) Ensure that all duties and responsibilities of the service director are not relinquished before a new or temporary replacement is functioning in that capacity.

(4) Complete a department-sponsored training within one year of assuming duties as a service director and at a minimum once every three years thereafter.

(5) Ensure the service program is in compliance with service program policy, Iowa Code chapter 147A and these rules.

(6) Ensure that duties of the service program's emergency medical care providers do not exceed the providers' scope of practice as referenced in 641—subrule 131.4(2) or the service program's EMS service level of authorization.

132.3(4) *Service program requirements.*

a. A service program shall:

(1) Not advertise or otherwise imply or hold itself out to the public as a service program unless currently authorized by the department.

(2) Only advertise at or otherwise hold itself out as having the level of full authorization.

(3) Select a new or temporary medical director if the current medical director cannot or no longer wishes to serve in that capacity. Selection shall be made before the current medical director relinquishes the duties and responsibilities of that position.

(4) Notify the department in writing within seven days prior to any change in medical director or any reduction or discontinuance of operations.

(5) Select a new or temporary service director if the current service director cannot or no longer wishes to serve in that capacity. Selection shall be made before the current service director relinquishes the duties and responsibilities of that position.

(6) Notify the department in writing within seven days prior to any change in service director or any reduction or discontinuance of operations.

(7) Notify the department within seven days prior to any change in location of a service program base of operations, administrative office, satellite, or affiliate.

(8) Notify the department within seven days when entering into agreements with one or more service programs or a management entity to form multiservice systems for shared service program management, administration, data submission, or other services to ensure compliance with these rules.

(9) Report the termination or resignation in lieu of termination of an emergency medical care provider due to negligence, professional incompetency, unethical conduct, substance use, or violation of any of these rules to the department in writing within seven days.

(10) Report theft of drugs to the department in writing within 48 hours following the occurrence of the incident.

(11) Develop a notification process for service members in the event of a motor vehicle collision involving a first response vehicle, ambulance, rescue vehicle or personal vehicle when used by a service program member responding as a member of the service program.

(12) Notify the department in writing within 48 hours of a motor vehicle collision resulting in personal injury or death.

(13) Ensure a response to an initial 911 or emergency call request to the service program, 24 hours per day, seven days per week.

(14) Utilize protocols developed and approved by the service program medical director that meet or exceed the minimum EMS clinical guidelines approved by the department.

(15) Ensure alterations to the minimum EMS clinical guidelines by the service program's medical director are approved by and filed with the department.

(16) Maintain a communication system at a minimum between medical direction, receiving facility, and other emergency responders.

(17) Maintain a current personnel roster utilizing a department-approved registry system. Ensure all rostered personnel are currently certified as active EMS providers in the state of Iowa.

(18) Maintain files with the medical director and department-approved physician, PA and RN exception forms for appropriate personnel. Physician, PA and RN forms are available on the department's website.

(19) Ensure all service program members who operate motorized emergency response vehicles, ambulances, and rescue vehicles when used by a service member responding as a member of the service have a valid driver's license and attend driver training prior to driving an emergency vehicle.

(20) Develop, maintain and follow a written driver training policy that includes a review of Iowa laws regarding emergency vehicle operations (Iowa Code section 321.231), frequency of service required driver training, a review of service program policies and criteria for response with lights or sirens or both, speed limits, procedure for approaching intersections, and use of the service program communications equipment.

(21) Ensure the emergency medical care provider with the highest level of certification attends the patient unless otherwise indicated by patient assessment and approved by the service program's guidelines.

b. A ground transport service program shall:

(1) Provide as a minimum, on initial 911 or emergency calls, the following staff on each primary response ambulance:

1. One currently certified emergency medical care provider certified at the service program full level of authorization.
2. One driver.

(2) Provide as a minimum on each subsequent call or nonemergency call, when responding, the following staff:

1. One currently certified EMT.
2. One driver.

(3) Establish a transport decision policy that requires a complete assessment of a patient in order to determine transport needs. The service transport decision policy shall include:

1. The Out-of-Hospital Trauma and Triage Destination Decision Guideline, as amended to August 1, 2024, and described in 641—Chapter 135.

2. Time critical condition considerations for transport to facilities that specialize in conditions such as cardiac conditions or stroke.

3. A process for a service program provider to determine transportation to a hospital, medical clinic, extended care facility, or other facilities where health care is routinely provided.

4. A process for patient refusal or nontransport if emergency transport is not warranted. The service program provider will obtain a signed transport/treatment refusal document or liability release if transport is not required.

5. A process by which a service program provider may make arrangements for alternate transport if emergency transport is not needed and remain with the patient until alternate transport arrives unless the provider is called to respond to another emergency.

c. Air transport service programs.

(1) An air transport service program operating fixed wing ambulances shall, at a minimum on each flight request, staff fixed wing ambulances with the following staff while a patient is being transported:

1. One health care clinician who is certified or licensed in the state from which the aircraft launches and is certified as an EMT or higher level; and

2. One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

(2) An air transport service program operating rotorcraft ambulances shall, at a minimum on each flight request, staff rotorcraft ambulances with the following staff while a patient is being transported:

1. Two health care clinicians who are certified or licensed in the state from which the aircraft launches, one of whom must at minimum be certified as a paramedic; and

2. One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

d. Nontransport service programs.

(1) Nontransporting service programs, when responding to 911 or emergency calls, shall provide as a minimum one currently certified emergency medical care provider certified at the service program full level of authorization.

(2) Nontransport service programs shall have an executed written transport agreement ensuring simultaneous dispatch with an authorized transport service program for all 911 or emergency calls.

(3) Nontransport service programs may transport patients in an ambulance only in an emergency situation when lack of transporting resources would cause an unnecessary delay in patient care.

e. Service programs electing to diagnose or treat police service dogs. A service program that elects to have rostered emergency medical care providers diagnose or treat severely injured police service dogs shall develop, maintain, and follow policies and procedures for diagnosing or treating police service dogs. The policies and procedures shall be developed in consultation with a veterinarian holding an active license to practice veterinary medicine in Iowa pursuant to Iowa Code chapter 169.

132.3(5) *Data reporting.*

a. A service program shall report data electronically to the department.

b. A service program shall submit data in a format approved by the department.

c. A service program shall submit reportable data to the department no later than the last day of the month following the month services were provided.

d. The data collected by the EMS data registry and furnished to the department pursuant to this rule are confidential records of the condition, diagnosis, care, or treatment of patients or former patients, including outpatients, pursuant to Iowa Code section 22.7. The compilations prepared for release or dissemination from the data collected are not confidential under Iowa Code section 22.7(2). However, information that individually identifies patients shall not be disclosed, and state and federal law regarding patient confidentiality shall apply.

e. The department may approve requests for reportable patient data for special studies and analysis provided:

(1) The request has been reviewed and approved by the department with respect to the scientific merit and confidentiality safeguards.

(2) The department has given administrative approval for the proposal.

(3) The confidentiality of patients is protected pursuant to Iowa Code section 22.7 and chapter 147A.

(4) The department may require those requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable data.

f. For the purpose of ensuring the completeness and quality of reportable data, the department or authorized representative may examine all or part of the data record as necessary to verify or clarify all reportable data submitted by a service program.

g. To the extent possible, activities under this subrule shall be coordinated with other health data collection methods.

h. A service program will develop, maintain and follow a written data submission policy.

132.3(6) *Patient care reporting.*

a. Each service program, satellite, and affiliate shall complete and maintain a patient care report documenting the care provided to each patient.

b. The patient care report is a confidential document and is exempt from disclosure pursuant to Iowa Code section 22.7(2) and shall not be accessible to the general public. Information contained in these reports, however, may be utilized by any of the indicated distribution recipients and may appear in any document or public health record in a manner that prevents the identification of any patient or person named in these reports.

c. To facilitate the continuum of care, transport service programs shall provide at a minimum, upon delivery of a patient to a receiving facility, a verbal patient care report that contains details of the assessment and care provided.

d. Transport service programs shall provide a final patient care report within 24 hours to the receiving facility. Transport services and receiving facilities must work together to initiate reasonable and realistic mechanisms (including but not limited to paper, secure email, secure links, secure electronic system retrieval, and access to printers at the receiving facility) to ensure the delivery of the patient care report.

e. A service program will develop, maintain, and follow a written patient care report policy.

132.3(7) *Continuous quality improvement (CQI).*

a. A service program shall develop, maintain, and follow a CQI program that follows a written CQI policy.

b. The CQI program shall include medical audits that review patient care provided.

c. The CQI program shall be utilized to identify deficiencies or potential deficiencies regarding medical knowledge or skill or procedure performance.

d. The CQI program shall review at a minimum 911 response and scene times.

e. The CQI program shall develop a written plan that monitors, identifies and documents at a minimum continuing education, credentialing of skills and procedures, and personnel performance for the service program's emergency medical care providers, drivers, physicians, PA and RN exceptions.

f. The CQI program shall establish measurable outcomes that reflect the goals and standards of the service program.

g. The CQI program shall ensure completion of loop closure/resolution of identified areas of concern.

132.3(8) *Medications in service programs.*

a. A service program shall have written pharmacy agreements in accordance with the Iowa board of pharmacy's 657—Chapter 11.

b. A service program shall maintain all medications in accordance with the rules of the Iowa board of pharmacy's 657—Chapters 10 and 11.

c. A service program shall develop, maintain, and follow a written pharmacy policy.

132.3(9) *Vehicle standards, supplies, equipment and maintenance.*

a. All service programs, regardless of their designation as governmentally owned, not-for-profit, or privately operated, shall, at a minimum, annually systematically inspect, repair, and maintain, or cause to be systematically inspected, repaired, and maintained, all ambulances operated by the service program.

b. Ground transport and nontransport service programs shall utilize a vehicle inspection report approved by the department to record the results of an ambulance safety inspection. Safety inspection forms that comply with the requirements of 49 CFR 396 as amended to August 1, 2024, shall be approved

by the department. A sample vehicle inspection form that complies with the reporting requirements of 49 CFR 396 as amended to August 1, 2024, can be found on the department's website.

c. All service programs shall ensure individuals performing safety inspections are qualified and capable of performing an inspection by reason of experience, training, or both.

d. All service programs shall not use an ambulance that fails to meet or maintain the requirements of this subrule to transport patients.

e. Ground transport and nontransport service programs shall house primary response ambulances in a garage or other enclosed facility that is maintained in a clean, safe condition, free of debris or other hazards; is temperature controlled; and has an unobstructed exit to the street.

f. All service programs shall secure all equipment stored in the ambulance patient compartment so the patient and service program personnel are not injured by moving equipment.

g. For ground transport and nontransport service programs, new ambulances manufactured and placed into service shall meet at a minimum either the Commission on Accreditation of Ambulance Services (CAAS) Ground Vehicle Standard for Ambulances, as amended to August 1, 2024, or the National Fire Protection Association (NFPA) Standard for Automotive Ambulances (NFPA 1917) as amended to August 1, 2024.

h. All service programs shall maintain first response and rescue vehicles in safe operating condition and provide regular maintenance. Vehicles shall have the exterior clean and the interior clean and disinfected.

i. All service programs shall ensure medical and patient care supplies are monitored for expiration dates, cleaned, laundered or disinfected. All medical supplies shall be stored in clean environments.

j. All service programs shall ensure personal protection equipment and supplies are available to ensure emergency medical care responder safety during every response.

k. All service programs shall ensure supplies to properly dispose of biomedical hazardous waste are available in all response vehicles, and all waste shall be disposed of according to accepted biomedical waste practices.

l. All service programs shall ensure medical equipment is maintained per manufacturer requirements for safe emergency medical care provider and patient use.

m. All service programs will develop, maintain, and follow vehicle standards, supplies, and equipment maintenance policies.

[**ARC 9124C**, IAB 4/16/25, effective 5/21/25; **ARC 9958C**, IAB 1/7/26, effective 3/1/26]

641—132.4(147A) Waivers. If during a period of authorization, a service program is unable to maintain compliance with Iowa Code chapter 147A and these rules, the department may grant a waiver.

132.4(1) The department may grant waivers of these rules to a currently authorized service program.

132.4(2) Requests for waivers shall apply only to the service program requesting the waiver and shall apply only to those requirements and standards for which the department is responsible.

132.4(3) A service program shall apply for a waiver in accordance with 441—Chapter 2504.

[**ARC 9124C**, IAB 4/16/25, effective 5/21/25; Editorial change: IAC Supplement 6/10/26]

641—132.5(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal.

132.5(1) All complaints regarding the operation of authorized emergency medical care service programs, or those purporting to be or operating as the same, shall be reported to the department.

132.5(2) Complaints and the investigative process will be treated as confidential in accordance with Iowa Code section 22.7 and chapter 272C. An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days following knowledge of the violation.

132.5(3) Service program authorization may be denied, issued a civil penalty not to exceed $1,000, issued a citation and warning, placed on probation, suspended, revoked, or otherwise disciplined by the department in accordance with Iowa Code section 147A.5(3) for any of the following reasons:

a. Knowingly allowing the falsifying of a patient care report (PCR).

b. Failure to submit required reports and documents.

c. Delegating professional responsibility to a person when the service program knows that the person is not qualified by training, education, experience or certification to perform the required duties.

d. Practicing, condoning, or facilitating discrimination against a patient, student or employee based on race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability diagnosis, or social or economic status.

e. Knowingly allowing sexual harassment of a patient, student or employee. Sexual harassment includes sexual advances, sexual solicitations, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

f. Failure or repeated failure of the applicant or alleged violator to meet the requirements or standards established pursuant to Iowa Code chapter 147A or the rules adopted pursuant to that chapter.

g. Obtaining or attempting to obtain or renew or retain service program authorization by fraudulent means or misrepresentation or by submitting false information.

h. Engaging in conduct detrimental to the well-being or safety of the patients receiving or who may be receiving emergency medical care.

i. Failure to correct a deficiency within the time frame required by the department.

j. Engaging in any conduct that subverts or attempts to subvert a department investigation.

k. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

l. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

m. Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

n. Acceptance of any fee by fraud or misrepresentation.

o. Repeated failure to comply with standard precautions for preventing transmission of infectious diseases as issued by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

p. Violating privacy and confidentiality. A service program shall not disclose or be compelled to disclose patient information unless disclosure is required or authorized by law.

q. Practicing emergency medical services or using a designation of certification or otherwise holding itself out as practicing emergency medical services at a certain level of authorization when the service program is not authorized at such level.

r. Failure to respond within 30 days of receipt, unless otherwise specified, of communication from the department that was sent by registered or certified mail.

132.5(4) The department will notify the applicant of the granting or denial of authorization or renewal, or will notify the alleged violator of action to issue a citation and warning, place on probation or suspend or revoke authorization or renewal pursuant to Iowa Code sections 17A.12 and 17A.18.

132.5(5) Appeal rights. Notice of the right to appeal the denial, citation and warning, probation, suspension or revocation of service program authorization or renewal will be given in accordance with 441—Chapter 16 and may be appealed pursuant to 441—Chapter 2506.

[**ARC 9124C**, IAB 4/16/25, effective 5/21/25; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code chapter 147A and 2024 Iowa Acts, House File 2507.

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[1] See IAB, Inspections and Appeals Department.

[2] Rescission of paragraph 132.14(2)*"f"* inadvertently omitted from 2/2/05 Supplement.

CHAPTER 133
WHITE FLASHING LIGHT AUTHORIZATION

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—133.1(321) Definitions. For the purpose of these rules, the following definitions shall apply:

"Ambulance" means the same as defined in rule 641—132.1(147A).

"Authorization certificate" means a permit issued to an emergency medical care provider that authorizes the use of a white flashing light.

"Authorized vehicles" means any vehicles owned by members of the service program that are authorized by the department to use white flashing lights.

"Emergency medical care provider" means the same as defined in Iowa Code section 147A.1.

"First response vehicle" means the same as defined in rule 641—132.1(147A).

"Medical director" means the same as defined in rule 641—132.1(147A).

"Member" means any individual utilized by an ambulance or nontransport service to provide emergency medical care.

"Nontransport service" means the same as defined in rule 641—132.1(147A).

"Rescue vehicle" means the same as defined in Iowa Code section 321.1.

"Service director" means the same as defined in rule 641—132.1(147A).

"Service program" or *"service"* means the same as defined in Iowa Code section 147A.1.

"White light" means a white or clear rotating, flashing, or strobe lighting device utilized for identification purposes only. Any such lighting device shall not display a constant white or clear light to the rear of the vehicle.

[**ARC 9075C**, IAB 4/2/25, effective 6/1/25]

641—133.2(321) Purpose.

133.2(1) White flashing lights may be used on emergency vehicles or other authorized vehicles utilized by emergency medical care providers and service programs for identification purposes only.

133.2(2) White flashing lights shall be used only on an authorized vehicle and shall not be used except in any of the following circumstances:

a. When responding to an emergency in the line of duty requiring the services of the member.

b. When at the scene of an emergency.

c. When transporting a patient during a disaster situation.

133.2(3) Owners and operators of authorized vehicles are responsible for ensuring that the lighting devices are utilized in a safe manner. This includes but is not limited to ensuring that lighting devices do not:

a. Obstruct the view of the vehicle operator.

b. Overburden the electrical system of the vehicle.

c. Interfere with the vision of the vehicle operator, passengers, or drivers of other vehicles.

133.2(4) Operators of authorized vehicles shall ensure that the authorization certificate is carried in the vehicle.

[**ARC 9075C**, IAB 4/2/25, effective 6/1/25]

641—133.3(321) Application.

133.3(1) Authorization certificates will be issued by the service director for service vehicles and vehicles owned by emergency medical care providers who are members in good standing with the service. Authorization certificates are available from the department upon request. Vehicle authorization is limited to:

a. Vehicles owned or exclusively operated by the ambulance or nontransport service.

b. Vehicles owned or operated by emergency medical care provider members of the ambulance or nontransport service.

c. Vehicles owned or operated by the service program's medical director.

d. One authorization certificate per vehicle.

133.3(2) Nothing in these rules prevents the use of white flashing lights on vehicles that are authorized to use red or blue flashing lights.

133.3(3) The service director shall provide, upon request of the department or its agents, issued authorization certificates.

133.3(4) The authorization expires five years from the date issued unless sooner suspended or revoked.

133.3(5) The department may issue authorization certificates for vehicles used by employees of the department when responding to emergencies or disasters.

[**ARC 9075C**, IAB 4/2/25, effective 6/1/25]

641—133.4(321) Approval, denial, probation, suspension and revocation of authorization.

133.4(1) The service director or the department may approve or deny an application and the department may place on probation, suspend or revoke an authorization certificate if the service director or the department finds reason to believe that the applicant or certificate holder:

a. Has failed to meet all applicable requirements of these rules.

b. Has been convicted of a moving violation while using white flashing lights.

c. Has utilized a white flashing light without obtaining an authorization certificate.

d. Does not have a valid driver's license.

e. Does not have a current vehicle registration.

133.4(2) The authorization certificate shall be surrendered upon the request of the department or its agents.

133.4(3) An emergency medical care provider or service director who has knowledge of any emergency medical care provider or service program that has violated Iowa Code chapter 147A, 641—Chapter 132 or these rules shall, within 30 days, report that information to the department.

133.4(4) A denial, probation, suspension or revocation ordered by the department shall be effected in accordance with 441—Chapter 16 and may be appealed according to the provisions set forth in 441—Chapter 2506.

[**ARC 9075C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

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CHAPTER 134
TRAUMA CARE FACILITY CATEGORIZATION AND VERIFICATION

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—134.1(147A) Definitions. For the purposes of these rules, the following definitions apply:

"ACS-COT" means the American College of Surgeons Committee on Trauma.

"Categorization" means the same as defined in Iowa Code section 147A.21.

"Certificate of verification" means a document awarded by the department that identifies a hospital or emergency care facility's level and term of verification as a trauma care facility.

"Criteria deficiency" or *"deficiency"* means a failure to meet criteria requirements as outlined in subrule 134.2(3).

"Emergency care facility" means the same as defined in Iowa Code section 147A.21.

"Emergency medical care provider" means emergency medical care provider as defined in Iowa Code section 147A.1.

"Final report" means the verification report issued by the department following a verification review conducted by trauma survey team members and department staff.

"Governing body" means a group of individuals responsible for the governance of a hospital, including but not limited to a board of directors or board of trustees.

"Hospital" means any hospital licensed under Iowa Code chapter 135B.

"On-site verification survey" means an on-site survey conducted by the department or survey team members to assess a hospital or emergency care facility's ability to meet the level of categorization requested.

"Persistently occurring deficiencies" means deficiencies identified in two sequential verification reviews.

"Trauma" means the same as defined in Iowa Code section 147A.21.

"Trauma care facility" means the same as defined in Iowa Code section 147A.21.

"Trauma survey team" means a group of health care providers contracted by the department to assist in verifying trauma care facilities' compliance with trauma criteria adopted in subrule 134.2(3).

"Type I criteria" or *"type I criteria deficiency"* indicates criteria requirements that may significantly impact a trauma care facility's ability to provide optimal care for trauma patients.

"Type II criteria" or *"type III criteria deficiency"* indicates criteria that are required but have a less critical impact on the trauma care facility's ability to provide optimal care for trauma patients than type I criteria.

"Verification" means the same as defined in Iowa Code section 147A.21.

[**ARC 9125C**, IAB 4/16/25, effective 6/1/25]

641—134.2(147A) Trauma care facility categorization and verification. Categorization and verification of trauma care facilities will be made by the department in accordance with Iowa Code section 147A.23.

134.2(1) Categorization applications shall be submitted by all hospitals. New hospitals and emergency care facilities shall submit a categorization application no later than 90 days after licensing by the department of inspections, appeals, and licensing.

134.2(2) Categorization levels for trauma care facilities shall be identified as:

a. Level I.

b. Level II.

c. Level III.

d. Level IV.

134.2(3) Adoption by reference. Criteria specific to level I, II, and III trauma care facilities identified in the "Resources for Optimal Care of the Injured Patient" 2022 Standards published by the American College of Surgeons (ACS) is incorporated and adopted by reference for level I, II, and III hospital and emergency care facility categorization criteria. Criteria specific to level IV trauma care facilities identified in the "Resources for Optimal Care of the Injured Patient 2014" published by the ACS is incorporated and adopted by reference for level IV hospital and emergency care categorization criteria.

For any differences that may occur between the adopted references and these administrative rules, the administrative rules shall prevail.

134.2(4) Categorization shall not be construed to imply any guarantee on the part of the department as to the level of trauma care services available at a trauma care facility.

134.2(5) A verified trauma care facility may apply to the department for a change in level of categorization through submission of a self-assessment categorization application.

134.2(6) Verification of a trauma care facility will be determined by the department upon successful completion of the categorization application and completion of a verification survey. All categorized hospitals and emergency care facilities shall be verified. Each hospital location operating on a single hospital license must provide the same level of trauma care or be verified separately to the level of trauma care services at that location.

a. Level I and II trauma care facilities shall be verified by the ACS-COT.

b. Trauma care facilities verified by the ACS-COT will be accepted by the department as equivalent for categorization and verification as a trauma care facility in Iowa provided that all policy, reporting, and administrative rules have been met. The department may issue a certification of verification provided that the trauma care facility has been verified by the ACS-COT. The facility shall provide the department documentation including but not limited to a current copy of the ACS-COT verification.

c. A level I or II trauma care facility that fails to attain ACS-COT verification shall submit an application to the department to be verified as a level III or IV trauma care facility to ensure compliance with Iowa Code section 147A.23(2)*"a."*

d. Level III and IV trauma care facilities will be verified by the department in consultation with the trauma survey team.

134.2(7) The department will conduct a verification survey for categorized hospitals or emergency care facilities.

a. Type I and II criteria deficiencies identified during the verification process shall be resolved in accordance with the trauma care facility's final report. Failure to rectify deficiencies in accordance with the trauma care facility's final report may result in disciplinary action.

b. The department may conduct electronic review or on-site verification that criteria deficiencies have been resolved as outlined in final reports or disciplinary actions.

c. The department will notify the applicant in writing as to the approval or denial of verification as a trauma care facility within 90 days after the completion of a verification survey.

d. Verification cannot be construed to imply any guarantee on the part of the department as to the level of trauma care services available at a hospital or emergency care facility.

e. Trauma care facility verification is valid for a period of three years from the effective date unless otherwise specified on the certificate of verification or unless sooner suspended or revoked.

f. Trauma care facilities shall be fully operational at their verified level upon the effective date specified on the certificate of verification.

g. Trauma care facilities that are unable to maintain their categorization or verification, or both, must notify the department within 48 hours.

h. The director, pursuant to 441—Chapter 2504, may grant a waiver from the requirements of rules adopted under this chapter for any trauma care facility.

i. Proceedings, records, and reports developed pursuant to this chapter constitute peer review records under Iowa Code section 147.135 and are not subject to discovery by subpoena or admissible as evidence. All information and documents received from a hospital, emergency care facility, or trauma care facility under Iowa Code chapter 147A are confidential pursuant to Iowa Code section 272C.6(4).

[**ARC 9125C**, IAB 4/16/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—134.3(147A) Complaints, investigations and appeals.

134.3(1) The department may deny verification as a trauma care facility or may give a citation and warning, place on probation, suspend, or revoke existing verification if the department finds reason to believe that the facility has not been operating or will not be operated in compliance with Iowa Code section 147A.23 and these administrative rules or that there is insufficient assurance of adequate protection for the public.

134.3(2) All complaints regarding the operation of a trauma care facility, or those purporting to be or operating as the same, shall be reported to the department.

134.3(3) Complaints and the investigative process shall be treated as confidential to the extent that they are protected by Iowa Code section 22.7 and chapter 272C.

134.3(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

134.3(5) Notice of denial, citation and warning, probation, suspension or revocation shall be effected in accordance with the requirements of 441—Chapter 16 and appealed pursuant to 441—Chapter 2506.

134.3(6) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, news media or employer.

[**ARC 9125C**, IAB 4/16/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code section 147A.23.

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CHAPTER 135
TRAUMA TRIAGE AND TRANSFER PROTOCOLS

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—135.1(147A) Definitions. For the purposes of these rules, the following definitions apply:

"Out-of-Hospital Trauma Triage Destination Decision Protocols" means written directives to assist in trauma and triage decision-making, established and approved by the department, to be followed by the service program.

"Service program" or *"service"* means the same as defined in Iowa Code section 147A.1.

"Transfer" means the process of a patient being transferred from the scene of an injury to a trauma care facility or from one trauma care facility to another.

"Trauma care facility" means the same as defined in Iowa Code section 147A.21.

"Trauma triage and transfer" means to determine the trauma care facility destination.

[**ARC 9076C**, IAB 4/2/25, effective 6/1/25]

641—135.2(147A) Trauma triage and transfer protocols. Trauma triage and transfer protocols approved by the department assist personnel from each service program and trauma care facility. These protocols do not preclude service programs or trauma care facilities from making emergency revisions of the approved triage and transfer protocols when an incident overburdens medical care resources, causing an unnecessary delay in patient care.

135.2(1) Adoption by reference. The 2021 National Guideline for the Field Triage of Injured Patients, as amended to August 1, 2024, is incorporated by reference and adopted as the Out-of-Hospital Trauma Triage Destination Decision Protocol for the state of Iowa.

135.2(2) Revisions and modifications to the protocols adopted by reference in subrule 135.2(1) may be made upon recommendation to and approval of the department.

[**ARC 9076C**, IAB 4/2/25, effective 6/1/25]

641—135.3(147A) Offenses and penalties. The department may deny verification as a trauma care facility or deny authorization as a service program or may give a citation and warning, place on probation, suspend, or revoke existing trauma care facility verification or service program authorization if the department finds reason to believe that the facility or service program has not been or will not be operated in compliance with Iowa Code section 147A.27 and these administrative rules. The denial, citation and warning, period of probation, suspension, or revocation shall be effected in accordance with 441—Chapter 16 and may be appealed in accordance with the requirements of 441—Chapter 2506.

[**ARC 9076C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

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CHAPTER 136
TRAUMA REGISTRY

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—136.1(147A) Definitions. For the purposes of these rules, the following definitions apply:

"Health care providers" for the purpose of this chapter includes licensed physicians, advanced registered nurse practitioners, physician associates, and registered nurses.

"Inclusion criteria" means criteria determined by the department and adopted by reference to determine which trauma patients are to be included in the trauma registry.

"Reportable patient data" means data and definitions determined by the department to be reported to the trauma registry on trauma patients meeting the inclusion criteria.

"Trauma care facility" means the same as defined in Iowa Code section 147A.21.

"Trauma patient" means a victim of an external cause of injury that results in major or minor tissue damage or destruction caused by intentional or unintentional exposure to thermal, mechanical, electrical or chemical energy, or by the absence of heat or oxygen.

"Trauma registry" means the data repository approved by the department to collect and analyze reportable patient data on the incidence, severity, and causes of trauma, and that serves as the central registry for brain and spinal cord injuries described in rule 641—21.1(135) and farm-related injuries.

"Trauma survey team" means a group of health care providers contracted by the department to assist in verifying trauma care facilities' compliance with trauma criteria adopted by reference in 641—subrule 134.2(3).

[**ARC 9077C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—136.2(147A) Trauma registry.

136.2(1) Trauma care facilities shall submit reportable patient data electronically to the department. Data shall be submitted in the trauma registry format approved by the department. The department may require those requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable patient data.

136.2(2) Quality assurance of reported data.

a. For the purpose of ensuring the completeness and quality of reportable patient data, the department or its designated trauma survey team may examine medical records to validate the accuracy of data submitted by a trauma care facility.

b. Review of medical records by the department or its designated trauma survey team may be scheduled in advance with the trauma care facility.

[**ARC 9077C**, IAB 4/2/25, effective 6/1/25]

641—136.3(147A) Offenses and penalties. All complaints, offenses and penalties will be addressed pursuant to rule 641—134.3(147A).

[**ARC 9077C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code section 147A.26.

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CHAPTER 137
TRAUMA EDUCATION AND TRAINING

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—137.1(147A) Definitions. For the purposes of these rules, the following definitions apply:

"Advanced registered nurse practitioner" or *"ARNP"* means a nurse as defined in rule 655—7.1(152).

"Formal education" means education in standardized educational settings with a curriculum.

"Licensed practical nurse" or *"LPN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Physician associate" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Practitioner" means a person who practices medicine or one of the associated health care professions.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Trauma" means the same as defined in Iowa Code chapter 147A.

"Trauma care facility" means the same as defined in Iowa Code chapter 147A.

"Trauma patient" means a victim of an external cause of injury that results in major or minor tissue damage or destruction caused by intentional or unintentional exposure to thermal, mechanical, electrical or chemical energy, or by the absence of heat or oxygen.

"Verification" means the same as defined in Iowa Code chapter 147A.

[**ARC 9078C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—137.2(147A) Initial trauma education requirements.

137.2(1) Trauma education is required of physicians, physician associates, advanced registered nurse practitioners, registered nurses, and licensed practical nurses who are identified or defined as trauma team members by a trauma care facility and who participate directly in the initial resuscitation of the trauma patient.

137.2(2) Requirements for initial trauma education. Specific requirements for initial trauma education for each provider category are as follows:

a. Physicians, PAs and ARNPs shall comply with education criteria specific to the level for which the trauma care facility is verified. Physicians, PAs and ARNPs at verified level I, II, and III trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of Injured Patients 2022 Standards" published by the American College of Surgeons. Physicians, PAs and ARNPs at verified level IV trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of the Injured Patient 2014" published by the American College of Surgeons.

b. RNs and LPNs shall comply with education criteria specific to the level for which the trauma care facility is verified. RNs and LPNs at verified level I, II, and III trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of Injured Patients 2022 Standards" published by the American College of Surgeons. RNs and LPNs at verified level IV trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of the Injured Patient 2014" published by the American College of Surgeons.

[**ARC 9078C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—137.3(147A) Continuing trauma education requirements. Specific requirements for continuing trauma education for each provider category are as follows:

137.3(1) Physicians, PAs and ARNPs shall comply with education criteria specific to the level for which the trauma care facility is verified. Physicians, PAs and ARNPs at verified level I, II, and III trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of Injured Patients 2022 Standards" published by the American College of Surgeons. Physicians, PAs and ARNPs at verified level IV trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of the Injured Patient 2014" published by the American College of Surgeons.

137.3(2) RNs and LPNs shall comply with education criteria specific to the level for which the trauma care facility is verified. RNs and LPNs at verified level I, II, and III trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of Injured Patients 2022 Standards"

published by the American College of Surgeons. RNs and LPNs at verified level IV trauma care facilities shall comply with criteria according to the "Resources for Optimal Care of the Injured Patient 2014" published by the American College of Surgeons.

[**ARC 9078C**, IAB 4/2/25, effective 6/1/25]

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CHAPTER 138
TRAUMA SYSTEM ADVISORY COUNCIL
Rescinded **ARC 9177C**, IAB 4/30/25, effective 7/1/25

CHAPTER 139
EMERGENCY MEDICAL SERVICES—TRAINING PROGRAMS—STUDENTS—COMPLAINTS AND INVESTIGATIONS

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—139.1(147A) Definitions.

"Advanced emergency medical technician" or *"AEMT"* means the same as defined in rule 641—131.1(147A,147D,272C).

"CAAHEP" means the same as defined in rule 641—131.1(147A,147D,272C).

"CAPCE" means the same as defined in rule 641—131.1(147A,147D,272C).

"CEH" means the same as defined in rule 641—131.1(147A,147D,272C).

"Certification" or *"certificate"* means the same as defined in rule 641—131.1(147A,147D,272C).

"Certified" means the same as defined in rule 641—131.1(147A,147D,272C).

"CoAEMSP" means Committee on Accreditation for the EMS Professions.

"Core continuing education" means the same as defined in rule 641—131.1(147A,147D,272C).

"Course completion date" means the date of the final classroom session of an emergency medical care provider course.

"Course coordinator" means an individual who has been assigned by the training program to coordinate the activities of an emergency medical care provider course.

"Critical care paramedic" or *"CCP"* means the same as defined in rule 641—131.1(147A,147D,272C).

"Emergency medical care" means any medical procedure authorized by Iowa Code chapter 147A and 641—Chapter 131.

"Emergency medical care provider" means the same as defined in Iowa Code section 147A.1.

"Emergency medical care student" or *"student"* means any individual enrolled in an EMS training program.

"Emergency medical responder" or *"EMR"* means the same as defined in rule 641—131.1(147A,147D,272C).

"Emergency medical services" or *"EMS"* means the same as defined in Iowa Code section 147A.1.

"Emergency medical technician" or *"EMT"* means the same as defined in rule 641—131.1(147A,147D,272C).

"EMS evaluator" or *"EMS-E"* means an individual who has successfully completed an EMS evaluator curriculum approved by the department and is currently endorsed by the department as an EMS-E.

"EMS instructor" or *"EMS-I"* means the same as defined in rule 641—131.1(147A,147D,272C).

"EMS training program" or *"training program"* means a program offered by an Iowa college approved by the Higher Learning Commission, an Iowa hospital, or a service program that has received authorization from the department to conduct emergency medical care training.

"Endorsement" or *"endorsed"* means the same as defined in rule 641—131.1(147A,147D,272C).

"Higher Learning Commission" means the independent corporation that accredits degree-granting postsecondary institutions in the north central region of the United States.

"NREMT" means the same as defined in rule 641—131.1(147A,147D,272C).

"Out-of-state student" means any individual participating in clinical or field experience as a student in an approved out-of-state training program.

"Out-of-state training program" means an EMS training program located outside the state of Iowa that is approved by the authorizing agency of the program's home state to conduct initial EMS training for EMR, EMT, AEMT, paramedic or other levels certified by the department.

"Outreach course coordinator" means an individual assigned by the training program to coordinate the activities of an emergency medical care provider course held outside the training program facilities.

"Paramedic" or *"PM"* means the same as defined in rule 641—131.1(147A,147D,272C).

"Physician" means an individual licensed under Iowa Code chapter 148.

"Physician associate" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Preceptor" means an individual assigned by the training program, clinical facility or service program to supervise EMS students while the students are completing their clinical or field experience. A preceptor shall be an emergency medical care provider certified at the level at which the preceptor is providing supervision or at a higher level or be licensed as a physician, physician associate or registered nurse.

"Primary instructor" means an individual who is responsible for teaching the majority of an emergency medical care provider course.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Service program" or *"service"* means the same as defined in Iowa Code section 147A.1.

"Training program director" means a health care professional (full-time educator or practitioner of emergency or critical care) assigned by the training program to direct the operation of the training program.

"Training program medical director" means a physician licensed under Iowa Code chapter 148 who is responsible for providing medical oversight to an EMS training program.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—139.2(147A) Initial application, renewal application, inspection and approval.

139.2(1) *Initial application, inspection and approval.*

a. An applicant seeking initial authorization as an EMS training program shall complete and submit to the department an Iowa EMS training program self-assessment application. The application is available from the department upon request.

b. The department will perform an on-site inspection of the applicant's facilities and clinical resources. The purpose of the inspection is to examine educational objectives, patient care practices, facilities and administrative practices.

c. A training program's initial authorization is for one year.

d. No person shall interfere with the inspection activities of the department or its agents. Interference with or failure to allow an inspection may be cause for denial of authorization.

139.2(2) *Renewal application, inspection and approval.*

a. A training program seeking renewal as an EMS training program shall complete and submit to the department the Iowa EMS training program self-assessment renewal application. The application is available from the department upon request.

b. EMS training program renewal applications will be submitted at least 90 days before the end of the current authorization period.

c. The department will complete an on-site inspection and review the self-assessment prior to the end of the current authorization period.

d. Following the on-site inspection, the department will provide the training program a renewal application report detailing the status of the application.

e. The department will authorize the training program or determine timelines for the correction of deficiencies in the renewal application.

f. If the deficiencies are not corrected within the time period established by the department, the training program is subject to disciplinary action as described in rule 641—139.8(147A).

g. A training program's approved renewal authorization will not exceed four years.

h. No person shall interfere with the inspection activities of the department or its agents. Interference with or failure to allow an inspection may be cause for denial of authorization.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25]

641—139.3(147A) Training program standards, student requirements and waivers.

139.3(1) *Education standards.* A training program shall:

a. Have a sponsoring institution that has received authorization from the department to conduct emergency medical care services training.

b. Use the U.S. Department of Transportation's National Emergency Medical Services Education Standards (December 2021) for any courses leading to Iowa certification.

c. Use the Iowa CCP curriculum (January 2024) for courses leading to the CCP endorsement.

d. Be accredited by CAAHEP or have a letter of review from CoAEMSP if graduating students at the paramedic certification level.

e. Document equivalent training and what portions of any course have been waived for equivalency. A training program may waive portions of the required emergency medical care provider training for students currently certified as emergency medical care providers or licensed in other health care professions, including but not limited to physician, nursing, physician associate, respiratory therapist, dentistry, and military.

139.3(2) *Clinical or field experience resources.* Training programs shall:

a. Have a mechanism to clearly identify students in the clinical or field setting, or both.

b. Ensure that clinical experiences available are consistent with the needs of the curriculum and adequate for the number of students enrolled.

c. Ensure that clinical affiliations that are outside of the sponsoring training program are established and confirmed in written agreements with institutions or agencies that provide clinical experience under appropriate medical direction and clinical supervision.

d. Only allow students to perform skills and procedures in the clinical or field setting for which the students have received training with direct supervision by a preceptor designated and approved by the training program.

139.3(3) *Staff.* Training programs shall:

a. Have a training program director who is a health care professional (full-time educator or practitioner of emergency or critical care) assigned by the training program to direct the operation of the training program.

b. Have a training program medical director who shall, at a minimum, review the educational content of each training program curriculum, evaluate the quality of medical instruction, and supervise delivery of the curriculum by the faculty members.

c. Have qualified faculty through academic preparation, training, and experience to teach and evaluate the courses or topics to which they are assigned. At a minimum, each course coordinator, outreach course coordinator, and primary instructor utilized by the training program shall be endorsed as an Iowa EMS instructor.

139.3(4) *Student eligibility.* Training programs shall ensure that emergency medical care students meet the following requirements:

a. Be at least 17 years of age on the date of enrollment.

b. Have a high school diploma or its equivalent if enrolling in an AEMT or paramedic course.

c. Be able to speak, write and read English.

d. Be able to meet the minimum requirements for the department- or NREMT-approved testing requirements with reasonable and appropriate accommodations for those persons with documented disabilities, as required by the Americans with Disabilities Act (ADA) as amended to August 1, 2024.

e. Be currently certified, at a minimum, as an EMT if enrolling in an AEMT or paramedic course.

f. Be a current emergency medical care provider, RN, PA, or physician when applying for the EMS instructor endorsement.

139.3(5) *Students.* Training programs shall:

a. Have defined processes for review of academic history, criminal history, and health-related issues for the admission of students.

b. Have a process to evaluate students on a recurring basis and with sufficient frequency to provide both the student and training program faculty with valid and timely indicators of the student's progress and achievement of the competencies and objectives stated within the program's curriculum.

c. Have student guidance procedures that include documentation of regular and timely discussions with qualified faculty or counselors.

d. Maintain student records for each student enrolled in each program.

e. Notify the NREMT of each student's successful completion of a training course to ensure NREMT cognitive examination eligibility.

f. Verify that a student completes all training program requirements before being eligible to attempt the department- or NREMT-approved testing requirements.

g. Ensure that students only perform skills or procedures learned in the training program until an Iowa emergency medical care provider certification is obtained.

h. Ensure that a student is not substituted for the regular personnel of any affiliated medical facility or service program but may be employed while enrolled in the training program.

139.3(6) *Financing and administration.* Training programs shall:

a. Have sufficient equipment and supplies to be used in the provision of instruction. The equipment and supplies shall be available and consistent with the needs of the curriculum and adequate for the number of students enrolled.

b. Have sufficient classrooms, laboratories, and administrative offices and facility design to accommodate the number of students in the program and the supporting faculty.

c. Notify the department, in writing, of any change in ownership or control of the training program.

d. Have liability insurance or offer liability insurance to enrolled students.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—139.4(147A) Out-of-state training programs.

139.4(1) *Application, inspection and approval.*

a. An out-of-state training program shall complete and submit to the department for review and approval the out-of-state training program self-assessment application. The application is available from the department upon request.

b. An out-of-state training program's approval by the department shall not exceed four years.

c. An out-of-state training program seeking initial or renewal approval must be accredited by CAAHEP or have a letter of review from CoAEMSP if graduating students at the paramedic certification level.

d. An out-of-state training program shall be limited to utilization of clinical sites or field sites, or both, within Iowa.

e. An authorized out-of-state training program shall provide the department with a current roster of students who will be participating in the clinical or field experience within the state of Iowa and, for each program, the sites where the students will be participating. This roster will be provided prior to commencement of any clinical or field experience.

f. An out-of-state training program shall provide documentation of liability insurance for each student participating in the clinical or field setting within the state of Iowa.

g. Failure to comply with these requirements may lead to disciplinary action or denial of utilization of clinical or field sites in Iowa.

h. The department may perform an on-site inspection of the out-of-state training program's facilities and clinical and field resources as part of the initial or renewal review process.

i. The department, without prior notification, may make inspections at times, at places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

j. No person shall interfere with the inspection activities of the department or its agents. Interference with or failure to allow an inspection may be cause for disciplinary action regarding training program approval.

k. Representatives of the training program may be required to meet with the department at the time the application and inspection report are discussed.

l. A written report of department action and the department inspection report will be sent to the training program.

m. A training program shall notify the department, in writing, of any change in ownership or control within 30 days.

139.4(2) Reserved.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25]

641—139.5(147A) Failure to comply with rules. Failure of a training program to comply with these rules may result in disciplinary action according to rule 641—139.8(147A).

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25]

641—139.6(147A) Temporary waivers. If during a period of authorization there is some occurrence that temporarily causes a training program to be in noncompliance with these rules, the department may grant a temporary waiver.

139.6(1) Waivers of these rules may be granted by the department to a currently authorized training program.

139.6(2) Requests for waivers apply only to the training program requesting the waiver and apply only to those requirements and standards for which the department is responsible.

139.6(3) A training program can apply for a waiver in accordance with 441—Chapter 2504.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—139.7(147A) Continuing education providers—approval, recordkeeping and inspection.

139.7(1) A training program may conduct or authorize other entities to provide continuing education courses.

139.7(2) Each training program shall assign a sponsor number to each core continuing education course using an assignment system approved by the department.

139.7(3) Course approval shall be completed prior to the course being offered.

139.7(4) Each training program shall maintain a participant record that includes, at a minimum, each participant's:

a. Name.

b. Address.

c. Certification number.

d. Course sponsor number.

e. Course instructor.

f. Date of course.

g. CEHs awarded.

139.7(5) The department may request additional information or inspect the records of any continuing education provider who is currently approved or who is seeking approval.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25]

641—139.8(147A) Discipline—denial, citation and warning, probation, suspension, or revocation of training program approval or renewal.

139.8(1) This rule is not subject to waiver pursuant to 441—Chapter 2504 or any other provision of law.

139.8(2) Method of discipline. The department has the authority to impose the following disciplinary sanctions against a training program:

a. Issue a citation and warning.

b. Impose a period of probation under specific conditions.

c. Prohibit permanently, until further order of the department, or for a specific period, a program's ability to engage in specific procedures, methods, acts or activities incident to the practice of the profession.

d. Suspend an authorization until further order of the department or for a specific period.

e. Deny an application for authorization.

f. Revoke an authorization.

g. Impose such other sanctions as allowed by law and as may be appropriate.

139.8(3) The department may impose any of the disciplinary sanctions provided in subrule 139.8(2) when it finds that the training program or applicant has failed to meet the applicable provisions of these rules or has committed any of the following acts or offenses:

a. Fraud in procuring approval or renewal.

b. Falsification of training or continuing education records or failure to document training or continuing education.

c. Suspension or revocation of approval to provide emergency medical care training or other disciplinary action taken pursuant to Iowa Code chapter 147A. A certified copy of the record or order of suspension, revocation or disciplinary action is conclusive or prima facie evidence.

d. Engaging in any conduct that subverts or attempts to subvert a department investigation.

e. Failure to respond within 30 days of receipt of communication from the department that was sent by registered or certified mail.

f. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

g. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

h. Submission of a false report of continuing education.

i. Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

j. Representing itself as an approved training program or continuing education provider when approval has been suspended or revoked or when approval has lapsed or has been placed on inactive status.

k. Using an unqualified individual as an instructor or evaluator.

l. Allowing verbal or physical abuse of a student or staff.

m. Failing to verify registration of a student with the department within the timeline established by the department or allowing an unregistered student to function in a clinical environment.

n. Sexually harassing a patient, student or coworker. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal or physical conduct of a sexual nature communicated in person, in writing, via a third person or through electronic communication.

o. Betrayal of a professional confidence.

p. Engaging in a professional conflict of interest.

q. Discrimination. A training program or continuing education provider shall not practice, condone, or facilitate discrimination against a patient, student, or supervisee on the basis of race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability, diagnosis, or social or economic status.

r. Failure to comply with the 2015 Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions published by the Commission on Accreditation of Allied Health Education Programs.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

641—139.9(147A) Complaints, investigations and appeals.

139.9(1) All complaints regarding an emergency medical care student, training programs or continuing education providers or those purporting to be or operating as the same shall be reported to the department in writing.

139.9(2) Any emergency medical care provider, emergency medical care student, training program or continuing education provider who has knowledge of an emergency medical care provider or service program that has violated Iowa Code chapter 147A, 641—Chapter 132 or these rules shall report such information to the department.

139.9(3) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

139.9(4) A determination of mental incompetence by a court of competent jurisdiction automatically suspends a certificate for the duration of the certificate unless the department orders otherwise.

139.9(5) Notice of denial, issuance of a citation and warning, probation, suspension or revocation shall be effected in accordance with the requirements of 441—Chapter 16 and can be appealed pursuant to 441—Chapter 2506.

[**ARC 9079C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code chapter 147A.

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[Editorial change: IAC Supplement 6/10/26]

CHAPTER 140
EMERGENCY MEDICAL SERVICES SYSTEM DEVELOPMENT GRANTS FUND

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—140.1(135) Definitions. For the purpose of these rules, the following definitions apply:

"Ambulance service" means the same as defined in 641—132.1(147A).

"CEHs" means the same as defined in 641—131.1(147A,147D,272C).

"Continuing education" means the same as defined in 641—131.1(147A,147D,272C).

"County EMS association" means a countywide group of EMS providers and various agency and organization representatives and consumers who provide leadership for the local EMS system on needs and objectives. The county EMS association should also include representatives of services located in a neighboring county if service is provided on a regular basis to residents of the county receiving funding.

"Emergency medical care provider" means the same as defined in Iowa Code section 147A.1.

"Emergency medical services" or *"EMS"* means the same as defined in Iowa Code section 147A.1.

"EMS course" means a course for emergency medical care personnel pursuant to Iowa Code section 147A.4(2).

"Infrastructure" means those elements that make up an EMS system.

"Nontransport service" means nontransport service as defined in 641—132.1(147A).

"Regional EMS council" means a multicounty nonprofit corporation whose purpose is to facilitate EMS development on a regional basis.

"Service program" means service program as defined in Iowa Code section 147A.1.

"Strategic plan" means a document produced via a multiagency effort to evaluate and define needs and goals to improve the local EMS system.

"Training" means EMS-related courses designed and intended for EMS providers and includes any item used in training, including but not limited to slides, films, mannequins, emergency care devices, books and other items pertinent and necessary for training purposes.

[**ARC 9080C**, IAB 4/2/25, effective 6/1/25]

641—140.2(135) County EMS associations. Each county will have a county EMS association, council or board to develop and maintain the countywide EMS system strategic plan and to provide leadership on related EMS system development funding needs and objectives.

[**ARC 9080C**, IAB 4/2/25, effective 6/1/25]

641—140.3(135) County EMS system development grants. Grants for EMS system development proposals at the regional, county, and local level are available through a grant process from the department to county boards of supervisors or local boards of health for equipment, training, and support of infrastructure needs as identified in the countywide EMS strategic plan and the department system standards. County boards of supervisors or local boards of health shall not take any administrative fee from these funds to support their work under this rule. County recipients of funds may subcontract work under this agreement to a county EMS association. Funds for training will be used to train members of a service program that provides service on a regular basis to residents of the county being funded. Funds for equipment require a $1 match of regional, county, or local funds for each $1 of EMS system development grant funds.

140.3(1) *Eligible costs.* Costs eligible for EMS system development grant expenditures as defined in the request for proposal (RFP) include:

a. Training.

(1) Reimbursement for initial training tuition, fees and materials up to an amount that is the lowest fee charged by the training entity following successful completion of an EMS course. Practical and written examination fees may also be included.

(2) Payment of continuing education tuition, fees and materials. Education provided by an EMS program for the general public is an allowable expense.

(3) Payment for EMS training aids.

b. Other equipment as defined by the RFP.

c. Infrastructure support.

(1) Development and enhancement of EMS systems.

(2) Office equipment and supplies necessary to coordinate a countywide EMS system.

(3) Personnel services for staffing to provide countywide continuous quality improvement and medical direction.

The title to any EMS equipment purchased with these funds does not lie with the department but will be determined by the county.

140.3(2) *Ineligible costs.* Costs not eligible for funding include:

a. Certification/recertification fees.

b. Building and construction costs.

c. Debt amortization.

d. Land.

e. Rent.

f. Utilities.

g. Vehicles including ambulances, fire apparatus, boats, rescue/first-response vehicles, snowmobiles and vehicle parts.

[**ARC 9080C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code section 135.25.

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CHAPTER 141
LOVE OUR KIDS GRANT
Rescinded **ARC 9959C**, IAB 1/7/26, effective 3/1/26

CHAPTER 142
OUT-OF-HOSPITAL DO-NOT-RESUSCITATE ORDERS

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—142.1(144A) Definitions. For the purpose of these rules, the following definitions apply:

"Adult" means an individual 18 years of age or older.

"Attending provider" means the same as defined in Iowa Code section 135J.1.

"Comfort care" means care within the scope of the health care provider's training and certification to alleviate pain and suffering but does not include resuscitative measures.

"Emergency medical care" means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by rule by the department.
5. Any other medical procedure approved by the department, by rule, as appropriate to be performed by emergency medical care providers who have been certified in that procedure.

"EMS provider" means an emergency medical care provider as defined in Iowa Code section 147A.1.

"Health care provider" means the same as defined in Iowa Code section 144A.2.

"Hospital" means any hospital licensed under the provisions of Iowa Code section 135B.1.

"Life-sustaining procedure" means the same as defined in Iowa Code section 144A.2.

"Medical direction" means direction, advice, or orders provided by a medical director or supervising physician.

"Medical director" means any physician licensed under Iowa Code chapter 148 who is responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Online medical direction" means immediate medical direction provided directly to service program emergency medical care providers, in accordance with written parameters and protocols, by the medical director or supervising physician, either on scene or by any telecommunications system.

"Out-of-hospital do-not-resuscitate identifier" or *"OOH DNR identifier"* means a durable yet easily removable unique identification approved by the department and worn by a patient who has an out-of-hospital do-not-resuscitate order.

"Out-of-hospital do-not-resuscitate order" or *"OOH DNR order"* means the same as defined in Iowa Code section 144A.2.

"Out-of-hospital do-not-resuscitate protocol" or *"OOH DNR protocol"* means the statewide protocol approved by the department and intended to avoid unwarranted resuscitation by emergency medical care providers when a valid out-of-hospital do-not-resuscitate order or identifier is encountered.

"Patient" means any individual who is sick, injured, or otherwise incapacitated.

"Physician" means any individual licensed under Iowa Code chapter 148.

"Physician associate" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Qualified patient" means any patient who is an adult as defined in Iowa Code section 144A.2.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Resuscitation" means the same as defined in Iowa Code section 144A.2.

"Service program" or *"service"* means any medical care ambulance service or nontransport service that has received authorization by the department.

"Supervising physician" means any physician licensed under Iowa Code chapter 148.

"Terminal condition" means the same as defined in Iowa Code section 144A.2.

[**ARC 9081C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0784D**, IAB 11/25/26, effective 1/1/27]

641—142.2(144A,147A) Responsibilities of the department.

142.2(1) *Attending provider order.* The department designates the OOH DNR order form contained in Appendix A as the uniform OOH DNR order form to be used statewide. If an attending provider issues

an OOH DNR order for a qualified patient, the attending provider must use the form contained in Appendix A.

142.2(2) *OOH DNR personal identifier.* The department designates the identifier supplied by MedicAlert® as the uniform personal identifier to be used for mobile qualified patients statewide. Instructions for obtaining a uniform personal identifier are contained in Appendix A.

142.2(3) *OOH DNR protocol.* The department designates the OOH DNR protocol contained in Appendix B as the uniform protocol to be used by EMS providers in implementing an OOH DNR order.

142.2(4) *Appendix A and Appendix B forms.* Forms referenced in subrules 142.3(1) through 142.3(3) are available through the department's website or by request.

[**ARC 9081C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0784D**, IAB 11/25/26, effective 1/1/27]

641—142.3(144A,147A) EMS providers.

142.3(1) *Uniform protocol.* EMS providers shall act in accordance with the department's OOH DNR protocol when implementing an OOH DNR order. EMS service programs shall incorporate the OOH DNR protocol as part of their service protocols and, using educational materials consistent with the curriculum developed and approved by the department, shall inform and educate EMS providers on the protocol's requirements as well as the requirements of Iowa Code chapter 144A and these rules.

142.3(2) *Responsibility of the EMS provider.* The EMS provider responding outside a hospital as a member of a service program shall:

a. Evaluate the patient's status and needs through an assessment consistent with the provider's training and certification.

b. Determine the existence of an OOH DNR order or that the patient is wearing an OOH DNR identifier.

c. Honor the OOH DNR order or OOH DNR identifier worn by the patient.

d. Discontinue resuscitation if the OOH DNR order or OOH DNR identifier worn by the patient is discovered after resuscitation has begun.

e. Follow the OOH DNR protocol.

f. Provide comfort care to the patient at all times.

g. Contact on-line medical direction for further instructions as necessary to provide appropriate patient care.

h. If uncertainty exists regarding the validity or applicability of the OOH DNR order or identifier, the EMS provider shall provide the necessary and appropriate resuscitation.

i. Document compliance or noncompliance with the OOH DNR order and the reasons for not complying with the order, including evidence that the order was revoked or uncertainty regarding the validity or applicability of the order.

[**ARC 9081C**, IAB 4/2/25, effective 6/1/25]

641—142.4(144A) Guidelines for non-EMS health care providers, patients, and organizations. In order to encourage understanding and implementation of OOH DNR orders and protocols throughout Iowa and honor a qualified patient's wishes and intent regarding the provision of life-sustaining procedures in an out-of-hospital setting consistent with the requirements of Iowa Code chapter 144A, the following guidelines should be considered.

142.4(1) *Attending providers who issue OOH DNR orders.* The attending provider should ensure that the following are accomplished:

a. Establish that the patient is qualified because the patient:

(1) Is an adult; and

(2) Has a terminal condition.

b. Explain to the patient or the individual legally authorized to act on the patient's behalf the implications of an OOH DNR order.

c. If the qualified patient or individual legally authorized to act on the patient's behalf decides that the patient should not be resuscitated, the attending provider may issue the OOH DNR order on the prescribed uniform order form. The order will direct health care providers to withhold or withdraw resuscitation.

d. Explain to the qualified patient or the individual legally authorized to act on the patient's behalf how the OOH DNR order is revoked.

e. Include a copy of the order in the qualified patient's medical record.

f. Provide a copy of the order to the qualified patient or the individual legally authorized to act on the patient's behalf.

142.4(2) *Qualified patients or legally authorized persons.* A qualified patient or a person legally authorized to act on a qualified patient's behalf should:

a. Make an informed decision concerning resuscitation in the face of a terminal condition.

b. Ensure that the qualified patient's family members are aware of this decision and inform them of the location of the OOH DNR order and the purpose of an OOH DNR identifier.

c. Understand the process for revocation as described in rule 641—142.5(144A).

142.4(3) *Non-EMS health care providers.* A non-EMS health care provider contemplating resuscitation for a patient should:

a. Evaluate the patient's status and needs through an assessment consistent with the provider's training, certification and licensure.

b. Determine that the presenting condition is within the scope of the patient's terminal condition and is not the result of a motor vehicle collision, fire, mass casualty or other cause of a sudden accident or injury.

c. Determine the existence of an OOH DNR order or that the patient is wearing an OOH DNR identifier.

d. Honor the OOH DNR order or OOH DNR identifier worn by the patient.

e. Discontinue resuscitation if the OOH DNR order or OOH DNR identifier worn by the patient is discovered after resuscitation has begun.

f. Provide comfort care to the patient at all times.

g. If uncertainty exists regarding the validity or applicability of the OOH DNR order or identifier, the health care provider shall provide the necessary and appropriate resuscitation.

h. Document compliance or noncompliance with the OOH DNR order and the reasons for not complying with the order, including evidence that the order was revoked or uncertainty regarding the validity or applicability of the order or OOH DNR identifier.

142.4(4) *Hospitals.* A hospital:

a. Is not precluded from honoring an OOH DNR order entered in accordance with this chapter and in compliance with established hospital policies and protocols.

b. Should, to avail itself of the immunities provided within Iowa Code chapter 142, establish such policies and protocols to address an OOH DNR order or identifier encountered on a person who presents to the emergency department or in any other area within the facility if the person presents as a patient or visitor.

c. Should integrate policies and procedures with the OOH DNR protocol for hospital-based ambulance service programs, if present.

142.4(5) *Other health care organizations.* A nursing home, home health care agency, hospice, or other health care organization should establish policies and protocols consistent with these rules to address admitted patients who have OOH DNR orders.

[**ARC 9081C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0784D**, IAB 11/25/26, effective 1/1/27]

641—142.5(144A) Revocation of the out-of-hospital do-not-resuscitate order. An OOH DNR order is deemed revoked at any time that a patient, or an individual authorized to act on the patient's behalf as designated on the OOH DNR order, is able to communicate in any manner the intent that the order be revoked, without regard to the mental or physical condition of the patient. A revocation is only effective as to the health care provider upon communication to that provider by the patient, an individual authorized to act on the patient's behalf as designated in the OOH DNR order, or by another person to whom the revocation is communicated by the patient.

[**ARC 9081C**, IAB 4/2/25, effective 6/1/25]

641—142.6(144A) Personal wishes of family members or other individuals who are not authorized to act on the patient's behalf. The personal wishes of family members or other individuals who are not authorized in the order to act on the patient's behalf cannot supersede a valid OOH DNR order.
[**ARC 9081C**, IAB 4/2/25, effective 6/1/25]

641—142.7(144A) Transfer of patients. Attending providers shall comply with the provisions of Iowa Code section 144A.8.
[**ARC 9081C**, IAB 4/2/25, effective 6/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0784D**, IAB 11/25/26, effective 1/1/27]

641—142.8(144A) Application to existing orders.

142.8(1) An OOH DNR order or similar order executed prior to September 10, 2003, is valid and shall be honored in accordance with the then-applicable provisions of the law.

142.8(2) Health care providers may honor an OOH DNR order or identifier from another state if it can be validated and applied in a manner consistent with the OOH DNR order or identifier prescribed in these rules. In cases where there is uncertainty, clarification should be sought through on-line medical direction or resuscitation efforts should be initiated.
[**ARC 9081C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code sections 144A.7A and 147A.4.

APPENDIX A

Iowa Department of Health and Human Services
OUT-OF-HOSPITAL DO-NOT-RESUSCITATE ORDER
(Please type or print)

Date of Order: _____/_____/_____
Patient Information:
Name: (Last)_____(First)_____(Middle)_____
Address: _____(City)_____(Zip)_____
Date of Birth: _____/_____/_____ Sex (Circle): M or F
Name of Hospice or Care Facility (if applicable): _____
_____

Attending Provider Order

As the attending provider for the above-named patient, I certify that this individual is over 18 years of age and has a terminal diagnosis. After consultation with this patient (or the patient's legal representative), I hereby direct any and all health care providers, including qualified emergency medical services (EMS) personnel, to withhold or withdraw the following life-sustaining procedures in accordance with Iowa law (Iowa Code chapter 142A):

- Cardiopulmonary Resuscitation/Cardiac Compression (Chest Compressions).
- Endotracheal Intubation/Artificial or Mechanical Ventilation (Advance Airway Management).
- Defibrillation and Related Procedures.
- Use of Resuscitation Drugs.

This directive does NOT apply to other medical interventions for comfort care.

_____ _____/_____/_____
Signature of Attending Provider **Date**

_____ (_____)_____-_____
Printed Name of Attending Provider **Provider's Telephone (Emergency)**

To the extent that it is possible, a person designated by the patient may revoke this order on the patient's behalf. If the patient wishes to authorize any other person(s) to revoke this order, the patient MUST list those persons' names below:

Name: _____
Name: _____
Name: _____
Name: _____

Patients, please note: Directions for obtaining a uniform identifier are listed on the back of this form. The uniform identifier is the key way the health care provider and/or EMS personnel can quickly recognize that you have an Out-of-Hospital Do-Not-Resuscitate order. If you are not wearing an identifier, the health care provider and/or EMS personnel may not realize that you do not want to be resuscitated.

Attending providers, please note: Information regarding the completion of an Out-of-Hospital Do-Not-Resuscitate order is on the back of this form.

APPENDIX A

Directions for obtaining a uniform identifier:

The uniform identifier may be obtained through MedicAlert®[1], which requires:

1. A completed MedicAlert® application, which is available in physician, physician associate, or ARNP offices or through MedicAlert® by phoning (800)432-5378 or by visiting the website www.medicalert.org, and submitting the fee.
2. A copy of this completed OOH DNR order, which must accompany the MedicAlert® application or be sent to MedicAlert® prior to the identifier's being mailed.

[1]*MedicAlert® is a nonprofit 501C membership organization.*

Suggested guidelines for attending providers:

1. Please review the Iowa Out-of-Hospital Do-Not-Resuscitate order and related protocol with the patient/patient's legal representative(s). The following points may be helpful:

- Patient/patient's legal representative(s) listed on this order must understand the significance of this order, that in the event the patient's heart or breathing stops or malfunctions, the anticipated result of this order is death.
- Patient/patient's legal representative(s) listed on this order may revoke this directive at any time. However, the desire to revoke must be communicated to the EMS or other health care professionals at the scene.
- It is important to emphasize that this order does not apply to medical interventions to make the patient more comfortable.
- The importance of wearing the uniform identifier for those qualified patients who would benefit from the mobility this offers should be stressed. It is also helpful to walk patients through the process they must follow to acquire the identifier.

2. Provide a copy of this order to the patient/patient's legal representative(s) listed on this order and place the original in the patient's medical records.

The OOH DNR Order form is available through the department's website.

[**ARC 7550B**, IAB 2/11/09, effective 3/18/09; **ARC 9617C**, IAB 10/15/25, effective 12/1/25; Editorial change: IAC Supplement 6/10/26; **ARC 0784D**, IAB 11/25/26, effective 1/1/27]

APPENDIX B

EMS OUT-OF-HOSPITAL DO-NOT-RESUSCITATE PROTOCOL

Purpose: This protocol is intended to avoid unwarranted resuscitation by emergency care providers in the out-of-hospital setting for a *qualified patient*.[1] There must be a valid Out-of-Hospital Do-Not-Resuscitate (OOH DNR) order signed by the qualified patient's attending provider or the presence of the OOH DNR identifier indicating the existence of a valid OOH DNR order.

No resuscitation: Means withholding any medical intervention that utilizes mechanical or artificial means to sustain, restore, or supplant a spontaneous vital function, including but not limited to:

1. Chest compressions,
2. Defibrillation,
3. Esophageal/tracheal/double-lumen airway; endotracheal intubation, or
4. Emergency drugs to alter cardiac or respiratory function or otherwise sustain life.

Patient criteria: The following patients are recognized as qualified patients to receive no resuscitation:

1. The presence of the uniform OOH DNR order or uniform OOH DNR identifier, or
2. The presence of the attending provider to provide direct verbal orders for care of the patient.

The presence of a signed attending provider order on a form other than the uniform OOH DNR order form approved by the department may be honored if approved by the service program EMS medical director. However, the immunities provided by law apply only in the presence of the uniform OOH DNR order or uniform OOH DNR identifier. When the uniform OOH DNR order or uniform OOH DNR identifier is not present, contact must be made with on-line medical control and on-line medical control must concur that no resuscitation is appropriate.

Revocation: An OOH DNR order is deemed revoked at any time that a patient, or an individual authorized to act on the patient's behalf as listed on the OOH DNR order, is able to communicate in any manner the intent that the order be revoked. The personal wishes of family members or other individuals who are not authorized in the order to act on the patient's behalf shall not supersede a valid OOH DNR order.

Comfort Care (♥): When a patient has met the criteria for no resuscitation under the foregoing information, the emergency care provider should continue to provide that care which is intended to make the patient comfortable (a.k.a. **♥Comfort Care**). Whether other types of care are indicated will depend upon individual circumstances for which medical control may be contacted by or through the responding ambulance service personnel.

♥***Comfort Care*** *may include but is not limited to:*

1. *Pain medication.*
2. *Fluid therapy.*
3. *Respiratory assistance (oxygen and suctioning).*

[1]*Qualified patient* means an adult patient determined by an attending provider to be in a terminal condition for which the attending provider has issued an Out-of-Hospital DNR order in accordance with the law. (Rule 641—142.1(144A), definitions)

[Editorial change: IAC Supplement 6/10/26; **ARC 0784D**, IAB 11/25/26, effective 1/1/27]

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CHAPTER 143
AUTOMATED EXTERNAL DEFIBRILLATOR MAINTENANCE

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—143.1(613) Definition. For the purposes of these rules, the following definition applies:

"Automated external defibrillator" or *"AED"* means an external semiautomatic device that determines whether defibrillation is required.

[**ARC 9082C**, IAB 4/2/25, effective 6/1/25]

641—143.2(613) AED maintenance. The person or entity maintaining the AED shall:

143.2(1) Ensure that the AED is maintained and inspected in accordance with the manufacturer's guidelines.

143.2(2) Ensure that the AED is programmed to conform to nationally accepted guidelines for treatment of cardiac arrest patients.

[**ARC 9082C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code section 613.17.

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[Filed ARC 3396C (Notice ARC 3204C, IAB 7/19/17), IAB 10/11/17, effective 11/15/17]
[Filed ARC 9082C (Notice ARC 8457C, IAB 12/25/24), IAB 4/2/25, effective 6/1/25]

CHAPTER 144
EMERGENCY MEDICAL SERVICES—AIR MEDICAL SERVICE PROGRAM AUTHORIZATION

Rescinded **ARC 9083C**, IAB 4/2/25, effective 6/1/25

CHAPTER 145
IOWA PHYSICIAN ORDERS FOR SCOPE OF TREATMENT

Rescinded **ARC 9960C**, IAB 1/7/26, effective 3/1/26

CHAPTER 146
STROKE CARE REPORTING

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/1/30

641—146.1(135) Definitions.

"Comprehensive stroke center" means a hospital certified as a comprehensive stroke center by a nationally recognized certifying body with certification criteria consistent with the most current nationally recognized, evidence-based stroke guidelines related to reducing the occurrence of and disabilities and death associated with stroke.

"Primary stroke center" means a hospital certified as a primary stroke center by a nationally recognized certifying body with certification criteria consistent with the most current nationally recognized, evidence-based stroke guidelines related to reducing the occurrence of and disabilities and death associated with stroke.

"Stroke" means a clinical diagnosis of acute stroke or principal International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM) discharge code of "stroke," or "transient ischemic attack," or "cerebral infarction," or "cerebral hemorrhage."

"Stroke care" means care provided to individuals with confirmed cases of stroke.

[**ARC 9084C**, IAB 4/2/25, effective 6/1/25]

641—146.2(135) Stroke care reporting.

146.2(1) *Iowa statewide stroke database.* The department designates the Get with the Guidelines stroke module of the American Heart Association/American Stroke Association as the Iowa stroke database established in Iowa Code section 135.191.

146.2(2) *Who is required to report.* All nationally certified comprehensive stroke centers and all nationally certified primary stroke centers operating in the state of Iowa are required to report stroke data. Nationally certified acute stroke-ready hospitals and emergency medical services operating in the state of Iowa are encouraged to report stroke care data.

146.2(3) *What is to be reported.* Reportable data are those data identified by a clinical diagnosis of acute stroke or by the following ICD-10 coding:

ICD-10-CM Code	Short Description
I60.00 - I60.9	Nontraumatic subarachnoid hemorrhage
I61.0 - I61.9	Nontraumatic intracerebral hemorrhage
I63.00 - I63.9	Cerebral infarction (occlusion and stenosis of cerebral and precerebral arteries, resulting in cerebral infarction)
G45.0 - G45.2	TIA and related syndromes
G45.8 - G45.9	TIA and related syndromes
O99.411 - O99.43	Diseases of the circulatory system complicating pregnancy, childbirth and puerperium
G97.31 - G97.32	Intraoperative hemorrhage and hematoma of a nervous system organ or structure complicating a procedure
G97.51 - G97.52	Postprocedural hemorrhage and hematoma of a nervous system organ or structure following a procedure
I97.810 - I97.821	Intraoperative and postoperative cerebrovascular infarction

[**ARC 9084C**, IAB 4/2/25, effective 6/1/25]

641—146.3(135) Method and frequency of reporting.

146.3(1) Stroke centers shall report the required stroke care information for any reportable stroke case no later than 120 days after the patient was discharged, transferred to another hospital, or pronounced dead.

146.3(2) Reports shall meet the data quality, format, and timeliness standards prescribed by the Iowa statewide stroke database.

[**ARC 9084C**, IAB 4/2/25, effective 6/1/25]

641—146.4(135) Confidentiality. The Iowa statewide stroke database will comply with federal and state law and other health information and data collection, storage, and sharing requirements of the department.
[**ARC 9084C**, IAB 4/2/25, effective 6/1/25]

641—146.5(135) Penalties and enforcement. If a stroke center reporting under this chapter does not comply with the reporting requirements, the department may request a review of the certification of the comprehensive or primary stroke center by the certifying entity.
[**ARC 9084C**, IAB 4/2/25, effective 6/1/25]

These rules are intended to implement Iowa Code section 135.191.

[Filed ARC 3748C (Notice ARC 3575C, IAB 1/17/18), IAB 4/11/18, effective 5/16/18]
[Filed ARC 9084C (Notice ARC 8465C, IAB 12/25/24), IAB 4/2/25, effective 6/1/25]

CHAPTERS 147 to 149
Reserved

CHAPTER 150
IOWA REGIONALIZED SYSTEM OF PERINATAL HEALTH CARE

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—150.1(135) Participation and designation. Hospitals within the state must determine whether to participate in Iowa's regionalized system of perinatal health care and will select the hospital's level of participation in the regionalized system. A hospital having determined to participate in the regionalized system must comply with the rules appropriate to the levels of participation for maternal care and neonatal care selected by the hospital. Maternal levels of designation and neonatal levels of designation are evaluated separately, and a hospital may have a level of designation for maternal care that is different from the level of designation for neonatal care; however, a pregnant woman should be cared for at the hospital that best meets both her and her newborn infant's needs.
[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.2(135) Definitions.

"Categorization" means a preliminary determination by the department that a hospital is capable of providing maternal care and neonatal care at Level I, Level II, Level III, or Level IV.

"Certificate of verification" means a document awarded by the department that identifies a hospital's level of maternal care and neonatal care at Level I, Level II, Level III, or Level IV and the term of verification at that level.

"Hospital" means a facility licensed under Iowa Code chapter 135B.

"Late preterm" means that a newborn infant is born between 34 0/7 and 36 6/7 weeks' gestation.

"Levels-of-care assessment tool" or *"tool"* means a tool to assess the maternal and neonatal risk-appropriate care, using the minimum information necessary to identify a hospital's maternal level of care based on criteria by the American Congress of Obstetricians and Gynecologists/Society for Maternal-Fetal Medicine and a hospital's neonatal level of care based on criteria by the American Academy of Pediatrics. The tool will be chosen by the department in consultation with the perinatal guidelines advisory committee.

"Neonate" means a newborn infant, up to 28 days of life.

"On-site verification survey" means an on-site survey conducted by the department's statewide perinatal care team based at the University of Iowa health care medical center or by a survey team of members (medical experts) contracted to assess a hospital's ability to meet the level of designation selected by the hospital.

"Perinatal" means the five months before and one month after birth.

"Perinatal center" means a medical facility capable of providing complex obstetric, fetal and neonatal care.

"Prenatal" means during pregnancy.

"Readily available" means on site or at a closely related institution by prearranged consultative agreement.

"Regionalized system of perinatal health care" means the department's program for designating regional perinatal health care services at a verified level of care, based on a hospital's functional capabilities. Levels of care designations are stratified in an increasing order of intensity and complexity for both maternal health care and neonatal health care.

"Regionalized system of perinatal health care coordinator" means the department's program manager for the regionalized system of perinatal health care.

"Respiratory distress" means tachypnea (respiratory rate of 60 or more per minute), grunting, tugging, retracting, nasal flaring, or cyanosis. Any or all of these may constitute respiratory distress in a neonate.

"Reverification" means the process of periodic review, conducted at least every six years, to certify that a hospital has maintained its designated level of care in accordance with criteria established under these rules for hospitals that are participating in the regionalized system of perinatal health care.

"Statewide perinatal care program" means a program consisting of the regionalized system of perinatal health care coordinator, the statewide perinatal care team contracted by the department, and the regionalized system of perinatal health care as defined in these rules.

"Statewide perinatal care team" means the educational team based at the University of Iowa health care medical center and contracted by the department to support the regionalized system of perinatal health care and to provide services to decrease perinatal morbidity and mortality.

"Verification" means a process by which the department certifies a hospital's capacity to provide perinatal care in accordance with criteria established under these rules for hospitals that are participating in the regionalized system of perinatal health care.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25; **ARC 0785D**, IAB 11/25/26, effective 1/1/27]

641—150.3(135) Duties of statewide perinatal care team. The team will:

1. Promote evidence-based and evidence-informed care of pregnant women and newborns.
2. Provide education and consultation to regional and primary providers of perinatal care.
3. Provide chart review to assess quality of care provided and additional education required.
4. Promote change in practice when needed through sharing best practice ideas, policies and procedures.
5. Promote maternal-fetal transfer if delivery of an at-risk infant or mother is anticipated and a higher level of care is anticipated.
6. Provide on-site verification to determine a hospital's ability to meet its level-of-care designation.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.4(135) Duties of the department. The department will:

1. Certify a hospital's capacity to provide perinatal health care in accordance with criteria established under these rules.
2. Provide technical assistance to the hospitals that choose to participate.
3. Review the submitted levels-of-care assessment tool from all participating hospitals.
4. Conduct or coordinate the on-site verification of determined levels of care for maternal and neonatal care hospitals designated as Level I, Level II, Level III and Level IV.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.5(135) Maternal and neonatal levels of care—categorization and verification. Categorization and verification of hospitals participating in Iowa's regionalized system of perinatal health care will be made by the department based on national recommendations from the American Academy of Pediatrics and the American Congress of Obstetricians and Gynecologists.

150.5(1) *Application for initial verification.*

a. An application for initial verification may be submitted when:

(1) A new hospital with a perinatal service is opened;

(2) A hospital is reopening after a previously inactive obstetrical unit; or

(3) A hospital requests a change to a higher-level designation in maternal care or neonatal care.

b. A hospital requesting an initial verification may obtain application materials from the department.

c. Upon receipt of an application from a hospital that is requesting to change to a higher level of maternal or neonatal care, the department will request and review copies of the results of the last site visit to the hospital by the statewide perinatal team or request a site visit. The results of the site visit along with the application will be shared with the statewide perinatal team and any clinical experts appointed by the department to determine if all requirements are met. The recommendations will be sent to the department, which will notify the hospital if its application is approved or denied. If the application is denied, the applicant will be informed of the applicant's right to appeal the department's decision.

150.5(2) *Application for a hospital that has previously participated in the regionalized system of perinatal health care.*

a. If a hospital chooses to continue its participation, the hospital must select the levels for maternal care and neonatal care appropriate for the hospital's capacity to provide perinatal health care in accordance with the criteria outlined in these rules.

b. To maintain continuous participation in the regionalized system of perinatal health care, a hospital must complete the levels-of-care assessment tool and an attestation statement. These can be obtained from the department.

c. The department will set dates when each hospital's certification of verification will expire based on the statewide perinatal health care team's site visit schedule and the level of care selected.

150.5(3) *Reverification of level designation.* The levels-of-care assessment tool will be used for all reverifications. The process of reverification of a hospital participating in the regionalized system of perinatal health care will take place once every six years as follows:

a. Reverification of a Level I, Level II or Level III maternal care or neonatal care hospital will be completed through use of the levels-of-care assessment tool and an on-site reverification visit. A hospital must complete and return the levels-of-care assessment tool to the department at least 120 days before the hospital's certification is due to expire. The department will ensure that arrangements are made for the on-site reverification visit. Level II and Level III hospitals may utilize one of two on-site reverification visit options:

(1) A review conducted by the statewide perinatal care team, or

(2) A review by an independent out-of-state team identified by the hospital, approved by the department and paid for by the hospital.

b. Reverification of a Level IV maternal care and neonatal care hospital will be completed through the same process as that for a Level I, Level II or Level III maternal care or neonatal care hospital except that the on-site reverification team will consist of an out-of-state team identified by the hospital and approved by the department. The team will include, at a minimum, a maternal-fetal specialist, a neonatologist, an obstetrical nurse and a neonatal nurse. The Level IV hospital will pay the expense of the review team. All department staff and staff contracted by the department involved in the on-site reverification process will sign a confidentiality statement that will be kept on file at the department.

c. Reverification shall not be construed to imply any guarantee on the part of the department as to the level of perinatal health care services available at a hospital.

d. Hospital reverification of the level of care is valid for a period of six years from the effective date unless otherwise specified on the certificate of verification or unless sooner suspended or revoked.

e. As part of the reverification and renewal process, the department or a designated survey team may conduct periodic on-site reviews of the services of the maternal care and neonatal care hospitals, including chart reviews.

150.5(4) *Level designation maintenance, waiver and confidential records.*

a. A hospital that is unable to maintain its designated level of care will notify the department, in writing, within 60 days of the change in capacity to meet the designated level of care.

b. The director may grant a waiver from the requirements of rules adopted under this chapter for any hospital participating in the regionalized system of perinatal health care.

c. Proceedings, records, and reports developed pursuant to this chapter are confidential pursuant to Iowa Code section 135.11(22) and constitute peer review records under Iowa Code section 147.135, and are not subject to discovery, subpoena, or other means of legal compulsion for their release to a person other than the affected hospital, and are not admissible in evidence in a judicial or administrative proceeding other than a proceeding involving verification of the participating hospital.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.6(135) Levels of maternal care. The levels of maternal care include basic obstetrical care Level I, specialty care Level II, subspecialty care Level III and regional perinatal health care Level IV. The levels reflect the overall evidence for risk-appropriate care in a hospital through the availability of appropriate personnel, physical space, equipment, technology, and organization. Each level reflects the minimal capabilities, provider type and functional criteria required.

150.6(1) *Level I maternal care hospital.*

a. Provider of basic obstetrical care. A Level I maternal care hospital provides care to women who are low risk and are expected to have an uncomplicated birth.

b. Capabilities. A Level I maternal care hospital has the following capabilities:

(1) To perform routine intrapartum and postpartum care that is anticipated to be uncomplicated. Care of uncomplicated pregnancies includes the ability to detect, stabilize and initiate management of unanticipated maternal, fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a facility that provides specialty maternal care.

(2) To begin an emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.

c. Types of health care providers. A Level I maternal care hospital will have:

(1) Maternity care providers, including certified nurse-midwives, family practice physicians, or obstetrician-gynecologists, available to attend all births.

(2) Every birth attended by at least two professionals, including the primary maternal care provider and a person competent to provide neonatal resuscitation and postnatal care to stabilize the infant.

(3) Adequate numbers of registered nurses available who have completed orientation and demonstrated competence in the care of obstetric patients, including women and fetuses, consistent with Level I care criteria and who are able to stabilize and transfer high-risk women and newborns.

(4) Nursing leadership with expertise in perinatal nursing care.

(5) A provider with privileges to perform an emergency cesarean delivery, available to attend all deliveries. The provider may be a general surgeon, an obstetrician-gynecologist, or a family practice physician with certification.

(6) A provider of anesthesia services available to provide labor analgesia and surgical anesthesia.

d. Functional criteria of support services. Support services include but are not limited to access to obstetric ultrasonography, laboratory testing, and blood bank supplies at all times. A Level I maternal care hospital will:

(1) Have protocols and capabilities in place for:

1. Massive transfusion,
2. Emergency release of blood products (before full compatibility testing is complete),
3. Management of multiple component therapy.

(2) Ensure optimal care of all pregnant women by having formal transfer plans established in partnership with a higher-level receiving hospital. These plans will include:

1. Risk identification,
2. Determination of conditions necessitating consultation,
3. Referral and transfer, and
4. A reliable, accurate, and comprehensive communication system between the participating hospital and the transport team.

(3) Have education and quality improvement programs to maximize patient safety, provide such programs through collaboration with facilities with higher levels of care that receive transfers, or both.

(4) Have data collection, storage and retrieval to support quality improvement.

150.6(2) *Level II maternal care hospital.*

a. Provider of specialty care. In addition to meeting the criteria of a Level I maternal care hospital, a Level II maternal care hospital provides care of appropriate high-risk pregnant women, both those directly admitted to the hospital and those transferred from another hospital.

b. Capabilities. In addition to having the capabilities of a Level I maternal care hospital, a Level II maternal care hospital has the following capabilities:

(1) The infrastructure for continuous availability of adequate numbers of registered nurses who have demonstrated competence in the care of obstetric patients (women and fetuses).

(2) Orientation and demonstrated competence consistent with Level II care criteria and the capability to stabilize and transfer high-risk women and newborns who exceed Level II care criteria.

c. Types of health care providers. In addition to meeting the health care provider requirements of a Level I maternal care hospital, a Level II maternal care hospital will have:

(1) Health care providers, including certified nurse-midwives or family physicians.

(2) Nursing leaders and staff with formal training and experience in the provision of perinatal nursing care who can coordinate with respective neonatal care services.

(3) An attending obstetrician-gynecologist available at all times.

(4) A board-certified or board-eligible obstetrician-gynecologist with special interest and experience in obstetric care as the director of obstetric services.

(5) Access to a maternal-fetal medicine subspecialist for consultation, available on site, by telephone, or by telemedicine as needed.

(6) A provider of anesthesia services available at all times to provide labor analgesia and surgical anesthesia.

(7) A board-certified or board-eligible anesthesiologist with special training or experience in obstetric anesthesia, available for consultation.

(8) Medical and surgical consultants available to stabilize obstetric patients who have been directly admitted to the facility or transferred from other hospitals.

d. Functional criteria of support services. In addition to meeting the support services requirements of a Level I maternal care hospital, a Level II maternal care hospital will have:

(1) Computed tomography scan and, ideally, magnetic resonance imaging with interpretation available.

(2) Basic ultrasonographic imaging services for maternal and fetal assessment at all times, either in house or on call.

(3) Special equipment needed to accommodate the care and services needed for obese women. In addition, based on the patient's BMI and other risk factors, a consultation with an obstetrician-gynecologist or a maternal fetal medicine specialist should be considered.

(4) The ability to provide high-risk obstetrical care, but efforts should be made to transfer women whose newborns are likely to need a higher level of care than a Level II maternal care hospital can provide, or when the pregnancy has risk factors that require the consultation or care of a maternal-fetal medicine specialist.

150.6(3) *Level III maternal care hospital.*

a. Provider of subspecialty care. A Level III maternal care hospital provides care to women that includes all Level I and Level II services and has subspecialists available on site, by telephone, or by telemedicine to assist in providing care for more complex maternal and fetal conditions.

b. Capabilities. A Level III maternal care hospital functions as the regional perinatal health care center for some areas of Iowa if there are no Level IV maternal care hospitals available. In these areas, a Level III maternal care hospital will be responsible for the leadership; facilitation of transport and referral; educational outreach; and data collection, storage and retrieval to support quality improvement. Designation of Level III maternal care hospital should be based on the demonstrated experience and capability of the facility to provide comprehensive management of severe maternal and fetal complications.

c. Types of health care providers. In addition to meeting the health care provider requirements of a Level II maternal care hospital, a Level III maternal care hospital will have:

(1) An obstetrician-gynecologist with inpatient privileges, available on site at all times.

(2) A maternal-fetal medicine subspecialist with inpatient privileges, available at all times, either on site, by telephone, or by telemedicine.

(3) A director of the maternal-fetal medicine service who is a board-certified or board-eligible maternal-fetal medicine subspecialist.

(4) A board-certified or board-eligible obstetrician-gynecologist with special interest and experience in obstetric care directing obstetric services.

(5) A provider of anesthesia services available at all times on site.

(6) A board-certified or board-eligible anesthesiologist with special training or experience in obstetric anesthesia who is in charge of obstetric anesthesia services.

(7) A full complement of subspecialists, available for inpatient consultations, including subspecialists in:

1. Critical care,
2. General surgery,
3. Infectious disease,
4. Hematology,
5. Cardiology,
6. Nephrology,
7. Neurology, and
8. Neonatology.

(8) Nursing leaders and adequate numbers of registered nurses who have completed orientation and demonstrated competence in the care of obstetric patients (women and fetuses) consistent with Level III care criteria, including the transfer of high-risk women who exceed Level III care criteria, and who have special training and experience in the management of women with complex maternal illnesses and obstetric complications. Nursing personnel will be continuously available.

d. Functional criteria of support services. In addition to meeting the support services requirements of a Level II maternal care hospital, a Level III maternal care hospital will have:

(1) An on-site intensive care unit to accept pregnant women.

(2) Critical care providers on site to actively collaborate with maternal-fetal specialists at all times.

(3) Equipment and personnel with expertise available on site to ventilate and monitor women in the labor and delivery unit until they can be safely transferred to the intensive care unit.

(4) The ability to provide the following imaging services, with interpretation available at all times:

1. Basic interventional radiology,
2. Maternal echocardiography,
3. Computed tomography,
4. Magnetic resonance imaging, and
5. Nuclear medicine imaging.

(5) The ability to perform detailed obstetric ultrasonography and fetal assessment, including Doppler studies.

150.6(4) *Level IV maternal care hospital.*

a. Provider of services as a regional perinatal health care center. In addition to meeting the requirements for a Level III maternal care hospital, a Level IV maternal care hospital provides care to women with additional requirements and has considerable experience in the care of the most complex and critically ill pregnant women throughout antepartum, intrapartum, and postpartum care. The particular specialty of fetal surgery, advanced neurosurgery, transplant, and advanced cardiovascular capabilities may not all be available at an individual Level IV maternal care hospital. In some cases, specific advanced care will require care coordination to the Level IV maternal care hospital by availability of specific expertise, including but not limited to fetal surgery, advanced neurosurgery, transplant, and advanced cardiovascular capabilities. Each hospital will have a clear understanding of the categories of perinatal patients who can be managed appropriately in the local hospital and those who must be transferred.

b. Capabilities. Although Level III and Level IV maternal care hospitals may seem to overlap, a Level IV maternal care hospital is distinct from a Level III maternal care hospital in the approach to the care of pregnant women and women in the postpartum period with complex and critical illnesses. In addition to having an intensive care unit on site for obstetric patients, a Level IV maternal care hospital must have evidence of a maternal-fetal medicine care team that has the expertise to assume responsibility for pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions. The maternal-fetal medicine team collaborates actively in the co-management of all obstetric patients who require critical care and intensive care unit services, including co-management of intensive care unit-admitted obstetric patients.

c. Types of health care providers. In addition to meeting the health care provider requirements of a Level III maternal care hospital, a Level IV maternal care hospital will have:

(1) A maternal-fetal medicine team member with full privileges, available at all times for on-site consultation and management.

(2) A board-certified maternal-fetal medicine subspecialist with expertise in critical care obstetrics to lead the team.

(3) A maternal-fetal medicine team with expertise in critical care at the physician level, nursing level, and ancillary services level.

(4) Institutional support for the routine involvement of a maternal-fetal medicine care team with the critical care units and specialists. A key principle of caring for critically ill pregnant and peripartum women is the hospital's recognition of the need for seamless communication between maternal-fetal medicine subspecialists and other subspecialists in the planning and facilitation of care for women with the most high-risk complications of pregnancy.

(5) A commitment to having physician and nursing leaders with expertise in maternal intensive and critical care, as well as adequate numbers of available registered nurses in a Level IV maternal care hospital who have experience in the care of women with complex medical illnesses and obstetric complications; this experience includes completed orientation and demonstrated competence in the care of obstetric patients (women and fetuses) consistent with Level IV maternal care criteria.

(6) A director of obstetric services who is a board-certified maternal-fetal medicine subspecialist or a board-certified obstetrician-gynecologist with expertise in critical care obstetrics.

(7) A provider of anesthesia services available on site at all times.

(8) A board-certified anesthesiologist with special training or experience in obstetric anesthesia who is in charge of obstetric anesthesia services.

(9) Adult medical and surgical specialty and subspecialty consultants, a minimum of those listed for a Level III maternal care hospital, available on site at all times to collaborate with the maternal-fetal medicine care team.

d. Functional criteria of support services. In addition to meeting the support services requirements of a Level III maternal care hospital, a Level IV maternal care hospital will have:

(1) The capability for on-site medical and surgical care of complex maternal conditions (e.g., congenital maternal cardiac lesions, vascular injuries, neurosurgical emergencies, and transplants) with the availability of critical (or intensive) care unit beds.

(2) Perinatal system leadership, including facilitation of maternal referral and transport, outreach education for facilities and health care providers in the region and analysis and evaluation of regional data, including perinatal complications, outcomes and quality improvement.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.7(135) Maternal-fetal transport—all levels. Maternal-fetal transport is an essential component of perinatal care. A hospital participating in the regionalized system of perinatal health care must be familiar with its own resources and capabilities in dealing with obstetrical and neonatal complications. In most instances, maternal-fetal transport is preferable to neonatal transport. Each hospital, when transporting or accepting a transport, needs a system in place to facilitate a smooth transition of care in the most expeditious manner possible. The majority of maternal-fetal transports can be carried out by ground transportation. It is important for ambulance services to be equipped for maternal-fetal transport and have appropriately trained staff.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.8(135) Levels of neonatal care. The levels of neonatal care include basic neonatal care Level I, specialty care Level II, and subspecialty intensive care Level III and Level IV. The levels reflect the overall evidence for risk-appropriate care through the availability of appropriate functional criteria, physical facilities, medical and nursing personnel, outreach education, allied health personnel and services, infection control, newborn or neonatal safety, neonatal transport and quality improvement.

150.8(1) *Level I neonatal care hospital.*

a. Provider of basic neonatal care. A Level I neonatal care hospital provides a basic level of care to neonates without complications. A Level I neonatal care hospital has the following capabilities:

(1) To provide neonatal resuscitation at every delivery.

(2) To evaluate and provide postnatal care to stable term newborn infants.

(3) To stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable.

(4) To stabilize newborn infants who are ill and those born at less than 35 weeks' gestation until transfer to a higher level of care.

(5) To provide leadership in early risk identification before and after birth.

(6) To seek consultation or referral for high-risk neonates.

(7) To provide public and professional education.

b. Functions. A Level I neonatal care hospital has a family-centered philosophy. Parents have reasonable access to their newborns 24 hours a day within all functional units and are encouraged to participate in the care of their newborns. Generally, a newborn can be with its parents in the mother's room.

c. Physical facilities. A Level I neonatal care hospital will maintain a nursery for normal-term or late preterm neonates.

d. Medical personnel. At a Level I neonatal care hospital, neonatal care is under the supervision of one of the following:

(1) A board-eligible or board-certified neonatologist,

(2) A pediatrician,

(3) A family medicine physician,

(4) A board-eligible or board-certified advanced registered nurse practitioner, or

(5) A physician associate.

e. Nursing personnel. At a Level I neonatal care hospital, a registered nurse assigned to the neonatal service has nursing orientation to and demonstrates competency in the care of a neonate.

f. Outreach education. A Level I neonatal care hospital will assume an active role in the development and coordination of wellness and preventive programs concerning neonatal and child health at the community level, including parenting, breastfeeding, and cessation of smoking.

g. Allied health personnel and services. A Level I neonatal care hospital will have available, at a minimum, the following allied health personnel and services:

(1) Dietitian with knowledge of maternal and neonatal nutrition management,

(2) Social worker,

(3) Bioengineer-safety and environmental control,

(4) Pharmacy,

(5) Radiology,

(6) Laboratory,

(7) Pathology, and

(8) Chaplain, spiritual support.

h. Infection control.

(1) Each Level I neonatal care hospital will establish written policies and procedures for assessing the health of personnel assigned to the perinatal care services and of those who have significant contact with the newborn. The policies and procedures will include restricting contact with patients when necessary and screening per department recommendations for health care providers. Routine culturing of specimens obtained from personnel is not useful, although selective culturing may be of value when a pattern of infection is suspected.

(2) No special or separate isolation facility is required for neonates born at home or in transit to the hospital. Detailed descriptions of the isolation categories and requirements will be available in each hospital's infection control manual.

i. Newborn safety. At a Level I neonatal care hospital, the protection of newborns is the responsibility of all personnel in the neonatal care hospital. Newborns will always be within the sight and supervision of hospital staff, the mother, or other family members or friends designated by the mother. Each neonatal care hospital has a policy established that addresses strategies to promote newborn safety.

150.8(2) *Level II neonatal care hospital.*

a. Provider of specialty care. In addition to meeting the requirements for care and services as a Level I neonatal care hospital, a Level II neonatal care hospital will:

(1) Provide management of certain high-risk neonates with selected complications.

(2) Have a board-certified or board-eligible neonatologist(s) or a board-certified or board-eligible pediatrician(s) on staff, one of whom directs the special care nursery.

b. Functions. In addition to performing the functions of a Level I neonatal care hospital, a Level II neonatal care hospital will have the capability to:

(1) At a minimum, manage neonates of greater than or equal to 32 weeks' gestation and weighing greater than or equal to 1,500 grams who have physiological immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis and, for neonates of 32 weeks' gestation and weighing less than 1,500 grams, recommend consultation with a higher-level facility by prearranged consultative agreement.

(2) Provide mechanical ventilation for a brief duration (less than 24 hours).

(3) Provide continuous positive airway pressure as needed (less than 24 hours).

(4) Stabilize infants born before 32 weeks and weighing less than 1,500 grams until transfer to a Level III or Level IV neonatal care hospital.

(5) Provide care for infants convalescing after intensive care.

c. Physical facilities. In addition to having the physical facilities of a Level I neonatal care hospital, a Level II neonatal care hospital will have:

(1) A special care nursery (a special area designated for the care of sick neonates),

(2) A mechanical ventilator,

(3) A portable X-ray machine,

(4) A laboratory with a blood gas analyzer,

(5) Physiologic monitoring equipment, and

(6) A pharmacy.

d. Medical personnel. In addition to having the medical personnel of a Level I neonatal care hospital, a Level II neonatal care hospital will:

(1) Be under the co-direction/supervision of a board-eligible or board-certified neonatologist or pediatrician.

(2) Have a neonatologist or pediatrician on staff. Other provider types that may be utilized include a pediatric hospitalist, a neonatal nurse practitioner or pediatric nurse practitioner or a physician associate with appropriate training.

(3) Have allied medical specialists in various disciplines on staff, including specialists in internal medicine, radiology, and pathology.

e. Nursing personnel. In addition to having the nursing personnel of a Level I neonatal care hospital, a Level II neonatal care hospital has nursing orientation to and demonstrates competency in the care of sick neonates.

f. Outreach education. A Level II neonatal care hospital has the same responsibility for outreach education as that of a Level I neonatal care hospital.

g. Allied health personnel and services. In addition to having the allied health personnel and services of a Level I neonatal care hospital, a Level II neonatal care hospital has:

(1) Respiratory therapists,

(2) Certified laboratory technicians/blood gas technicians, and

(3) X-ray technologists and ultrasound technicians with neonatal/perinatal experience.

h. Infection control. A Level II neonatal care hospital has the same infection control guidelines as those for a Level I neonatal care hospital.

i. Neonatal safety. A Level II neonatal care hospital has the same requirements for newborn safety as those for a Level I neonatal care hospital.

j. Neonatal transport. In addition to having the Level I neonatal care hospital capabilities for neonatal transport, a Level II neonatal care hospital is expected to accept patient referrals when appropriate. A critical function of providers at a Level II neonatal care hospital is to communicate with the providers at a Level I neonatal care hospital in deciding whether a particular patient should be transported to the Level II neonatal care hospital. Careful assessment of the hospital's capabilities for perinatal management will be critical in these decisions. This information will need to be disseminated among the hospital staff. Providers of obstetric care need to know the critical gestational age limitations for their particular nursery. Below this gestational age, maternal-fetal transport should be utilized if delivery is anticipated and the circumstances permit.

k. Perinatal care committee.

(1) A Level II neonatal care hospital must maintain a perinatal care committee. Members of this committee will represent, at a minimum, the fields of:

1. Obstetrics,
2. Pediatrics,
3. Family practice,
4. Nursing,
5. Administration,

6. Laboratory,
7. Respiratory therapy,
8. Anesthesia, and
9. Social services.

(2) Responsibilities of the perinatal care committee include the following:

1. To develop policies for the unit, including provisions to ensure adequate patient care by qualified providers.
2. To conduct a meeting, at least semiannually, to resolve problems related to the unit.
3. To review educational activities conducted by the unit.
4. To serve as a general liaison between the various groups represented on the committee.

150.8(3) *Level III neonatal care hospital.*

a. Provider of subspecialty intensive care. In addition to providing the care and services of a Level II neonatal care hospital, a Level III neonatal care hospital will manage high-risk neonates, including infants born at less than 32 weeks or weighing less than 1,500 grams. High-risk neonates requiring surgical intervention or pediatric subspecialty should go to a Level IV neonatal care hospital.

b. Functions. In addition to performing the functions of a Level II neonatal care hospital, a Level III neonatal care hospital will have the capability to:

(1) Provide sustained life support.

(2) Provide comprehensive care for infants born at less than 32 weeks and weighing less than 1,500 grams and infants born at all gestations and birth weights who have critical illness.

(3) Provide an organized program for monitoring treatment and follow-up of retinopathy of prematurity.

(4) Maintain a prearranged consultative agreement with a higher-level hospital within the Level III neonatal care hospital's referral area.

(5) Transfer a surgical patient within approximately two hours from the time the referral call is made until arrival at the referral hospital.

(6) Provide follow-up care for high-risk newborns.

c. Physical facilities. In addition to having the physical facilities of a Level II neonatal care hospital, a Level III neonatal care hospital:

(1) Has a neonatal intensive care unit with continuously available personnel, including a neonatologist, neonatal nurses and respiratory therapists to provide life support for as long as necessary.

(2) Provides a full range of respiratory support that includes invasive mechanical ventilation and may include high-frequency ventilation or inhaled nitric oxide or both.

(3) Performs advanced imaging, with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography.

(4) Maintains a neonatal transport team for the regional area served.

d. Medical personnel. In addition to having the medical personnel of a Level II neonatal care hospital, a Level III neonatal care hospital will:

(1) Have a medical director of the neonatal intensive care unit who is a full-time, board-eligible or board-certified neonatologist.

(2) Provide prompt and readily available access to the following, either on site or by prearranged consultative agreement. Using telemedicine technology or telephone consultation, a prearranged consultation can be performed from a distant location by:

1. Pediatric medical subspecialists,
2. A pediatric surgical specialist,
3. A pediatric anesthesiologist, and
4. A pediatric ophthalmologist.

(3) Have a neonatologist on the premises when an unstable critically ill infant is in the Level III neonatal care hospital.

e. Nursing personnel. A Level III neonatal care hospital has the same requirements for nursing personnel as those of a Level II neonatal care hospital.

f. Outreach education. Outreach education is provided to each hospital in the referral area at least once per year. This outreach education can be achieved by one or more of the following:

(1) Sponsoring an annual conference.

(2) Visiting a Level I neonatal care hospital and a Level II neonatal care hospital.

(3) Providing educational programs and materials for the staff members of the Level I and Level II neonatal care hospitals.

g. Allied health personnel and services. In addition to having the allied health personnel and services of a Level II neonatal care hospital, a Level III neonatal care hospital has:

(1) X-ray technologists and ultrasound technicians with neonatal/perinatal experience, available on a 24-hour basis.

(2) Social work services with social workers assigned specifically to the neonatal units.

h. Infection control. A Level III neonatal care hospital has the same infection control guidelines as those of a Level I neonatal care hospital.

i. Neonatal safety. A Level III neonatal care hospital has the same requirements for newborn safety as those for a Level I neonatal care hospital.

j. Neonatal transport. In addition to having the Level II neonatal care hospital transport capabilities, a Level III neonatal care hospital is capable of providing neonatal transport with crews who have demonstrated competence in neonatal resuscitation and stabilization. Important decisions to be made jointly will include:

(1) The appropriateness of transport.

(2) The best mode of transportation.

(3) The need for additional personnel accompanying the transport.

(4) The appropriate medical management to initiate prior to transport.

k. Perinatal care committee. A Level III neonatal care hospital shall maintain a perinatal care committee that meets the same criteria as those for a Level II neonatal care hospital.

150.8(4) *Level IV neonatal care hospital.*

a. Provider of subspecialty intensive care. In addition to providing the level-of-care services of a Level III neonatal care hospital, a Level IV neonatal care hospital manages higher-risk neonates. The differentiating factor between a Level III neonatal care hospital and a Level IV neonatal care hospital is primarily one of having additional professional staff with considerable experience in the care of the most complex and critically ill infants and having the ability to provide surgical repair of complex congenital or acquired conditions.

b. Physical facilities. In addition to having the physical facilities of a Level III neonatal care hospital, a Level IV neonatal care hospital has more equipment, more extensive physical facilities and will serve a more complicated patient population.

c. Medical personnel. In addition to having the medical personnel of a Level III neonatal care hospital, a Level IV neonatal care hospital will:

(1) Have a medical director of the neonatal intensive care unit who is a full-time, board-certified neonatologist.

(2) Have anesthesia providers on staff with special training or experience in pediatric anesthesia.

(3) Maintain a full range of pediatric medical subspecialists and pediatric surgical subspecialists at the site.

(4) Have the subspecialist physicians immediately available to the Level IV neonatal care hospital.

(5) Have a neonatologist on the premises when an unstable critically ill infant is in the Level IV neonatal care hospital.

d. Nursing personnel. A Level IV neonatal care hospital has the same requirements for nursing personnel as those for a Level II neonatal care hospital.

e. Outreach education. A Level IV neonatal care hospital has the same responsibilities for outreach education as those for a Level III neonatal care hospital.

f. Allied health personnel and services. A Level IV neonatal care hospital has the same level of allied health personnel and services as that of a Level III neonatal care hospital.

g. Infection control. A Level IV neonatal care hospital has the same infection control guidelines as those for a Level I neonatal care hospital.

h. Neonatal safety. A Level IV neonatal care hospital has the same requirements for neonatal safety as those for a Level I neonatal care hospital.

i. Neonatal transport. In addition to meeting the neonatal transport requirements of a Level III neonatal care hospital, a Level IV neonatal care hospital is capable of providing ground and air transportation with crews who have demonstrated competencies in neonatal resuscitation and stabilization.

j. Perinatal care committee. In addition to maintaining a perinatal care committee that meets the same criteria as those for a Level II neonatal care hospital, a Level IV neonatal care hospital maintains a perinatal care committee that has additional representation by surgical specialties. The Level IV neonatal care hospital's perinatal care committee will maintain and analyze data on long-term outcomes to evaluate the effectiveness of the delivery of perinatal health care services.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25; Editorial change: IAC Supplement 6/10/26]

641—150.9(135) Grant or denial of certificate of verification; and offenses and penalties.

150.9(1) Upon receipt of the levels-of-care assessment tool and the on-site survey results, if required, the department will within 90 days issue its decision to grant or deny the hospital a certificate of verification. The department may deny verification or may give a citation and warning, place on probation, suspend, or revoke existing verification if the department finds reason to believe the hospital's perinatal care program has not been or will not be operated in compliance with these rules. The denial, citation and warning, period of probation, suspension or revocation will be effected and may be appealed in accordance with the requirements of Iowa Code section 17A.12.

150.9(2) All complaints regarding the operation of a participating hospital's perinatal care program shall be reported to the department and to the department of inspections, appeals, and licensing.

150.9(3) Complaints and the investigative process will be treated as confidential to the extent they are protected by Iowa Code sections 22.7 and 135.11(27).

150.9(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

150.9(5) Notice of denial, citation and warning, probation, suspension or revocation will be effected in accordance with the requirements of Iowa Code section 17A.12. Notice to the hospital of denial, citation and warning, probation, suspension or revocation will be served by certified mail, return receipt requested, or by personal service.

150.9(6) Any request for a hearing concerning the denial, citation and warning, probation, suspension or revocation must be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice to take action. If the request is made within the 20-day time period, the notice to take action will be deemed to be suspended pending the hearing. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. If no request for a hearing is received within the 20-day time period, the department's notice of denial, citation and warning, probation, suspension or revocation will become the department's final agency action.

150.9(7) Upon receipt of a request for hearing, the request will be forwarded within five working days to the department of inspections, appeals, and licensing pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information, which may be provided by the aggrieved party, shall also be provided to the department of inspections, appeals, and licensing.

150.9(8) The hearing shall be conducted according to the procedural rules of the department of inspections, appeals, and licensing found in 481—Chapter 10.

150.9(9) When the administrative law judge makes a proposed decision and order, it will be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

150.9(10) Any appeal to the director for review of the proposed decision and order of the administrative law judge must be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal will also be mailed to the administrative law judge. Any request for an appeal must state the reason for appeal.

150.9(11) Upon receipt of an appeal request, the administrative law judge will prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections and rulings on them.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

150.9(12) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and will be delivered by certified mail, return receipt requested, or by personal service.

150.9(13) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

150.9(14) Any petition for judicial review of a decision and order must be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal will be sent to the department by certified mail, return receipt requested, or by personal service.

150.9(15) The party that appeals a final agency action to the district court must pay the cost of the preparation of a transcript of the contested case hearing for the district court.

150.9(16) Final decisions of the department relating to disciplinary proceedings may be transmitted to the department of inspections, appeals, and licensing and to the appropriate professional associations or news media.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.10(135) Prohibited acts. A hospital that imparts or conveys, or causes to be imparted or conveyed, that it is a participating hospital in Iowa's regionalized system of perinatal health care, or that uses any other term, such as a designated level of care, to indicate or imply that the hospital is a participating hospital in the regionalized system of perinatal health care without having obtained a certificate of verification from the department is subject to licensure disciplinary action by the department of inspections, appeals, and licensing, as well as to the application by the director to the district court for a writ of injunction to restrain the use of the term or terms "Level I maternal care or neonatal care hospital," "Level II maternal care or neonatal care hospital," "Level III maternal care or neonatal care hospital" and "Level IV maternal care or neonatal care hospital" in relation to the provision of perinatal health care services.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.11(135) Construction of rules. Nothing in these administrative rules shall be construed to restrict a hospital from providing any services for which it is duly authorized.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

These rules are intended to implement Iowa Code section 135.11.

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[Filed ARC 9178C (Notice ARC 8532C, IAB 12/11/24), IAB 4/30/25, effective 7/1/25]
[Editorial change: IAC Supplement 6/10/26]
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CHAPTER 151
TOBACCO USE PREVENTION AND CONTROL COMMUNITY PARTNERSHIP INITIATIVE

Rescinded **ARC 9706C**, IAB 11/12/25, effective 1/1/26

CHAPTER 152
TOBACCO USE PREVENTION AND CONTROL FUNDING PROCESS

Rescinded **ARC 9961C**, IAB 1/7/26, effective 3/1/26

CHAPTER 153
SMOKEFREE AIR

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—153.1(142D) Definitions. For the purposes of this chapter, definitions found in Iowa Code section 142D.2 and the following definitions apply:

"Ashtray" means any receptacle, including a can, bottle, bowl, tray, or other vessel that is used for extinguishing or disposing of any lighted cigar, cigarette, pipe, or other tobacco product in any manner or form including ash, cigarette butts or filters, or cigar stubs. However, "ashtray" shall not include any receptacle located outdoors and on the perimeter of any public place, the perimeter of the grounds of any public building, the perimeter of school grounds, or the perimeter of any other outdoor space subject to the prohibition in Iowa Code chapter 142D.

"Entrance" means any doorway to an enclosed area used by the public or employees for ingress to any public place or place of employment, but does not include any doorway designated for use as an exit in an emergency only. "Entrance" also includes the commonly understood points of entry to an outdoor area, subject to the prohibitions of this chapter, such as a driveway, sidewalk, pathway, access road, gate, or dedicated point of entry, but not including a street, road, highway, or sidewalk in the public right-of-way.

"Grounds of any public building" means an outdoor area of a public building that is used in connection with the building, including but not limited to a sidewalk or driveway immediately adjacent to the building, but not including a sidewalk in the public right-of-way; a sitting or standing area immediately adjacent to the building; a patio; a deck; a curtilage or courtyard; a swimming or wading pool; a beach; or any other outdoor area as designated by the person having custody or control of the public building. A person having custody or control of a public building may exclude from the designated grounds of any public building the following: a parking lot, the course of play at a golf course, a hiking trail, locations of an individual campsite or campfire, or a lake, river, or other body of water. Nothing in this definition prohibits any owner, operator, manager, or other person having custody or control of an area that is exempt from the prohibitions of Iowa Code chapter 142D from declaring the entire area or property a nonsmoking place.

"Incidental to the sale of tobacco products" means that the gross revenue of a retail tobacco store derived from the sale of products other than tobacco products is not more than 20 percent of the retail tobacco store's total gross revenue.

"Public building" means an enclosed area owned, leased, or operated by or under the control of the state government or its political subdivisions.

"Retail tobacco store" means the same as defined in Iowa Code chapter 142D.

"Solid wall" means any physical barrier, whether temporary or permanent, covering more than 75 percent of the combined surface area of the vertical planes constituting the perimeter of the area. Solid walls also include the floor and ceiling of the enclosed area.

[**ARC 8756C**, IAB 1/8/25, effective 7/1/25; **ARC 0785D**, IAB 11/25/26, effective 1/1/27]

641—153.2(142D) Duties of employers, owners, operators, managers, and persons having custody or control of a public place, place of employment, area declared nonsmoking pursuant to Iowa Code chapter 142D or outdoor areas where smoking is prohibited.

153.2(1) The employer, owner, operator, manager, or person having custody or control of a place where smoking is prohibited under Iowa Code chapter 142D shall:

a. Not permit smoking in a public place, place of employment, outdoor area where smoking is prohibited, or area declared nonsmoking pursuant to Iowa Code chapter 142D.

b. Inform all current employees and all prospective employees upon application for employment of the prohibitions of Iowa Code chapter 142D.

c. Not retaliate against any employee, applicant for employment, or customer who exercises any rights, registers a complaint, or attempts to prosecute a violation pursuant to Iowa Code chapter 142D.

d. Post signs in and at every entrance to the public place, place of employment, area declared nonsmoking, and outdoor area where smoking is prohibited that inform persons that they are entering a "no smoking" facility or area.

(1) The signs shall be clear and conspicuous in or at the entrance where posted.

(2) The signs shall be at least 24 square inches in size (for example, 4 inches by 6 inches) and shall be in legible font type.

(3) The signs shall contain the words "No Smoking" or the international "no smoking" symbol; the telephone number for reporting complaints, 1.888.944.2247; and the department website, hhs.iowa.gov/smokefreeair.

e. Place "no smoking" signs in every vehicle that constitutes a public place, place of employment, or area declared nonsmoking pursuant to Iowa Code section 142D.5.

(1) Such signs shall be clear and conspicuous from the exterior of the vehicle.

(2) The signs shall be at least 9 square inches (for example, 3 inches by 3 inches) and shall be in legible font type.

(3) The signs shall contain the words "No Smoking" or the international "no smoking" symbol; the telephone number for reporting complaints, 1.888.944.2247; and the department's website, hhs.iowa.gov/smokefreeair.

(4) Nothing in this rule requires the placement of a sign in any vehicle that the director of the department of administrative services or the director of transportation orders to receive a regular registration plate pursuant to Iowa Code section 321.19.

f. Remove all ashtrays from areas where smoking is prohibited.

153.2(2) The owner or operator of a building or facility that contains more than one public place, place of employment, or area declared nonsmoking pursuant to Iowa Code chapter 142D that is controlled by other employers, owners, or operators shall comply with the provisions of these rules for the area of the building or facility under the owner's or operator's control.

153.2(3) An employer, owner, or operator of a public place, place of employment or area declared nonsmoking pursuant to Iowa Code chapter 142D that is within a public place that is owned or operated by another person shall comply with the provisions of these rules for the area under the control of the employer, owner, or operator within that public place.

153.2(4) An employer, owner, operator, manager, or person having custody or control of a place where smoking is prohibited under Iowa Code chapter 142D shall inform any individual smoking in a place where smoking is prohibited that the individual is violating the smokefree air Act and shall request that the individual stop smoking immediately.

a. If the individual refuses to stop smoking, the employer, owner, operator, manager, or person having custody or control of the place where smoking is prohibited may discontinue service to that individual.

b. If the individual refuses to stop smoking, the employer, owner, operator, manager, or person having custody or control of the place where smoking is prohibited may request that the individual leave the area where smoking is prohibited.

c. If the individual refuses to leave the area where smoking is prohibited, the employer, owner, operator, manager, or person having custody or control of the place where smoking is prohibited may notify the state or local law enforcement agency with jurisdiction over the area where smoking is prohibited.

[**ARC 8756C**, IAB 1/8/25, effective 7/1/25]

641—153.3(142D) Leases. Any lease entered into by the state or its political subdivisions shall require that all areas where smoking is prohibited pursuant to Iowa Code chapter 142D comply with the provisions of these rules and Iowa Code chapter 142D.

[**ARC 8756C**, IAB 1/8/25, effective 7/1/25]

641—153.4(142D) Complaints and enforcement.

153.4(1) *Duties of department.* The department will maintain a system for receiving and investigating complaints against persons who own, operate, manage, or otherwise have custody or control of a place where smoking is prohibited and who fail to comply with the provisions of Iowa Code chapter 142D.

a. The department may designate one or more public agencies through a 28E agreement or other written contract to assist with enforcement.

b. The department may refer complaints regarding a violation to the law enforcement authorities of the state or of the political subdivision of the state in which the alleged violation occurred.

153.4(2) *Enforcement against a person who smokes in an area where smoking is prohibited.* Pursuant to Iowa Code chapter 142D, the department designates the law enforcement authorities of the state and of each political subdivision of the state to assist with enforcement. A peace officer may issue a citation in lieu of arrest pursuant to Iowa Code chapter 805 against a person who smokes in an area where smoking is prohibited pursuant to Iowa Code chapter 142D, and such person shall pay a civil penalty pursuant to Iowa Code section 805.8C(3) for each violation.

153.4(3) *Enforcement against a person who owns, operates, manages, or otherwise has control of a place where smoking is prohibited.* Pursuant to Iowa Code chapter 142D, the department designates the law enforcement authorities of the state and of each political subdivision of the state to assist with enforcement. The department or its designee may initiate a civil action against an owner, operator, manager, or person who otherwise has custody or control of a place where smoking is prohibited pursuant to Iowa Code chapter 142D, and such person shall pay the applicable civil penalty pursuant to Iowa Code chapter 142D.

153.4(4) *Manner of filing a complaint.* Any person may register a complaint with the department by calling the toll-free number, 1.888.944.2247, or on the department's website, hhs.iowa.gov/smokefreeair.

153.4(5) *Contents of the complaint.* A complaint filed with the department shall include:

a. The name or location of the public place, place of employment, area declared a nonsmoking place pursuant to Iowa Code chapter 142D, or outdoor area where smoking is prohibited that is the subject of the complaint;

b. A description of the occurrence that prompted the complaint; and

c. Any other information relevant to the occurrence.

153.4(6) *Review of complaint by department.* Upon receipt of a complaint, the department or its designee may contact the individual making the complaint to confirm the details of the complaint and obtain any additional information.

153.4(7) *Information from inspections.* Information received by the department of one or more violations of Iowa Code chapter 142D as a result of an inspection of a public place by the state or political subdivision of the state shall be considered a credible complaint under this rule.

153.4(8) *Notice of potential violation.* If the department determines that a complaint against a public place, place of employment, area declared nonsmoking pursuant to Iowa Code chapter 142D, or outdoor areas where smoking is prohibited is credible:

a. For the first complaint, the department shall:

(1) Issue a written notice of potential violation to the owner, operator or person having custody or control including the details of the complaint.

(2) Include in the notice educational materials about how to comply with Iowa Code chapter 142D, and information on whom to contact for further information and assistance for compliance.

b. For the second and subsequent complaints within one year, the department:

(1) Shall issue a subsequent notice of potential violation to the owner, operator, or person having custody or control.

(2) May authorize one or more public agencies to conduct a compliance check of the location.

(3) May pursue any remedy authorized by Iowa Code chapter 142D, including the enforcement of civil penalties.

[**ARC 8756C**, IAB 1/8/25, effective 7/1/25]

641—153.5(142D) Limitation of rules. Nothing in these rules is intended to limit any other state administrative rule or federal regulation that prohibits smoking.

[**ARC 8756C**, IAB 1/8/25, effective 7/1/25]

These rules are intended to implement Iowa Code chapter 142D.

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CHAPTER 154
MEDICAL CANNABIDIOL PROGRAM

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/14/29

641—154.1(124E) Definitions. For the purposes of these rules, the following definitions shall apply:

"Acceptance criteria" means the specified limits placed on characteristics of an item or method that are used to determine data quality.

"Action level" means the threshold value that provides the criterion for determining whether a sample passes or fails a test performed pursuant to these rules.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of medical cannabidiol.

"Analyte" means a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

"Analytical batch" means a group of samples that are prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and common analytical quality control checks.

"Analytical method" means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

"Audit" means a review by authorized personnel that includes select scope engagement or other methods of review that analyze operational or compliance issues.

"Background investigation" means a thorough review of an entity, an owner, investors, and employees conducted by the department of public safety, including but not limited to state and national criminal history records, credit records, and internal revenue service records.

"Batch" means a specifically identified quantity of dried flower and other cannabis plant matter that is uniform in strain or cultivar, harvested at the same time, and cultivated using the same pesticides and other crop inputs.

"Biosecurity" means a set of preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases in crops;
2. Quarantined pests;
3. Invasive alien species;
4. Living modified organisms.

"Cannabinoid" means a chemical compound that is unique to and derived from cannabis.

"Cannabis" means seeds, plants, cuttings, or plant waste material from *Cannabis sativa* L. or *Cannabis indica* used in the manufacture of medical cannabidiol.

"CBD" means cannabidiol, Chemical Abstracts Service number 13956-29-1.

"CBDA" means cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

"Certificate of analysis" means the report prepared for the requester about the analytical testing performed and the results obtained by a laboratory.

"Certified" means that a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified in the department's requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements.

"Certified reference material" means a reference material prepared by a certifying body.

"Combusted" means the addition of a flame to medical cannabidiol or raw flower cannabis for the purposes of burning for inhalation, or smoking cannabis.

"Consumable hemp product" means a hemp product that includes a substance that is metabolized or is otherwise subject to a biotransformative process when introduced into the human body.

1. A consumable hemp product may be introduced into the human body by ingestion or absorption by any device including but not limited to an electronic device.
2. A consumable hemp product may exist in a solid or liquid state.

3. A hemp product is deemed to be a consumable hemp product if it is any of the following:

- Designed by the processor, including the manufacturer, to be introduced into the human body.
- Advertised as an item to be introduced into the human body.
- Distributed, exported, or imported for sale or distribution to be introduced into the human body.

"Consumable hemp product" includes but is not limited to any of the following:

1. A noncombustible form of hemp that may be digested, such as food; internally absorbed, such as chew or snuff; or absorbed through the skin, such as a topical application.

2. Hemp processed or otherwise manufactured, marketed, sold, or distributed as food, a food additive, a dietary supplement, or a drug.

"Consumable hemp product" does not include a hemp product if the intended use of the hemp product is introduced into the human body by any method of inhalation, as prohibited under Iowa Code section 204.14A.

"Crop input" means any substance applied to or used in the cultivation and growth of a cannabis plant. "Crop input" includes but is not limited to pesticides, fungicides, fertilizers, and other soil or medium amendments.

"Date of expiration" means one year from the date of issuance of the medical cannabidiol registration card by the department of transportation.

"Date of issuance" means the date of issuance of the medical cannabidiol registration card by the department.

"Debilitating medical condition" means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:

- Severe or chronic pain.
- Nausea or severe vomiting.
- Cachexia or severe wasting.

2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn's disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:

- Severe or chronic pain.
- Nausea or severe vomiting.
- Cachexia or severe wasting.

8. Parkinson's disease.
9. Chronic pain.
10. Severe, intractable autism with self-injurious or aggressive behaviors.
11. Post-traumatic stress disorder.
12. Corticobasal degeneration.
13. Ulcerative colitis.
14. Any medical condition that is recommended by the medical cannabidiol board and adopted by the board of medicine by rule pursuant to Iowa Code section 124E.5 and that is listed in 653—subrule 13.15(1).

"Dispensary" means an individual or entity licensed by the department to dispense medical cannabidiol to patients and primary caregivers pursuant to Iowa Code chapter 124E and these rules. "Dispensary" includes the employees and agents of the dispensary.

"Dispensary facility" means any secured building, space, grounds, and physical structure of a dispensary licensed by the department to dispense medical cannabidiol and where the dispensing of medical cannabidiol is authorized.

"Dispense" or *"dispensing"* means to supply medical cannabidiol to patients pursuant to Iowa Code chapter 124E and these rules.

"Disqualifying felony offense" means the same as defined in Iowa Code section 124E.2.

"Edible medical cannabidiol products" means food items containing medical cannabidiol. "Edible medical cannabidiol products" does not include pills, tinctures, oils, or other forms of medical cannabidiol that may be consumed orally or through the nasal cavity that do not contain food or food additives; provided that food or food additives used as carriers, excipients, or processing aids shall not be considered food or food additives.

"Field duplicate sample" means a sample that is taken in the identical manner and from the same batch, process lot, or lot being sampled as the primary sample. A field duplicate sample is analyzed separately from the primary sample and is used for quality control only.

"Health care practitioner" means the same as defined in Iowa Code section 124E.2.

"Inspection" means an on-site evaluation by the department; the department of public safety; or a department-approved independent consultant of facilities, records, personnel, equipment, methodology, and quality assurance practices for compliance with these rules.

"Investor" means a person making a cash investment of at least 5 percent interest in an applicant or licensed manufacturer or dispensary with the expectation of receiving financial returns.

"Laboratory" means the same as defined in Iowa Code section 124E.2.

"Limit of detection" or *"LOD"* means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

"Limit of quantitation" or *"LOQ"* means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

"Lot" means a specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

"Lot number" means a unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain the manufacturer's number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

"Manufacture" or *"manufacturing"* means the process of converting harvested cannabis plant material into medical cannabidiol.

"Manufacturer" means an individual or entity licensed by the department to produce medical cannabidiol and distribute it to dispensaries pursuant to Iowa Code chapter 124E and these rules. "Manufacturer" includes the employees and agents of the manufacturer.

"Manufacturing facility" means any secured building, space, grounds, and physical structure of a manufacturer for the cultivation, harvesting, packaging, processing, storage, and distribution of cannabis or medical cannabidiol and where access is restricted to designated employees of a manufacturer and escorted visitors.

"Matrix" means the component or substrate that contains the analyte of interest.

"Matrix spike duplicate" means a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or other matrix that is as closely representative of the matrix under analysis as possible.

"Matrix spike sample" means a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

"Medical assistance program" means a medical assistance program as administered by a state, territory, or district Medicaid program.

"Medical cannabidiol" means the same as defined in Iowa Code section 124E.2.

"Medical cannabidiol waste" means medical cannabidiol that is unused, unwanted, damaged, defective, expired, or contaminated and that is returned to a dispensary or manufacturer for disposal.

"Medical cannabis goods" means medical cannabidiol process lots, medical cannabidiol products, and cannabis plant material, including dried tissue.

"Method blank" means an analyte-free matrix to which all reagents are added in the same volumes or proportions as are used in sample preparation.

"National criminal history background check" means fingerprint processing through the department of public safety and the Federal Bureau of Investigation (FBI) and review of records on file with national organizations, courts, and law enforcement agencies to the extent allowed by law.

"Owner" means a person with a 5 percent or greater ownership interest in an applicant or licensed manufacturer or dispensary.

"Patient" means a person who suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

"Patient registration number" means the unique identification number issued to a patient by the department upon approval of a patient's application by the department as described in these rules.

"Percent recovery" means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate.

"Plant material" means any plant of *Cannabis sativa* L. or *Cannabis indica*, or any part thereof, including flowers, leaves, trichomes, and tissue.

"Plant material waste" means plant material that is not used in the production of medical cannabidiol in a form allowable under these rules.

"Primary caregiver" means the same as defined in Iowa Code section 124E.2.

"Primary care provider" means any health care practitioner involved in the diagnosis and treatment of a patient's debilitating medical condition.

"Primary sample" means a portion of a batch, process lot, or lot that is used for testing for identity, strength, purity, and composition.

"Process lot" means any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and used for testing for identity, strength, purity, and composition prior to being packaged.

"Product expiration date" means the date after which a medical cannabidiol product shall not be sold by a manufacturer or a dispensary.

"Production" or *"produce"* means:

1. Cultivating or harvesting plant material;
2. Processing or manufacturing; or
3. Packaging of medical cannabidiol.

"Proficiency test" means an evaluation of a laboratory's performance against preestablished criteria by means of interlaboratory comparisons of test measurements.

"Qualitative analysis" means identification of an analyte in a substance or mixture.

"Quality assurance" means a set of operating principles to produce data of known accuracy and precision. "Quality assurance" encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

"Quality control" means a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels.

"Quality control samples" means samples produced and used for the purpose of ensuring quality control. Quality control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

"Reagent" means a compound or mixture added to a system to cause a chemical reaction or to test if a reaction occurs. A reagent may be used to tell whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

"Recall" means the return of medical cannabidiol from patients and dispensaries to a manufacturer because of the potential for serious health consequences from the use of the medical cannabidiol.

"Reference material" means a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

"Relative percent difference" or *"RPD"* means a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation: RPD = absolute value (primary sample

measurement - duplicate sample measurement) / ([primary sample measurement + duplicate sample measurement] / 2) × 100.

"Requester" means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed manufacturer or the department.

"Residual solvents and processing chemicals" means volatile organic chemicals that are used or produced in the manufacture or production of medical cannabidiol.

"Restricted access area" means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested, stored, packaged, or processed for sale under control of the manufacturer, and where no person under the age of 18 is permitted.

"Sample" means a representative part of or a single item from a larger whole or group.

"Sanitize" means to sterilize, disinfect, or make hygienic.

"Security alarm system" means the same as defined in rule 661—277.2(100C).

"Semiquantitative analysis" means less than quantitative precision and does not involve a full calibration. Analyte identification is based on a single-point reference or high-probability library match. The determination of amount uses the ratio of the unknown chemical analyte to that of a known analyte added to the sample before analysis. Uncertainty for semiquantitative results is higher than for quantitative results.

"Significant figures" means the number of digits used to express a measurement.

"Stability study" or *"studies"* means the process of determining the shelf-life or expiration date of a medical cannabidiol product. After storage of an unopened package of medical cannabidiol at a licensed manufacturing facility or dispensary facility, the contents shall not vary in concentrations of THC and CBD by more than an amount determined by the department and listed in the laboratory testing requirements and acceptance criteria document described in 641—Chapter 154.

"Standard operating procedure" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

"Synthetic or semisynthetic cannabinoid" means a cannabinoid extracted from a cannabis plant, a cannabis flower, a hemp plant, or hemp plant parts with a chemical makeup that is changed after extraction to create a different cannabinoid or other chemical compound by applying a catalyst other than heat or light. "Synthetic or semisynthetic cannabinoid" includes but is not limited to any tetrahydrocannabinol created from cannabidiol.

"Tamper-evident" means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

"Testing laboratory record" means information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

"THC" or *"delta-9 THC"* means tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

"THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

"Total tetrahydrocannabinol" means 87.7 percent of the amount of tetrahydrocannabinolic acid plus the amount of tetrahydrocannabinol.

"Tracking number" means the sales identification number assigned by a dispensary to a transaction at the time of the sale of a medical cannabidiol product.

"Trade name" means the name that manufacturers give to a product or range of products.

"Validation" means the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

"Valid photo identification" means any of the following for a patient or primary caregiver: (1) a valid driver's license, (2) a valid nonoperator's identification card, or (3) an alternative form of valid photo identification. An individual who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. An individual who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. An individual who applies for an exemption is subject to verification of the primary caregiver's identity through a process established

by the department to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

"Vaporization" means the heating of a medical cannabidiol concentrate or extract to a specific temperature using a device. For the purposes of these rules, vaporization does not include raw or dried cannabis flower.

"Written certification" means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, that states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; **ARC 0786D**, IAB 11/25/26, effective 1/1/27]

REGISTRATION CARDS

641—154.2(124E) Health care practitioner certification—duties and prohibitions.

154.2(1) Prior to a patient's submission of an application for a medical cannabidiol registration card pursuant to this rule, a health care practitioner shall follow all provisions of Iowa Code section 124E.3, this chapter and requests from the department for more information.

a. The written documentation required by Iowa Code section 124E.3(1)*"a"* shall be submitted on the application form at the department's website.

b. Explanatory information pursuant to Iowa Code section 124E.3(1)*"b"* is located at the department's website.

154.2(2) A health care practitioner may make a written request to the department to rescind a written certification the practitioner previously provided, based on reasons deemed appropriate by the health care practitioner.

154.2(3) Health care practitioner prohibitions. A health care practitioner shall not:

a. Accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a manufacturer or dispensary for the purposes of:

(1) Certifying a patient's condition, other than accepting a fee for a patient consultation to determine if the patient should be issued a certification under Iowa Code chapter 124E.

(2) Certifying an individual as a primary caregiver, other than accepting a fee for a consultation to determine if the individual is a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol.

b. Advertise the certification of patients as one of the health care practitioner's services.

c. Certify a qualifying debilitating medical condition for a patient who is the health care practitioner or a family or household member of the health care practitioner.

d. Be designated to act as a primary caregiver for a patient for whom the health care practitioner has certified a qualifying debilitating medical condition.

e. Receive or provide medical cannabidiol product samples.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.3(124E) Medical cannabidiol registration card—application and issuance to patient.

154.3(1) The department may issue a registration card to a patient who meets the criteria listed at Iowa Code section 124E.4(1). The application form is available on the department's website. The department shall not approve an application that does not include the information requested on the application form.

154.3(2) Upon the completion, verification, and approval of the patient's application and the receipt of the required fee, the department shall issue a registration card to the patient.

154.3(3) A registration card issued to a patient shall contain all of the following:

a. The patient's full legal name, current residence address, date of birth, and sex, as shown on the patient's valid photo identification. If the patient's information has changed since the issuance of the patient's valid photo identification, the patient shall first update the patient's valid identification to reflect the patient's current information.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the patient's social security number.

d. A statement that the registration card is not valid for identification purposes.

154.3(4) Every patient 18 years of age or older must obtain a valid registration card to use medical cannabidiol in Iowa.

154.3(5) An authorization to use medical cannabidiol or cannabis for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E and is not a valid registration card for purposes of purchasing medical cannabidiol at dispensaries in Iowa.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; **ARC 9617C**, IAB 10/15/25, effective 12/1/25; **ARC 0786D**, IAB 11/25/26, effective 1/1/27]

641—154.4(124E) Medical cannabidiol registration card—reciprocity. A medical cannabidiol registration card shall hold reciprocity with other states pursuant to Iowa Code section 124E.18.

154.4(1) A patient with a valid registration card from another state or jurisdiction shall maintain the affirmative defense for possession of medical cannabidiol, provided the form of cannabis product in the patient's possession is allowable in Iowa.

154.4(2) A patient with a valid registration card under the laws of another state or jurisdiction has no affirmative defense for medical cannabidiol if the cannabis product in the patient's possession is prohibited in Iowa. Prohibited forms of medical cannabidiol include:

a. Raw cannabis flower that may be combusted or smoked;

b. Edible products with a total THC concentration greater than 0.3 percent that is not a consumable hemp product.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.5(124E) Medical cannabidiol registration card—application and issuance to primary caregiver.

154.5(1) For a patient in a primary caregiver's care, the department may issue a registration card to a primary caregiver who meets the criteria listed at Iowa Code section 124E.4(3). The application form is available on the department's website. The department shall not approve an application that does not include the information requested on the application form.

154.5(2) Upon the completion, verification, and approval of the primary caregiver's application, the department shall issue a registration card to the primary caregiver.

154.5(3) A registration card issued to a primary caregiver shall contain all of the following:

a. The primary caregiver's full legal name, current residence address, date of birth, and sex, as shown on the primary caregiver's valid photo identification. If the primary caregiver's information has changed since issuance of the primary caregiver's valid photo identification, the primary caregiver shall first update the primary caregiver's valid photo identification to reflect the primary caregiver's current information.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the primary caregiver's social security number.

d. The registration number for each patient in the primary caregiver's care. This number shall not be the primary caregiver's or patient's social security number. If the patient in the primary caregiver's care is under the age of 18, the full name of the patient's parent or legal guardian shall be printed on the primary caregiver's registration card in lieu of the patient's registration number.

e. A statement that the registration card is not valid for identification purposes.

f. A statement distinguishing the registration cardholder as a primary caregiver.

154.5(4) An authorization to use, or to act as a primary caregiver for a patient authorized to use, medical cannabidiol or cannabis for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E and is not a valid registration card for purposes of purchasing medical cannabidiol at dispensaries in Iowa.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; **ARC 9617C**, IAB 10/15/25, effective 12/1/25]

641—154.6(124E) Denial and cancellation. The department may deny an application for a registration card, or may cancel a registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

2. The department is unable to verify the identity of the applicant from the photo identification or other documentation presented during application.

3. The department has reasonable belief, or proof, that the patient is engaged in diversion of medical cannabidiol.

4. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.

5. A patient, the patient's legal guardian, or other person with durable power of attorney requests in writing that the department cancel the patient's registration card. The department shall notify a primary caregiver in writing when the registration card of the primary caregiver's patient has been canceled.

6. A primary caregiver requests in writing that the department cancel the primary caregiver's registration card. The department shall notify a patient in writing when the registration card of the patient's primary caregiver has been canceled.

7. The department becomes aware of the death of a patient or primary caregiver.

8. A health care practitioner requests in writing that the department rescind the written certification the practitioner provided to a patient or caregiver.

9. A patient requests in writing that the department cancel the patient's primary caregiver's registration card.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.7(124E) Appeal.

154.7(1) *Written notice of denial or cancellation.* If the department denies an application for or cancels a registration card, the department shall inform the applicant or cardholder of the denial or cancellation, state the reasons for the denial or cancellation in writing, and state the effective date of the denial or cancellation. If the department cancels a card upon request from a patient or primary caregiver, or the department becomes aware of the death of a patient or primary caregiver, the cancellation is effective immediately upon issuance of the written notice of cancellation. If the department cancels a card upon any other ground listed, the cancellation shall become effective 30 days following issuance of the written notice of cancellation.

154.7(2) *Effect of written notice of cancellation on use and possession of medical cannabidiol.* A cardholder is authorized to purchase, possess, and use medical cannabidiol up to and including the effective date of the cancellation. For purposes of the affirmative defenses in Iowa Code section 124E.12, a patient or primary caregiver shall be deemed to be in possession of a valid registration card up to and including the effective date of the cancellation.

154.7(3) *Request for appeal.* A request for appeal concerning the denial or cancellation of a registration card shall be submitted pursuant to the provisions of 441—Chapter 2506. In the event of a timely appeal, cancellation of the card shall be deemed to be suspended pending the outcome of the contested case proceeding. If the cancellation is affirmed following the contested case proceeding, the card cancellation shall become effective 30 days following issuance of the department's final agency action.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; Editorial change: IAC Supplement 6/10/26]

641—154.8(124E) Duplicate card.

154.8(1) *Lost, stolen, or destroyed card.* To replace a registration card that is lost, stolen, or destroyed, a cardholder shall present to the department the cardholder's valid photo identification that was provided at the time of application.

154.8(2) *Change in card information and voluntary replacement.*

a. To replace a registration card that is damaged, the cardholder shall surrender the card to be replaced to the department and present the cardholder's valid photo identification that was provided at the time of application.

b. A patient or primary caregiver to whom a registration card is issued shall notify the department of a change in information listed on the card, within ten calendar days of the change. To replace a registration card to change the patient or primary caregiver's information, the cardholder shall surrender the card to be replaced to the department and present the patient or primary caregiver's updated valid photo identification.

c. To replace a registration card held by a primary caregiver to change, add, or remove a patient's registration number or the name of a patient's parent or legal guardian listed on the primary caregiver's card, the primary caregiver shall submit a new application to the department pursuant to rule 641—154.5(124E). A registration card issued pursuant to this paragraph shall not be considered a duplicate card.

154.8(3) *Expiration date.* A duplicate registration card shall have the same expiration date as the registration card being replaced, changed, or amended.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.9(124E) Renewal. A registration card shall be valid for one year from the date of issuance, unless canceled. Renewal of a registration card will follow the application and issuance rules of this chapter.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.10(124E) Confidentiality. The department will follow the confidentiality provisions in Iowa Code section 124E.11(1).

154.10(1) Personally identifiable information of patients and primary caregivers will be maintained as confidential and is not accessible to the public. The department will release aggregate and statistical information regarding the registration card program in a manner that prevents the identification of any patient or primary caregiver.

154.10(2) Personally identifiable information of patients and primary caregivers may be disclosed only pursuant to Iowa Code section 124E.11(1)*"b"* and to a patient, primary caregiver, or health care practitioner, upon written authorization of the patient or primary caregiver.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.11(124E) Registration card fees. All registration card fees are nonrefundable.

154.11(1) *Patient medical cannabidiol registration card fee.*

a. A registration card fee of $100 applies to all patients unless the patient qualifies for a reduced patient registration card fee under paragraph 154.11(1)*"b."*

b. If a patient attests to receiving social security disability benefits, supplemental security insurance payments, enrollment in a medical assistance program, or military veteran status, the patient registration card fee is reduced to $25.

154.11(2) *Primary caregiver medical cannabidiol registration card and renewal fees.*

a. A registration card fee of $25 applies to all primary caregivers.

b. A renewal fee of $25 applies to all primary caregivers.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; **ARC 0786D**, IAB 11/25/26, effective 1/1/27]

641—154.12(124E) Consumption of medical cannabidiol. In accordance with Iowa Code section 124E.12, patients and caregivers are entitled to a complete and affirmative defense for unlawful possession of marijuana. Medical cannabidiol is intended to be consumed privately, and patients are subject to all applicable laws regarding public impairment and operating a vehicle, including but not limited to Iowa Code section 123.46 and chapter 321J. Medical cannabidiol products shall not be consumed in the following places:

a. In places open to the public, except for within a health care facility if pursuant to the standard operating procedures of the health care facility.

b. On the property of a school, unless pursuant to the standard operating procedure of the school.

c. On the property of a medical cannabidiol dispensary or manufacturer.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.13(124E) Allowable forms of medical cannabidiol.

154.13(1) *Modification of allowable forms.* Allowable forms of medical cannabidiol may be modified by approval of a recommendation by the medical cannabidiol board, subsequent approval of the board of medicine, and adoption of the recommendations by the department.

154.13(2) *Allowable forms.*

a. A manufacturer may only manufacture medical cannabidiol in the following forms:

(1) Oral forms, including but not limited to:

1. Tablet.
2. Capsule.
3. Liquid.
4. Tincture.
5. Sublingual.

(2) Topical forms, including but not limited to:

1. Gel.
2. Ointment, cream or lotion.
3. Transdermal patch.

(3) Inhaled forms, limited to:

1. Nebulizable.
2. Vaporizable.

(4) Rectal/vaginal forms, including but not limited to suppository.

b. A manufacturer shall not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer shall not produce edible medical cannabidiol products.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

MANUFACTURER AND DISPENSARY LICENSING

641—154.14(124E) Notice to law enforcement. The department shall notify local law enforcement agencies and the department of public safety of the locations of manufactures and dispensaries. If the department has sufficient cause to believe that there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.15(124E) Manufacturer and dispensary licensure.

154.15(1) To be eligible for licensure, an applicant manufacturer or dispensary shall complete a background investigation pursuant to Iowa Code section 124E.19. Applicants must provide information on forms and in a manner required by the department of public safety.

154.15(2) The license shall be renewed annually unless a manufacturer or dispensary relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.

154.15(3) A license to manufacture or dispense medical cannabidiol issued by the department is not assignable or transferable unless for the purpose of intra-organization restructure, subject to review and approval by the department.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.16(124E) Collection of fees in competitive licensing. Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

154.16(1) *Fees to the department for manufacturers and dispensaries.*

a. Fees for manufacturing applicants are established by Iowa Code section 124E.6(4). Fees for dispensary applicants are established by Iowa Code section 124E.8(4).

b. Licensed manufacturers and dispensaries shall pay an annual fee to the department to cover costs associated with regulating and inspecting, and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license, payable to the department no later than December 1. Annual fees assessed by the department shall not exceed $100,000 for a manufacturing license and shall not exceed $50,000 for a dispensary license.

154.16(2) *Fees to the department of public safety.*

a. An applicant manufacturer or dispensary shall reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure. The department of public safety retains the right to bill a licensee for additional background investigations, as needed.

b. Each manufacturer or dispensary awarded a license shall, at the time of award to license, submit to the department of public safety a deposit of $10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer or dispensary.

c. A licensed manufacturer or dispensary shall pay a deposit of $200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the manufacturer or dispensary. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the manufacturer or dispensary shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer or dispensary. The department shall retain the right to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.

154.16(3) *Criminal background checks.*

a. A manufacturer or the owner of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history record check.

b. An employee of a manufacturer or a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

c. An applicant or licensed manufacturer or dispensary shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.17(124E) Licensure renewal.

154.17(1) A licensed manufacturer or dispensary shall apply to renew its license with the department at least six months before the license expires. The application shall be submitted on a form on the department's website.

154.17(2) The department shall notify a manufacturer or dispensary of the decision to approve or deny the manufacturer or dispensary's license by August 1 of the year in which the renewal application is submitted.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.18(124E) Suspension or revocation of a manufacturing or dispensary license.

154.18(1) The department may suspend or revoke a manufacturer or dispensary license upon any of the following grounds:

a. Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.

b. Failure to submit required reports and documents.

c. Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.

d. Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.

e. Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.

f. False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.

g. Discontinuance of operation for more than 30 days, unless the department approves an extension of such period for good cause shown.

h. Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.

i. Failure to correct a deficiency within the time frame required by the department.

j. Failure of a manufacturer or dispensary's business owner or investors to have a satisfactory result in a background investigation or national criminal history background check as determined by the department.

154.18(2) The department shall notify the manufacturer or dispensary of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

154.18(3) A request for appeal concerning the suspension or revocation of a license shall be submitted pursuant to the provisions of 441—Chapter 2506.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; Editorial change: IAC Supplement 6/10/26]

641—154.19(124E) Assessment of penalties. The department shall assess to a manufacturer a civil penalty of up to $1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.20(124E) Closure of operations.

154.20(1) A manufacturer or dispensary shall notify the department at least six months before the closure of the manufacturing facility.

154.20(2) If a manufacturer or dispensary ceases operation, the manufacturer or dispensary shall work with the department to verify the remaining inventory of the manufacturer or dispensary and ensure that any plant material, plant material waste, medical cannabidiol products, or combination thereof are destroyed at a waste facility or returned to a manufacturer.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.21(124E) Manufacturer and dispensary security requirements.

154.21(1) *Restricted access.* A manufacturer or dispensary shall limit entrance to all restricted areas by completing all of the following:

a. Mark restricted access areas with signs that state: "Do Not Enter—Restricted Access Areas Access Limited to Authorized Personnel Only".

b. Use a controlled access system that:

(1) Limits access to authorized individuals;

(2) Maintains a log of individuals with approved access, including dates of approvals and revocations;

(3) Tracks times of personnel entry to and exit from the facility;

(4) Stores data for retrieval for a minimum of one year; and

(5) Limits access to authorized individuals in the event of a power failure.

c. If the controlled access system cannot electronically record visitors, visitors to restricted access areas sign manifests with name, date, and times of entry and exit. These manifests shall be kept and stored for a minimum of one year.

d. Visitors wear badges that are visible at all times and identify them as visitors.

e. If requested by the department, submit stored controlled access system data to the department within five business days.

154.21(2) *Perimeter intrusion detection system.*

a. Computer-controlled video surveillance system. A manufacturer or dispensary shall operate and maintain a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days per week, and visually records:

(1) All phases of medical cannabidiol production, if applicable;

(2) All areas that might contain plant material, medical cannabidiol, or both;

(3) All points of entry and exit;

(4) The entrance to the video surveillance control room; and

(5) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. Camera specifications. Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a manufacturer or dispensary or its parking areas;

(2) Produce a clear, color still photograph live or from a recording;

(3) Have an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. Video recording specifications. Video recording equipment shall:

(1) Export still images in an industry standard image format, such as .jpg, .bmp, or .gif;

(2) Archive exported video in a format that ensures authentication and guarantees that the recorded image has not been altered; and

(3) Save exported video in an industry standard file format that can be played on a standard computer operating system.

d. Location. A dispensary shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A manufacturer or dispensary shall ensure that recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for at least 60 days; and

(3) Maintained free of alteration or corruption.

f. Required signage. A manufacturer or dispensary shall post a sign in capital letters in a conspicuous location at every entrance to the manufacturing facility or dispensary that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.21(3) *Security alarm system requirements.*

a. A manufacturer or dispensary shall use a professionally monitored security alarm system that provides intrusion and fire detection of all the following:

(1) Dispensary entrances and exits;

(2) Facility entrances and exits;

(3) Rooms with exterior windows;

(4) Rooms with exterior walls;

(5) Roof hatches;

(6) Skylights; and

(7) Storage rooms.

b. A manufacturer or dispensary's security alarm system and all devices shall continue to operate during a power outage.

c. A manufacturer or dispensary shall provide documentation of the annual inspection and device testing, by a qualified alarm vendor, to the department upon request.

154.21(4) *Personnel identification system.* A manufacturer or dispensary shall use a personnel identification system that controls and monitors individual employee access to restricted access areas.

a. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance and expiration;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A manufacturer or dispensary's employee shall keep the identification card visible at all times when the employee is in a manufacturing facility, a dispensary, or a vehicle transporting medical cannabidiol.

c. Upon termination or resignation of an employee, a manufacturer or dispensary shall immediately:

(1) Revoke the employee's access to the manufacturing facility or dispensary; and

(2) Destroy the employee's identification card, if possible.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.22(124E) Advertising and marketing.

154.22(1) *Permitted marketing and advertising activities.* A manufacturer or dispensary must include medical cannabidiol pricing and hours of operation on its website and may do the following:

a. Display the manufacturer or dispensary's business name and logo on medical cannabidiol labels, signs, website, and informational material provided to patients. The name or logo shall not include:

(1) Images of cannabis or cannabis-use paraphernalia;

(2) Colloquial references to cannabis;

(3) Names of cannabis plant strains or varieties;

(4) Unsubstantiated medical claims; or

(5) Medical symbols that bear a reasonable resemblance to established medical associations.

b. Display signs on the manufacturing facility or dispensary; and

c. Maintain a business website that contains the following information:

(1) The manufacturer or dispensary's name and contact information;

(2) The medical cannabidiol forms and quantities manufactured or available in Iowa; and

(3) Other information as approved by the department.

154.22(2) *Prohibited conduct, statements and illustration.*

a. An advertisement for medical cannabidiol shall not contain:

(1) Colloquial references to cannabis;

(2) Names of cannabis plant strains or varieties;

(3) Any statement that is false or misleading;

(4) Any statement that disparages a competitor's products;

(5) Any statement, design, or representation, picture or illustration that is obscene or indecent;

(6) Any statement, design, representation, picture or illustration that reasonably appeals to or targets children. Appealing to children means:

1. When taken literally or as a plan language reading, there is a resemblance to food or product used by children;

2. Contains child-appealing visuals/graphics, such as intense colors, bubble letters, or other interesting fonts or lettering;

3. Unconventional or interesting product names;

4. Unconventional or unexpected flavor, color, or shape of the product;

5. Games or activities present on the package; or

6. Presence of branded characters, spokespersons, licensed characters, cartoons, or celebrities;

(7) Any statement, design, representation, picture or illustration that encourages or represents the use of medical cannabidiol for a condition other than a qualifying debilitating medical condition;

(8) Any statement, design, representation, picture or illustration that encourages or represents the recreational use of medical cannabidiol or marijuana, tobacco or nicotine products, or alcohol;

(9) Any statement, design, representation, picture or illustration related to the safety or efficacy of medical cannabidiol, unless supported by substantial evidence, substantial clinical data, direct patient testimonials, or combination thereof;

(10) Any statement, design, representation, picture or illustration portraying anyone reasonably appearing to be under the age of 18, objects suggestive of the presence of anyone under the age of 18, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of 18, except that an advertisement may address medical cannabidiol products as they relate to minor patients;

(11) Any offer of a prize, award or inducement to a qualifying patient, primary caregiver, or health care practitioner related to the purchase of medical cannabidiol or a certification for the use of medical cannabidiol, except that non-product-specific price discounts are allowed;

(12) Any statement or assertion that medical cannabidiol products are safe because they are regulated under this chapter or have been tested by an approved laboratory;

(13) Any reference to a prohibited form of medical cannabidiol;

(14) Any statement that claims that medical cannabidiol products are endorsed or supported by any government agency; or

(15) Any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the department, the state of Iowa or any person or entity associated with the state of Iowa.

b. A manufacturer or dispensary shall not engage in any of the following activities:

(1) Host, promote, refer, or otherwise advertise a third-party patient certification service;

(2) Engage in any advertising, marketing, or branded educational activities within 1,000 feet of a school;

(3) Host, promote, sponsor, or otherwise participate in a cannabis consumption lounge or other such encouragement of public consumption of cannabis or medical cannabidiol; or

(4) Advertise, or make reference to, non-approved forms of medical cannabidiol in any of its advertisements, including but not limited to:

1. Referring to an approved form of medical cannabidiol as a prohibited form of medical cannabidiol.
2. Advertising non-approved forms of medical cannabidiol. Consumable hemp products regulated under Iowa Code chapter 204 and 641—Chapter 156 are exempt from this provision.

154.22(3) *Review of advertisements by the department.* Any advertisement for medical cannabidiol shall be submitted to the department, on a form or in a format prescribed by the department, at the same time as, or prior to, the dissemination of the advertisement.

a. The department may:

(1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the department determines that the advertisement would be false or misleading without such a disclosure; or

(2) Require changes that are necessary to protect the public health, safety and welfare; or

(3) Require statements for inclusion in the advertisement to address the specific efficacy of medical cannabidiol as it relates to specific disease states or approved debilitating medical conditions, disease symptoms, and population groups.

b. The department reserves the right to require that a licensee amend or remove a public advertisement.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.23(124E) Sales and inventory tracking system. The department shall establish and maintain a secure, electronic system that is available 24 hours per day, seven days per week to track:

1. Inventory of plant material and medical cannabidiol;
2. Transport of plant material and laboratory samples;
3. Application and use of crop inputs and other solvents and chemicals;
4. Sales of medical cannabidiol to dispensaries;
5. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.24(124E) Financial transactions.

154.24(1) A manufacturer or dispensary shall maintain records that reflect all financial transactions and the financial condition of the business.

154.24(2) The following records shall be maintained for at least five years and made available for review upon request of the department:

a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, including the items or services purchased, from whom the items were purchased, and the date of purchase;

b. Bank statements and canceled checks for all business accounts;

c. Accounting and tax records; and

d. Records of all financial transactions, including contracts and agreements for services performed or services received.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.25(124E) Inspection by department or independent consultant. A manufacturer or dispensary is subject to reasonable inspection by the department, a department-approved consultant, or another agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

154.25(1) *Types of inspections.* Inspections may include:

a. Aspects of the business operations;

b. The manufacturing facility or the physical location of a dispensary, including any storage facility;

c. Vehicles used for transport or delivery of medical cannabidiol or plant material;

d. Financial information and inventory documentation;

e. Physical and electronic security alarm systems;

f. Health and sanitary inspection; and

g. Other inspections as determined by the department.

154.25(2) *Compliance required.* A manufacturer or dispensary shall respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a manufacturer or dispensary shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the manufacturer or dispensary cannot reconcile the physical inventory with the inventory recorded in the secure sales and inventory tracking system, the manufacturer or dispensary shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

(3) Failure to complete actions in the action plan within the timelines mutually agreed upon by the manufacturer and the department shall result in assessment of penalties or in suspension or revocation of a manufacturer or dispensary license.

(4) At the department's request and in a timely manner, a manufacturer or dispensary shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

MANUFACTURING

641—154.26(124E) Manufacturer operations.

154.26(1) *Operating documents.*

a. A manufacturer shall maintain operating documents that accurately reflect the manufacturer's standard operating procedures. Unless otherwise noted, a manufacturer shall make the operating documents available to the department upon request, through secure means.

b. The operating documents of a manufacturer shall include all of the following:

(1) Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

1. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;

2. The methods of planting, harvesting, drying, and storing cannabis. A manufacturer may make operating documents for these procedures available on site only;

3. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;

4. The disposal methods for all waste materials;

5. Employee training methods for the specific phases of production. A manufacturer may make operating documents for these procedures available on site only;

6. Biosecurity measures and standard operating procedures used in the production and manufacturing of medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only;

7. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;

8. Sampling strategy and quality testing for labeling purposes. A manufacturer may make operating documents for these procedures available on site only;

9. Medical cannabidiol packaging and labeling procedures;

10. Procedures for recall of medical cannabidiol;

11. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary. A manufacturer may make operating documents for these procedures available on site only;

12. A business continuity plan. A manufacturer may make this operating document available on site only;

13. Records relating to all transport activities; and

14. Other information requested by the department.

(2) Procedures to ensure accurate recordkeeping.

(3) Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only.

154.26(2) *Prohibited activities.* In addition to following all provisions of Iowa Code section 124E.7, a manufacturer shall not:

a. Produce or manufacture medical cannabidiol in any location except in those areas approved by the department;

b. Sell, deliver, transport, or distribute medical cannabidiol from any location except its manufacturing facility or a dispensary facility;

c. Produce or manufacture medical cannabidiol in Iowa for sales or distribution outside of Iowa;

d. Sell or distribute medical cannabidiol to any person or business other than a dispensary or manufacturer licensed by the department under Iowa Code chapter 124E;

e. Refuse to sell, deliver, transport, or distribute medical cannabidiol in any form or quantity produced by the manufacturer to a dispensary, unless deemed appropriate in the manufacturer's reasonable business judgment and approved by the department in writing;

f. Transport or deliver medical cannabidiol to any location except as allowed in subrule 154.22(1);

g. Introduce synthetic or semisynthetic cannabinoids derived from hemp into medical cannabidiol products;

h. Produce synthetic or semisynthetic cannabinoids within the licensed manufacturing facility.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.27(124E) Recordkeeping requirements.

154.27(1) *Manufacturer sales and distribution.* A manufacturer shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

a. The date of each sale or distribution;

b. The item number, product name and description, and quantity of medical cannabidiol sold or otherwise distributed; and

c. The sale price.

154.27(2) *Manufacturer operations and inventory reporting other records.*

a. A manufacturer or dispensary shall maintain the following for at least five years, unless otherwise noted, and provide to the department upon request:

(1) All personnel records;

(2) Records of any theft, loss, or other unaccountability of any medical cannabidiol or plant material;

(3) Transportation manifests and incident reports; and

(4) Records of all samples sent to a testing laboratory and the quality assurance test results.

b. A manufacturer or dispensary shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

154.27(3) *Manufacturer entry into the secure sales and tracking system.*

a. A manufacturer or dispensary shall use the secure sales and inventory tracking system to maintain the following:

(1) Batch and harvest records;
(2) Crop input and additive records;
(3) Extraction and production records;
(4) Transportation records;
(5) Inventory records;
(6) Solvent and processing chemical records; and
(7) Other records as determined by the department.

b. Unless otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the secure sales and inventory tracking system. A manufacturer shall enter data in real time for data related to:

(1) Transport of medical cannabidiol, plant material, and laboratory samples;
(2) Sales of medical cannabidiol to dispensaries;
(3) The creation of process lots containing a unique identifier; and
(4) The creation of package lots containing a unique identifier.

c. A manufacturer shall enter inventory reports on key inventory events into the secure sales and inventory tracking system within five business days in which the event occurred. These inventory reports include but are not limited to:

(1) Batch reports;
(2) Crop input and additive reports;
(3) Harvest reports;
(4) Extraction reports;
(5) Solvent and processing chemical reports;
(6) Package lot reports;
(7) Certificates of analysis from a laboratory;
(8) Other records as determined by the department.

d. State of Iowa manufacturer API guide. The department shall maintain a document describing the IT requirements and acceptance criteria for reporting information to the secure sales and inventory tracking system. The department shall provide manufacturers no less than 14 days in which to comment on proposed revisions to the document, and the department shall provide no less than 30 days' notice before a revision takes effect. The document shall include:

(1) The schedule and means of data reporting;
(2) Integration requirements for third-party vendors; and
(3) Be available on the department's website (hhs.iowa.gov).

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.28(124E) Recall of medical cannabidiol products. Medical cannabidiol products may be recalled in the following ways:

154.28(1) Voluntarily by a licensed manufacturer.

154.28(2) By the department. If the department determines, based on an evaluation, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a manufacturer to recall such violative medical cannabidiol products from dispensaries. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the department and shall consider, but need not be limited to, each of the following factors:

a. Whether any disease or injuries have already occurred from the product.

b. Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation, statements, or both that the conclusion is the opinion of the individual(s) making the health hazard determination.

c. A holistic assessment of the hazard and its present and future potential consequences.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.29(124E) Quality assurance and control.

154.29(1) *Quality control program.* A manufacturer shall develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabidiol. Assessment includes a profile of the active ingredients, including stability studies, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

154.29(2) *Sampling protocols.* A manufacturer shall develop and follow written procedures for sampling medical cannabidiol that require the manufacturer to:

a. Conduct sample collection in a manner that provides analytically sound and representative samples;

b. Document every sampling event and provide this documentation to the department upon request;

c. Describe all sampling and testing plans in written procedures that include the sampling method and the number of units per lot to be tested;

d. Ensure that random samples from each lot are:

(1) Taken in an amount necessary to conduct the applicable test;

(2) Labeled with the lot number; and

(3) Submitted for testing;

e. Retain the results from the random samples for at least five years; and

f. Notify the department at least two business days prior to sample collection and allow the department or its designees to be present to observe the sampling procedures when the samples are to be sent to a laboratory for testing.

154.29(3) *Sampling and testing.* A manufacturer shall:

a. Work with the department and laboratory personnel to develop acceptance criteria for contaminants, including but not limited to cannabinoid content, metals, microbiological impurities, solvents, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;

b. Conduct sampling and testing of plant material and medical cannabidiol lots using acceptance criteria that are protective of patient health. Sampling method results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol are homogenous and representative of the process or package lot;

c. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, and any other relevant quality control criteria, when remixing and retesting are not warranted;

d. Develop and follow a written procedure for responding to results failing to meet established standards, and any other relevant quality control criteria, including:

(1) Criteria for when remixing and retesting are warranted;

(2) Instructions for destroying contaminated or substandard medical cannabidiol when remixing and retesting are not warranted; and

(3) Instructions for determining the source of contamination;

e. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.29(4) *Stability testing.*

a. The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration dates. The procedures shall describe:

(1) Sample size and test intervals based on departmental guidance pursuant to subrule 154.47(1);

(2) Storage conditions for samples retained for testing; and

(3) Reliable and specific test methods.

b. Stability studies shall include:

(1) Medical cannabidiol testing at appropriate intervals; and

(2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.

c. If product-expiration-date studies have not been completed, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information.

d. If a manufacturer determines a product expiration date beyond one year, a manufacturer shall submit justification to the department, and receive approval, prior to labeling a product with an expiration date beyond one year.

154.29(5) *Reserve samples.*

a. A manufacturer shall retain a uniquely labeled reserve sample that represents each lot of medical cannabidiol and store the reserve sample under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the medical cannabidiol is marketed or in one that has similar characteristics. The reserve sample shall consist of at least twice the quantity necessary to perform all the required tests.

b. A manufacturer shall retain the reserve for at least one year from the date of manufacture.

c. After one year from the date of manufacture, reserve samples shall be destroyed.

154.29(6) *Retesting.* If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of medical cannabidiol.

154.29(7) *Disposal of substandard product.* A manufacturer shall dispose of all medical cannabidiol when samples fail to meet established standards, and other relevant quality control criteria.

154.29(8) *Recall procedures.* Each manufacturer shall establish a procedure for recalling product from the market that has a reasonable probability of causing an unexpected or harmful response in a patient population, despite appropriate use, that outweighs the potential benefit of the medical cannabidiol. This procedure shall include:

a. Factors that make a recall necessary;

b. Manufacturer's personnel who are responsible for overseeing the recall; and

c. How to notify affected parties of a recall.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.30(124E) Packaging and labeling.

154.30(1) *Trade names.* A manufacturer's medical cannabidiol trade names shall comply with the following:

a. Names shall be limited to those that clearly reflect the form's medical cannabidiol nature;

b. Any name that is identical to, or similar to, the name of an existing nonmedical cannabidiol product is prohibited;

c. Any name that is identical to, or similar to, the name of an unlawful product or substance is prohibited; and

d. Any name that contains language that suggests using medical cannabidiol for recreational purposes or for a condition other than a qualifying debilitating medical condition is prohibited.

154.30(2) *Medical cannabidiol packaging.*

a. Requirements of medical cannabidiol package containers. The manufacturer shall use medical containers that are:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in paragraph 154.30(2)*"c"*;

(2) Designed to maximize the shelf life of the contained medical cannabidiol;

(3) Tamper-evident; and

(4) Child-resistant.

b. Medical cannabidiol package prohibitions. The packaging for medical cannabidiol shall not:

(1) Bear a reasonable resemblance to commonly available nonmedical commercial products;

(2) Depict images other than the manufacturer's business name or logo on the packaging;

(3) Reasonably appeal to children. More information is provided in rule 641—154.22(2); or

(4) Reasonably appeal to recreational or adult use.

c. Requirements of medical cannabidiol packaging. A manufacturer shall ensure that all medical cannabidiol packaging includes the following information:

(1) The name of the manufacturer, and trade name if applicable;

(2) A label claim concentration for cannabinoid content including:

1. Tetrahydrocannabinol;

2. Tetrahydrocannabinolic acid. Concentrations of tetrahydrocannabinolic acid may be omitted if the manufacturer uses decarboxylation or other means to substantially remove the acids from the product prior to testing;

3. Cannabidiol; and

4. Cannabidiolic acid. Concentrations of cannabinolic acid may be omitted if the manufacturer uses decarboxylation or other means to substantially remove the acids from the product prior to testing;

(3) The number of servings per package (excluding products intended for inhalation);

(4) The directions for use of the product, including recommended and maximum amount by age and weight, if applicable;

(5) All ingredients of the product shown with common or usual names, including but not limited to any additives, terpenes or artificial flavors, diluents and carriers, and preservatives, listed in descending order by predominance of weight. Any third-party hemp-derived cannabinoids in medical cannabidiol products shall be specifically indicated on the ingredients list, separately from medical cannabidiol produced within the manufacturer's facility;

(6) Instructions for storage, including light and temperature requirements, if any; and

(7) The universal warning symbol provided by the department.

d. The following information shall be included with medical cannabidiol packaging, or contained within a package insert:

(1) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";

(2) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal.";

A package may contain multiple labels if the information required by this rule is not obstructed.

154.30(3) *Medical cannabidiol labeling.*

a. After receiving a passing certification of analysis for a package lot from a laboratory, and prior to distribution to dispensaries, a manufacturer shall affix a label to each individual package of medical cannabidiol that contains the following information:

(1) A unique lot number;

(2) The date of manufacture;

(3) Product expiration date. This date shall be one year from the date of manufacture unless a manufacturer has conducted stability studies and received approval from the department for an extended expiration date.

b. Cannabinoid content for:

(1) Tetrahydrocannabinol;

(2) Tetrahydrocannabinolic acid. Concentrations of tetrahydrocannabinolic acid may be omitted if the manufacturer uses chemical decarboxylation or other means to substantially remove the acids from the product prior to testing;

(3) Cannabidiol; and

(4) Cannabidiolic acid.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.31(124E) Transportation of medical cannabidiol and plant material.

154.31(1) *Transport of medical cannabidiol or plant material.* A manufacturer is authorized to transport medical cannabidiol or plant material to and from:

a. Dispensaries;

b. A laboratory for testing;

c. A waste facility for disposal;

d. A manufacturer licensed by the department under Iowa Code chapter 124E;

e. Other sites only with departmental approval.

154.31(2) *Chain-of-custody tracking system.*

a. A manufacturer shall use the secure sales and inventory tracking system, if available, or a department-approved manifest system to track shipping of medical cannabidiol. The system shall include a chain of custody that records:

(1) The name and address of the destination;

(2) The unique ID of each individual process lot or package lot that is part of the shipment, and the total number of individual packages;

(3) The date and time the medical cannabidiol shipment is placed into the transport vehicle;

(4) The date and time the shipment is accepted at the delivery destination;

(5) The person's identity; and

(6) Any handling or storage instructions.

b. Before transporting medical cannabidiol, a manufacturer shall:

(1) Record in the secure sales and inventory tracking system or on the manifest information the material to be transported; and

(2) Notify the dispensary, laboratory, manufacturer, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, manufacturer, or waste facility, if applicable.

c. Each transport shall be approved electronically or in writing by:

(1) An authorized manufacturer employee when the transport vehicle is departing the manufacturing facility; and

(2) An authorized employee of the receiving dispensary, laboratory, manufacturer, or waste facility.

d. An authorized employee at the dispensary, laboratory, manufacturer, or waste facility receiving medical cannabidiol shall:

(1) Verify and document the type and quantity of the transported medical cannabidiol against the information in the secure sales and inventory tracking system or written manifest;

(2) Approve the transport electronically or return a signed copy of the manifest to the manufacturing facility; and

(3) Record the medical cannabidiol that is received as inventory in the secure sales and inventory tracking system, if available. If a manifest system is being used, the dispensary, laboratory, manufacturer, or waste facility shall also maintain a signed copy of the manifest and shall maintain records of the inventory received consistent with these rules.

e. A manufacturer shall maintain all manifests for at least five years and make them available upon request of the department.

154.31(3) *Vehicle requirements for transport.*

a. A manufacturer shall ensure that all medical cannabidiol transported on public roadways is:

(1) Packaged in tamper-evident, bulk containers;

(2) Transported so it is not visible or recognizable from outside the vehicle; and

(3) Transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical cannabidiol or bears the name or logo of the manufacturer.

b. When the motor vehicle contains medical cannabidiol, manufacturer employees who are transporting the medical cannabidiol on public roadways shall:

(1) Travel directly to a dispensary or other department-approved locations; and

(2) Document refueling and all other stops in transit, including:

1. The reason for the stop;
2. The duration of the stop; and
3. The location of the stop.

c. If the vehicle must be stopped due to an emergency situation, the employee shall notify 911 and complete an incident report on a form approved by the department.

d. Under no nonemergency circumstance shall any person other than a designated manufacturer employee have actual physical control of the motor vehicle that is transporting the medical cannabidiol.

e. An employee in a transport motor vehicle shall have telephone access with the manufacturer's personnel.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.32(124E) Disposal of medical cannabidiol and plant material.

154.32(1) *Return of medical cannabidiol from dispensaries and laboratory.* A manufacturer may collect at no charge medical cannabidiol waste from dispensaries. A manufacturer that chooses to collect medical cannabidiol waste may use it for research and development or retained samples, but the manufacturer shall not introduce medical cannabidiol returned from a laboratory into lots of products intended for sale. Notwithstanding this provision, a manufacturer shall:

a. Dispose of medical cannabidiol waste; and

b. Maintain a written record of disposal.

154.32(2) *Medical cannabidiol and plant material waste.* A manufacturer shall store, secure, manage, and record medical cannabidiol waste and plant material waste in accordance with all applicable federal, state, and local regulations.

a. The manufacturer shall dispose of medical cannabidiol waste and plant material waste at an approved facility.

b. Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable.

c. A manufacturer shall dispose of all liquid and chemical product waste generated in the process of cultivating, manufacturing, and distributing medical cannabidiol in accordance with applications regulations.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.33(124E) Production requirements.

154.33(1) *Cultivation and processing.*

a. All phases of production shall take place in designated, restricted access areas in accordance with rule 641—154.21(124E).

b. The production process shall be designed to limit contamination.

c. Each production area shall allow for access, observation, and inventory of each plant group.

154.33(2) *Crop inputs and plant batches.*

a. The manufacturer shall use the secure sales and inventory tracking system to maintain an electronic record of all crop inputs. The record shall include the following:

(1) The date of input application;

(2) The name of the employee applying the crop input;

(3) The crop input that was applied;

(4) The plants that received the application; and

(5) A copy of or electronic link to the safety data sheet for the crop input applied.

b. At the time of harvesting, all plants shall be tracked in a batch process with a unique batch number that shall remain with the batch through final processing into medical cannabidiol.

c. Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the secure sales and inventory tracking system or other manifest system.

154.33(3) *Production of medical cannabidiol.*

a. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process.

b. Medical cannabidiol shall be prepared, handled, and stored in compliance with the sanitation requirements in this rule.

c. A manufacturer shall produce shelf-stable, nonperishable forms of medical cannabidiol.

d. A manufacturer shall ensure that the cannabinoid content of the medical cannabidiol it produces is homogenous.

e. Each lot of medical cannabidiol shall be assigned a unique lot number and recorded in the secure sales and inventory tracking system or other manifest system.

154.33(4) *General sanitation requirements.* A manufacturer shall take all reasonable measures and precautions to ensure that:

a. Any employee who has a communicable disease does not perform any tasks that might contaminate plant material or medical cannabidiol;

b. Hand-washing facilities are:

(1) Convenient and furnished with running water at a suitable temperature;

(2) Located in all production areas; and

(3) Equipped with effective hand-cleaning and -sanitizing preparations and sanitary towel service or electronic drying devices;

c. All employees working in direct contact with plant material and medical cannabidiol use hygienic practices while on duty, including:

(1) Maintaining personal cleanliness; and

(2) Washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated;

d. Litter and waste are routinely removed and the operating systems for waste disposal are routinely inspected;

e. Floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair to inhibit microbial growth;

f. Lighting is adequate in all areas where plant material and medical cannabidiol are processed, stored, or sold;

g. Screening or other protection against the entry of pests is provided, including that rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests;

h. Any buildings, fixtures, and other facilities are maintained in a sanitary condition;

i. Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant material and medical cannabidiol and in accordance with applicable local, state, or federal law;

j. All contact surfaces, utensils, and equipment used in the production of plant material and medical cannabidiol are maintained in a clean and sanitary condition;

k. The manufacturing facility water supply is sufficient for necessary operations;

l. Employees have accessible toilet facilities that are sanitary and in good repair; and

m. Plant material and medical cannabidiol that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

154.33(5) *Storage.*

a. A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing, ensuring that:

(1) Plant material and medical cannabidiol are returned to a secure location immediately after completion; and

(2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area.

b. A manufacturer shall store all plant material and medical cannabidiol during production, transport, and testing, and all saleable medical cannabidiol:

(1) In areas that are maintained in a clean, orderly, and well-ventilated condition; and

(2) In storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind.

c. To prevent degradation, at all times, a manufacturer shall store all plant material and medical cannabidiol under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

d. A manufacturer shall maintain a separate secure storage area for medical cannabidiol that is returned from a dispensary.

154.33(6) *Scales.* All scales used to weigh usable plant material for purposes of these rules shall be certified in accordance with ISO/IEC 17025 dated 2017, which is incorporated herein by reference.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.34(124E) Supply and inventory.

154.34(1) *Reliable and ongoing supply.* A manufacturer shall provide a reliable and ongoing supply of medical cannabidiol to medical cannabidiol dispensaries.

154.34(2) *Inventory controls and procedures.* A manufacturer shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.34(3) *Inventory tracking required.* A manufacturer shall use the secure sales and inventory tracking system to track medical cannabidiol production from seed or plant cutting through distribution of medical cannabidiol to a dispensary.

154.34(4) *Reconciliation.* No less often than every two calendar weeks, a manufacturer shall reconcile its physical inventory with the inventory recorded in the secure sales and inventory tracking system.

a. Reconciliation shall include:

(1) Plant material at the manufacturing facility and in transit; and

(2) Medical cannabidiol at the manufacturing facility.

b. Discrepancies between the physical inventory of the manufacturer and the inventory recorded in the secure sales and inventory system shall be handled as follows:

(1) A manufacturer shall report suspected diversion of medical cannabidiol to the department within 72 hours of discovery.

(2) A manufacturer shall have up to 72 hours to reconcile discrepancies in the manufacturer's physical inventory with the inventory recorded in the secure sales and inventory tracking.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

DISPENSING

641—154.35(124E) Duties of the department.

154.35(1) *Inspection of dispensaries.* The department or its agents shall conduct regular inspections of dispensaries and their facilities.

154.35(2) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours per day, seven days per week to track:

a. Inventory of medical cannabidiol and waste material;

b. Sales of medical cannabidiol from dispensaries to patients and primary caregivers;

c. Total tetrahydrocannabinol purchased in the last 90 days by a patient and the patient's primary caregiver.

154.35(3) *Recall of medical cannabidiol products.* If the department determines, based on an evaluation of the health hazard presented, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a dispensary to recall such violative medical cannabidiol products from the dispensary facility and from patients. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the director of the department and shall consider, but need not be limited to, each of the following factors:

a. Whether any disease or injuries have already occurred from the product.

b. Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation, statements, or both that the conclusion is the opinion of the individual(s) making the health hazard determination.

c. A holistic assessment of the hazard and its present and future potential consequences.

154.35(4) *Permissible disclosure.* The department may disclose patient-specific dispensing data to the certifying provider upon written request by the patient, caregiver, or certifying provider.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.36(124E) Dispensary operations.

154.36(1) *Operating documents.*

a. A dispensary shall maintain operating documents that accurately reflect the dispensary's standard operating procedures. Unless otherwise noted, a dispensary shall make the operating documents available to the department upon request, through secure means.

b. The operating documents of a dispensary shall include all of the following:

(1) Procedures for the oversight of the dispensary, including descriptions of operational and management practices regarding:

1. The forms and quantities of medical cannabidiol products that will be stored and dispensed at the dispensary;
2. The estimated forms and quantities of medical cannabidiol waste to be generated or collected;
3. The disposal methods for all waste materials;
4. Employee training methods for the dispensary employees;
5. Strategies for identifying and reconciling discrepancies in inventory of medical cannabidiol;
6. Procedures to ensure the dispensary does not dispense more than a patient's certified limit of total tetrahydrocannabinol to a patient and the patient's primary caregiver(s) in a 90-day period;
7. Medical cannabidiol labeling procedures;
8. Procedures for recall of medical cannabidiol;
9. Plans for responding to a security breach at the dispensary facility;
10. A business continuity plan; and
11. Other information requested by the department.

(2) Procedures to ensure accurate recordkeeping.

(3) Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas of the dispensary facility containing medical cannabidiol.

154.36(2) *Prohibited activities.* In addition to following all provisions of Iowa Code section 124E.7, a dispensary shall not:

a. Dispense medical cannabidiol in any location except in those areas approved by the department;

b. Sell, receive, transport, or distribute medical cannabidiol from any location except its dispensary;

c. Sell, receive, or distribute medical cannabidiol from any entity other than a manufacturer licensed by the department;

d. Sell or distribute medical cannabidiol to any person other than an approved patient or primary caregiver;

(1) Transport or deliver medical cannabidiol to any location, unless approved by the department;

(2) Sell medical cannabidiol that is not packaged and labeled in accordance with rules;

(3) Repackage medical cannabidiol or remove the manufacturer's label.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.37(124E) Recordkeeping requirements.

154.37(1) *Dispensary sales.* Within one business day of sale, a dispensary shall record complete and accurate electronic sales transaction records in the secure sales and inventory tracking system, including:

a. The name of the patient and, if purchase is made by the primary caregiver, the name of the primary caregiver;

b. The date and time of each sale;

c. The item number, product name and description, and quantity of medical cannabidiol sold;

d. The sale price;

e. Other information required by the department.

154.37(2) Reserved.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.38(124E) Storage.

154.38(1) *Storage of saleable medical cannabidiol.*

a. A dispensary shall store medical cannabidiol to prevent diversion, theft, or loss, including ensuring that:

(1) Medical cannabidiol is kept in a secure and monitored location within the dispensary; and

(2) Cabinets or storage containers inside the secure and monitored area are locked at the end of a business day.

b. A dispensary shall store all medical cannabidiol:

(1) In areas that are maintained in a clean, orderly, and well-ventilated condition;

(2) In areas that are free from infestation by insects, rodents, birds, and other pests of any kind;

(3) According to the manufacturer's requirements regarding temperature, light exposure, or other environmental conditions;

(4) Under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

154.38(2) *Storage of returned medical cannabidiol.* A dispensary shall maintain a separate secure storage area for medical cannabidiol that is to be returned to a manufacturer for disposal, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the medical cannabidiol is collected by a manufacturer.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.39(124E) Dispensing.

154.39(1) *Access to all forms of product.* A dispensary shall provide access to all medical cannabidiol forms produced by each licensed manufacturer.

154.39(2) *Dispensing to a patient or primary caregiver.* Prior to dispensing any medical cannabidiol to a patient, a dispensary shall do all of the following:

a. Verify the patient or primary caregiver's identity using acceptable photo identification and that the patient or primary caregiver is over 18 years of age. Acceptable photo identification includes:

(1) A valid driver's license;

(2) A valid nonoperator's identification card;

(3) A U.S. passport;

(4) A U.S. military ID or veteran ID; or

(5) A tribal ID card/document;

b. Verify that the patient or primary caregiver, if applicable, is registered and listed in the secure sales and inventory tracking system and has a valid medical registration card;

c. Check the secure sales and inventory tracking system for the patient's total tetrahydrocannabinol 90-day purchase limit and the amount of total tetrahydrocannabinol that the patient and the patient's primary caregiver(s) have purchased on behalf of the patient in the past 90 days to ensure that the amount of total tetrahydrocannabinol sold by the dispensary to the patient does not exceed the patient's purchase limit;

d. Assign a tracking number to any medical cannabidiol that is to be dispensed to the patient or primary caregiver; or

e. Issue a label that contains the following information, which may be printed on a secondary label or package insert:

(1) The medical cannabidiol tracking number;

(2) The patient registration number;

(3) The date and time the medical cannabidiol is dispensed;

(4) The name and address of the dispensary; and

(5) Any specific instructions for use based upon manufacturer guidelines or department rules. Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; **ARC 0786D**, IAB 11/25/26, effective 1/1/27]

641—154.40(124E) Transportation of medical cannabidiol. A dispensary is not authorized to transport medical cannabidiol, unless approved by the department. Any approved transport shall be logged in the secure sales and inventory tracking system.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.41(124E) Disposal of medical cannabidiol.

154.41(1) *Identification of excess, expired, or damaged medical cannabidiol.* Dispensaries shall identify unused, excess, expired, or damaged medical cannabidiol.

154.41(2) *Return of medical cannabidiol from a patient or primary caregiver to a dispensary.*

a. A dispensary shall accept at no charge medical cannabidiol waste from any patient or primary caregiver. A dispensary may provide all medical cannabidiol waste to the manufacturer for disposal.

b. The dispensary shall enter the following information into the secure sales and inventory tracking system for medical cannabidiol returned from a patient or primary caregiver being returned to the manufacturer:

(1) The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable;

(2) The date the medical cannabidiol was returned;

(3) The quantity of medical cannabidiol returned; and

(4) The type and lot number of medical cannabidiol returned.

c. A dispensary shall store medical cannabidiol returned from patients and primary caregivers.

154.41(3) *Unused, excess, expired, damaged, or returned medical cannabidiol.* Unused, excess, expired, damaged, or returned medical cannabidiol shall be stored as described in subrule 154.38(2).

154.41(4) *Return of medical cannabidiol to a manufacturer.* A dispensary shall record information on all medical cannabidiol collected by the manufacturer in the secure sales and inventory tracking system. Information shall include:

a. The date the medical cannabidiol was collected by the manufacturer;

b. The quantity of medical cannabidiol collected; and

c. The type and lot number of medical cannabidiol collected.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.42(124E) Inventory.

154.42(1) *Inventory controls and procedures.* A dispensary shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.42(2) *Real-time inventory required.* A dispensary shall use the secure sales and inventory tracking system to maintain a real-time record of the dispensary's inventory of medical cannabidiol to include:

a. The quantity and form of saleable medical cannabidiol maintained at the dispensary on a daily basis;

b. The amount of damaged, expired, or returned medical cannabidiol being held at the dispensary for return to a manufacturer; and

c. Other information deemed necessary and requested by the department.

154.42(3) *Reconciliation.* At least once per calendar week, a dispensary shall reconcile all medical cannabidiol with the inventory recorded in the secure sales and inventory tracking system. Discrepancies shall be handled as follows:

a. A dispensary shall report suspected diversion of medical cannabidiol to the department and law enforcement within 24 hours of discovery.

b. A dispensary shall have up to 24 hours to reconcile the dispensary's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the dispensary cannot reconcile the dispensary's physical inventory with the secure sales and inventory tracking system's inventory within 24 hours but diversion of product is not suspected, the dispensary shall immediately contact the department to report the discrepancy and to initiate a compliance action.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.43(124E) Quality assurance and control. A dispensary shall cooperate with manufacturers and the department on quality assurance and control procedures, including participating in stability-testing studies, developing sampling strategies, and returning medical cannabidiol that has been recalled.
[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

MEDICAL CANNABIDIOL BOARD

641—154.44(124E) Purpose and duties of board. The purpose of the board is to administer the provisions of Iowa Code section 124E.5.
[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.45(124E) Organization of board and proceedings.

154.45(1) *Membership.* The board shall be composed of members as set forth in Iowa Code section 124E.5. The appointments, unless provided otherwise by law, shall be for three-year staggered terms that shall expire on June 30. Board members shall be knowledgeable about the use of medical cannabidiol. The medical practitioners appointed to the board shall be licensed in Iowa and be nationally board-certified in their area of specialty.

154.45(2) *Vacancies.* Vacancies shall be filled in the same manner in which the original appointments were made for the balance of the unexpired term.

154.45(3) *Absences.* Three consecutive unexcused absences shall be grounds for the governor to consider dismissal of a board member and to appoint another. Department staff is charged with providing notification of absences to the governor's office.

154.45(4) *Board meetings.*

a. Board meetings shall be conducted in accordance with the open meetings requirements of Iowa Code chapter 21.

b. The department's bureau of cannabis regulation shall schedule the time, date and location of meetings.

c. A majority of the members shall constitute a quorum for conducting business of the board.

d. An affirmative vote of a majority of the board members present at a meeting is required for a motion to pass.

154.45(5) *Facilities and staffing.* The department shall furnish the board with the necessary facilities and employees to perform the duties required by this chapter but shall be reimbursed for all costs incurred by fee revenue generated from licensing activities and registration card applications.

154.45(6) *Subcommittees.* The board may designate one or more subcommittees to perform such duties as may be deemed necessary.
[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.46(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases. Pursuant to Iowa Code section 124E.5(3)*"a,"* the board shall accept and review petitions to modify the list of debilitating medical conditions for the medical use of cannabidiol. The petition shall be in accordance with 7—Chapter 2502, except that the caption should read "Petition for Addition or Removal."

154.46(1) *Inquiries.* Inquiries concerning the status of a petition may be made to the bureau of cannabis regulation at the department's address.

154.46(2) *Additional information.* The board may request that the petitioner submit additional information concerning the petition. The board may also solicit comments from any person on the substance of the petition. Comments on the substance of the petition may be submitted to the board by any person.

154.46(3) *Presentation to the board.* The board may request or allow the petitioner to make an oral presentation of the contents of a petition at a board meeting following submission of the petition.

154.46(4) *Board response.* The board shall notify the petitioner in writing of the decision within six months after the filing, unless the petitioner agrees to a time extension. If the petition is granted, the board will recommend addition or removal of the medical condition, medical treatment or debilitating disease

to the board of medicine. If the petition is denied, the board will provide the rationale for the denial. Notification occurs when the board mails the writing to the petitioner.

154.46(5) *Denials.* Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the agency's rejection of the petition.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24; Editorial change: IAC Supplement 6/10/26]

LABORATORY TESTING

641—154.47(124E) Requirements of the department.

154.47(1) *Laboratory testing requirements and acceptance criteria.* The department shall work with manufacturers and laboratories to create and maintain a document describing required sampling methodology, acceptance criteria, stability-testing procedures, and other guidance for manufacturers and laboratories on testing procedures. The department shall provide manufacturers and laboratories no less than 14 days in which to comment on proposed revisions to the document, and the department shall provide no less than 30 days' notice before a revision takes effect. The document shall:

a. Describe the minimum number of sample units and reserve samples required for testing by the laboratory;

b. Describe an option for manufacturers to reduce the amount of testing conducted by allowing compositing of sample units or other techniques that reduce the number of tests required without compromising the safety of the products once a manufacturer has satisfactorily completed a control study for a specific extraction or production process;

c. Describe the minimum requirements for sample size and testing intervals for stability testing; and

d. Be available on the department's website (hhs.iowa.gov).

154.47(2) *Review and approval of manufacturer sampling protocols.* The department shall have two weeks to review and approve or request revisions to a manufacturer's sampling protocols.

154.47(3) *Review and approval of manufacturer stability-testing procedures.* The department shall have two weeks to review and approve or request revisions to a manufacturer's stability-testing procedures.

154.47(4) *Establish a laboratory review committee.* The department shall establish a laboratory review committee to assist with the review of applications by laboratories and the establishment of accepted laboratory testing standards and practices.

154.47(5) *Review of laboratory applications.* The department shall establish a process to review applications from prospective medical cannabidiol testing laboratories. Prospective laboratories shall apply on a form created by the department. The department will determine whether the laboratory meets the criteria for an independent medical cannabidiol testing facility as set forth in the definition of "laboratory" in Iowa Code section 124E.2 in addition to determining whether the laboratory meets laboratory requirements pursuant to these rules.

154.47(6) *Regulation of independent laboratories.* The department shall determine on an annual basis whether any approved independent laboratory continues to meet the application criteria of this rule. The department shall establish a process for the annual review of approved independent laboratories. An independent laboratory is subject to reasonable inspection by the department, a department-approved consultant, or another agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.48(124E) Requirements of a laboratory.

154.48(1) *Minimum testing requirements.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for the analyses of cannabinoids, residual solvents and processing chemicals, pesticides, microbiological impurities, and metals and other analyses as requested by the department.

154.48(2) *Level of quantitation.* A laboratory shall be able to demonstrate that its level of quantitation (LOQ) is below any action level established by the department.

154.48(3) *Inventory tracking.* A laboratory shall record the following:

a. The receipt of medical cannabidiol from a manufacturer for testing.

b. The return of medical cannabidiol or waste to a manufacturer.

154.48(4) *Hazardous waste disposal.* A laboratory shall do the following when dealing with hazardous waste:

a. Discard hazardous waste, including hazardous waste containing medical cannabis goods, in accordance with federal and state hazardous waste laws.

b. Document the waste disposal procedures followed for each sample.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.49(124E) Requirements of a manufacturer.

154.49(1) *Assuming costs.* A manufacturer shall assume the costs for all laboratory testing pertaining to verification studies on new products, the cost of standard testing protocols as outlined in a Laboratory Acceptance and Criteria Document and other tests as requested by the department. A manufacturer shall provide any necessary reference materials to the laboratory at no cost.

154.49(2) *Obtaining approval for sampling protocols.* A manufacturer shall obtain approval from the department for the manufacturer's sampling protocols prior to submitting samples for laboratory testing related to content and contamination.

154.49(3) *Obtaining approval for stability-testing procedures.* A manufacturer shall obtain approval from the department for the manufacturer's stability-testing procedures prior to submitting samples for laboratory testing related to stability testing and product-expiration-date studies.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.50(124E) Content testing.

154.50(1) *Cannabinoids.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall, at minimum, test for and report measurements for the following cannabinoid analytes:

(1) THC;

(2) THCA;

(3) CBD; and

(4) CBDA.

b. A laboratory shall report that the primary sample passed or failed THC and CBD potency testing according to guidance in the Laboratory Acceptance and Criteria Document described in subrule 154.47(1).

c. For each cannabinoid analyte test, a laboratory shall issue a certificate of analysis that contains the following:

(1) Concentrations of cannabinoid analytes in mg/ml for liquids and mg/g for solids, or other measures approved by the department.

(2) Whether the primary sample passed or failed the test in accordance with paragraph 154.50(1)*"b."*

d. The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.

154.50(2) *Contaminants testing.*

a. For each unique lot of medical cannabidiol, unless otherwise referenced in the laboratory testing requirements and acceptance criteria document described in subrule 154.47(1), a laboratory shall conduct contaminants testing for the following analytes:

(1) Residual solvents and processing chemicals.

(2) Pesticides.

(3) Microbiological impurities.

(4) Heavy metals.

b. The laboratory may test and provide test results for additional contaminants if asked to do so by a requestor.

c. The department shall provide a list of contaminants for which primary samples are to be tested with corresponding action levels on the department's website (hhs.iowa.gov).

d. For each contaminant for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of contaminant is at or below the action level approved by the department.

e. For each contaminant for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of contaminants is above the action level approved by the department.

f. If a laboratory is using gas chromatography-mass spectrometry instrumentation to analyze primary samples for contaminants and the laboratory determines that a primary sample contains contaminants or chemical analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the contaminant analytes.

g. The laboratory may test for and provide test results for additional contaminants or processing chemicals if asked to do so by a requester.

h. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each contaminant for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any contaminant that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.50(2)*"c"* and *"d."*

(3) The names and amounts of any additional contaminants identified by the laboratory.

i. If the primary sample fails testing for residual solvents and processing chemicals, the lot fails laboratory testing.

j. When a laboratory identifies additional contaminants in a primary sample, the laboratory shall:

(1) Notify the department of the additional contaminants and the amounts detected, if applicable.

(2) Refrain from issuing a final certificate of analysis until given approval to do so by the department.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.51(124E) Reporting requirements.

154.51(1) *Reporting test results.* The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer and the department.

154.51(2) *Tentatively identified analytes.* A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

a. Notify the department of the additional analytes detected.

b. Refrain from issuing a final certificate of analysis until given approval to do so by the department.

154.51(3) *Additional reporting requirements.* In addition to the requirements described in rule 641—154.50(124E), the certificate of analysis shall contain, at a minimum, the following information:

a. All requirements of ISO/IEC 17025 dated 2017;

b. Date of primary sample collection;

c. Date the primary sample was received by the laboratory;

d. Date of each analysis;

e. The LOQ and action level for each analyte, as applicable;

f. Whether the primary sample and lot passed or failed laboratory testing; and

g. A signature by the laboratory quality officer or delegate and the date the certificate of analysis was validated as being accurate by the laboratory quality officer or delegate.

154.51(4) *Measurements.*

a. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.

b. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.

c. Measurements greater than or equal to LOD but less than LOQ shall be reported as "detected but not quantified."

d. The number of significant figures reported shall reflect the precision of the analysis.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.52(124E) Recordkeeping requirements.

154.52(1) *Data package.* A laboratory shall create a data package for each analytical batch of primary samples that the laboratory analyzes. The data package shall contain at minimum the following information:

a. The name and address of the laboratory that performed the analytical procedures;

b. The names, functions, and signatures (electronic or handwritten) of the laboratory personnel who performed the primary sample preparation, analyzed the primary samples, and reviewed and approved the data;

c. All primary sample and analytical batch quality control sample results;

d. Raw data for each primary sample analyzed;

e. Instrument raw data, if any was produced;

f. Instrument test method with parameters;

g. Instrument tune report, if one was created;

h. All instrument standard calibration data;

i. Test-method worksheets or forms used for primary sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;

j. The quality control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

k. The analytical batch sample sequence;

l. The field sample log; and

m. The chain-of-custody form.

154.52(2) *Review of data package.* After the laboratory has compiled a data package, an individual at the laboratory who was not previously involved in the creation of the data package shall:

a. Assess the analytical results for technical correctness and completeness;

b. Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively;

c. Verify that the measurements can be traced back; and

d. Approve the measurement results by signing and dating the data package prior to release of the certificate of analysis by the laboratory.

154.52(3) *Data package record retention.* The entire data package shall be stored by a laboratory for a minimum of five years and shall be made available upon request by the department or the requester of the laboratory testing.

154.52(4) *Other records.* A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabidiol.

a. A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, the date the analysis was performed, the approver of the certificate of analysis, the reviewer and approver of the data package, the test method, and the materials that were used can be determined by the department.

b. Records shall be stored in such a way that the data may be readily retrieved when requested by the department.

c. All testing laboratory records shall be kept for a minimum of five years, unless otherwise noted in these rules.

d. The department shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, and laboratory notebooks.

e. A laboratory shall keep and make available to the department the following records related to the testing of medical cannabidiol:

(1) Personnel qualification, training, and competency documentation, including but not limited to résumés, training records, continuing education records, analytical proficiency testing records, and demonstration of competency records for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records and reference material analysis records.

(3) Quality control and quality assurance records, including the laboratory's quality assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These records shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records, including customer contracts, customer requests, certificates of analysis, customer transactions, customer feedback, records related to the handling of complaints and nonconformities, and corrective action pertaining to complaints.

(8) Nonconforming work and corrective action records, including corrective action, nonconformance, nonconformities resolved by correction, customer notification of nonconformities, internal investigations, implementation of corrective action, and resumption-of-work records.

(9) Internal-audit and external-audit records, including audit checklists, standard operating procedures, and audit observation and findings reports. These records shall include the date and name of the person performing the audit.

(10) Management review records, including technical data review reports and final management-review reports. These records shall include the review date and the name of the reviewer.

(11) Laboratory data reports, data review, and data approval records, including instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data. These records shall include the analysis date and the name of the analyst.

(12) Proficiency testing records, including the proficiency test schedule, proficiency tests, data-review records, data-reporting records, nonconforming work and corrective actions, and quality control and quality assurance records related to proficiency testing.

(13) Electronic data, backed up data, records regarding the protection of data, including unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, and authorized personnel records.

(14) Security data, including laboratory-security records and laboratory-access records, surveillance-equipment records, and security-equipment records. These records shall be stored for at least one year.

(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(16) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.53(124E) Quality control. The laboratory shall have quality control protocols that include the following elements:

154.53(1) *Quality control samples required.*

a. The laboratory shall run quality control samples with every analytical batch of samples for chemical and microbiological analysis.

b. For microbiological analysis, the laboratory shall develop procedures for quality control requirements for each analytical batch of samples.

c. The laboratory shall analyze the quality control samples in exactly the same manner as the test samples to validate the laboratory testing results.

154.53(2) *Types of quality control samples.* At a minimum, a laboratory shall have the following quality control samples as part of every analytical batch tested for chemical analytes:

a. Negative control (method blank). A laboratory shall prepare and run at least one method blank sample with an analytical batch of samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

b. Positive control (laboratory control sample). A laboratory shall prepare and run at least one laboratory control sample with an analytical batch of samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch.

c. Matrix spike sample. A laboratory shall prepare and run one or more matrix spike samples for each analytical batch.

(1) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. All quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance criteria shall be used. When necessary, the department may establish acceptance criteria on the department's website (hhs.iowa.gov).

(2) If quality control acceptance criteria are not acceptable, a laboratory shall investigate the cause, correct the problem, and rerun the analytical batch of samples. If the problem persists, the laboratory shall reprepare the samples and run the analysis again, if possible.

d. Field duplicate sample. A laboratory shall prepare and run a duplicate sample as described in the laboratory testing requirements and acceptance criteria document in subrule 154.47(1). The acceptance criterion between the primary sample and the duplicate sample is less than or equal to 20 percent relative percent difference.

154.53(3) *Certified reference material for chemical analysis.* The laboratory shall use a reference material for each analytical batch in accordance with the following standards:

a. The reference material should be certified and obtained from an outside source, if possible. If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material.

b. Reference material made in-house should be made from a different source of standards than the source from which the calibration standards are made.

c. The test result for the reference material shall fall within the quality control acceptance criteria. If it does not, the laboratory shall document and correct the problem and run the analytical batch again.

154.53(4) *Calibration standards.* The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of an instrument and quantitation of analyses in samples.

154.53(5) *Quality control-sample report.* A laboratory shall generate a quality control-sample report that includes quality control parameters and measurements, analysis date, and type of matrix.

154.53(6) *Limit-of-detection and limit-of-quantitation calculations.* For chemical method analysis, a laboratory shall calculate the limit of detection and limit of quantitation using generally accepted methodology.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

641—154.54(124E) Security requirements.

154.54(1) *Security policy requirement.* A laboratory shall maintain a security policy to prevent the loss, theft, or diversion of medical cannabidiol samples. The security policy shall apply to all staff and visitors at a laboratory facility.

154.54(2) *Restricted access.* A laboratory shall limit entrance to all restricted areas by completing all of the following:

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track when personnel enter and exit the laboratory;

(4) Track times of personnel movement between restricted access areas;

(5) Store data for retrieval for a minimum of one year; and

(6) Remain operable in the event of a power failure.

b. A laboratory shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

154.54(3) *Personnel identification system.* A laboratory shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the laboratory facility.

a. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance and expiration;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A laboratory employee shall keep the identification card visible at all times when the employee is in the laboratory.

c. Upon termination or resignation of an employee, a laboratory shall immediately:

(1) Revoke the employee's access to the laboratory; and

(2) Obtain and destroy the employee's identification card, if possible.

154.54(4) *Video monitoring and surveillance.* A laboratory shall operate and maintain in good working order a video surveillance system for its premises that operates 24 hours per day, seven days a week, and visually records all areas where medical cannabis goods are stored or tested.

a. Camera specifications. Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a restricted access area containing medical cannabis goods;

(2) Produce a clear, color still photograph live or from a recording;

(3) Have an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

b. Video recording specifications. Video recording equipment shall:

(1) Export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Archive in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Save exported video in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

c. Additional requirements. A laboratory shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

d. Retention. A laboratory shall ensure that 24-hour recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for a minimum of 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a laboratory is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

154.54(5) *Chain-of-custody policy and procedures.* A laboratory shall maintain a current chain-of-custody policy and procedures. The policy should ensure that:

a. Chain of custody is maintained for samples that may have probable forensic evidentiary value; and

b. Annual training is available for individuals who will be involved with testing medical cannabis goods.

154.54(6) *Information technology systems security.* A laboratory shall maintain information technology systems protection by employing comprehensive security controls that include security firewall protection, antivirus protection, network and desktop password protection, and security patch management procedures.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]

These rules are intended to implement Iowa Code chapter 124E.

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[1] July 10, 2019, effective date of Items 1, 4, 7, 10, 11, 12, 13, 15, 21, 22, and 24 of **ARC 4489C** delayed until the adjournment of the 2020 session of the General Assembly by the Administrative Rules Review Committee at its meeting held July 9, 2019.

[1] The effective date of **ARC 4928C** was corrected to June 1, 2020, in the March 11, 2020, Iowa Administrative Bulletin.

CHAPTER 155
LICENSURE STANDARDS FOR SUBSTANCE USE DISORDER AND PROBLEM GAMBLING TREATMENT PROGRAMS

[Prior to 7/27/88, see Substance Abuse, Iowa Department of[805] Ch 3]
[Prior to 3/29/06, see 643—Ch 3]

Chapter rescission date pursuant to Iowa Code section 17A.7: 10/1/30

641—155.1(125,135) Definitions. Unless otherwise indicated, the following definitions apply to the specific terms used in these rules:

"Accredited opioid treatment program" means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by the Substance Abuse and Mental Health Services Administration (SAMHSA).

"Addictive disorder" means a substance use disorder and problem gambling.

"Addictive disorder professional" means an individual who is qualified by virtue of certification or license and education, training and experience to provide program services.

"Administration" means the direct application of a prescription medication to a patient by a prescriber or the prescriber's authorized agent.

"Admission" means the point at which an initial assessment has been completed sufficient to determine the patient's need and eligibility for program services and the patient has agreed to begin treatment.

"Admission, continued service, and discharge criteria" means the ASAM criteria dimensions to be considered in determining the level of care appropriate for the patient.

"Applicant" means a person, facility, or legal entity that has applied for an initial license, renewal of a license, or a license under deemed status pursuant to these rules.

"Application" means the process through which an applicant requests an initial license, renewal of a license, or a license under deemed status pursuant to these rules.

"ASAM criteria" means the clinical guide for the treatment of addictive, substance use and co-occurring conditions as published by the American Society of Addiction Medicine (ASAM) and as amended to August 1, 2025.

"Assessment" means the ongoing process of evaluating a patient's strengths, resources, preferences, limitations, problems, and needs; determining the licensed program services needed by the patient; determining the patient's eligibility for program services; and identifying treatment plan priorities, in accordance with the ASAM criteria and accepted standards of practice.

"Care coordination" or *"case management"* means the collaborative process that assesses, plans, implements, coordinates, monitors and evaluates the options and services, both internal and external to the program, to meet patient needs, using communication and available resources to promote quality care and effective outcomes.

"Certification" means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the federal opioid treatment standards.

"Certification application" means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA.

"Certified opioid treatment program" means an opioid treatment program that is the subject of a current, valid certification.

"Chemical substance" means alcohol, wine, spirits and beer as defined in Iowa Code chapter 123 and controlled substances as defined in Iowa Code section 124.101.

"Clinically managed" means that program services are directed by addictive disorder professionals.

"Clinically managed high-intensity residential treatment" means the ASAM criteria level of care totaling at least 50 hours of clinically managed inpatient treatment services per week.

"Clinically managed low-intensity residential treatment" means the ASAM criteria level of care totaling at least five hours of clinically managed inpatient treatment services per week.

"Clinically managed medium-intensity residential treatment" means the ASAM criteria level of care totaling at least 30 hours of clinically managed inpatient treatment services per week.

"Clinical oversight" means oversight provided by an individual who, by virtue of certification or license and education, training and experience is qualified to oversee treatment services in accordance with subrule 155.21(3).

"Comprehensive maintenance treatment" means maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

"Concerned person" means an individual who is seeking treatment services due to problems arising from a personal relationship with an individual with an addictive disorder.

"Confidentiality" means protection of patient information in compliance with state and federal law.

"Crisis stabilization" means medically monitored subacute inpatient services for individuals with urgent addictive disorder needs requiring immediate intervention, assessment, and mobilization of family, community and program resources.

"Data reporting" means the required submission of certain patient demographic and program services information to the department by a program.

"Dimension" means one of the six ASAM criteria patient biopsychosocial areas to be considered in the assessment process to identify patient needs and determine the appropriate level of care for admission and continued services.

"Discharge" means the point at which the patient ceases participation in licensed program services, marking the end of a specific encounter or episode of care. Discharge does not require termination of the relationship between the patient and the program.

"Discharge planning" means the process, begun at admission, of determining a patient's continued need for licensed program services and of developing a plan to address ongoing patient needs following discharge.

"DSM" means the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association as amended to August 1, 2025, and all references to the DSM herein are as amended to August 1, 2025.

"Early intervention" means the ASAM criteria level of care that explores and addresses problems or risk factors that appear to be related to an addictive disorder and that helps the individual recognize potential harmful consequences.

"Enhanced program" means a licensee that provides enhanced treatment services in accordance with paragraph 155.2(2)*"j"* and rule 641—155.34(125,135).

"Enhanced treatment services" means licensed program services provided in accordance with paragraph 155.2(2)*"j"* and rule 641—155.34(125,135).

"Facility" means an institution or an installation providing care, maintenance or treatment for persons with substance use disorders licensed by the department under Iowa Code section 125.13, hospitals licensed under Iowa Code chapter 135B, or the state mental health institutes designated by Iowa Code chapter 226. "Facility" also means the physical areas such as grounds, buildings, or portions thereof under administrative control of the program.

"Governing body" means the person, group, or legal entity that has ultimate authority and responsibility for the overall operation of the program.

"Inpatient" means 24-hour licensed program services.

"Intensive outpatient treatment" means the ASAM criteria level of care totaling a minimum of nine hours of clinically managed outpatient treatment services per week for adults or a minimum of six hours of clinically managed outpatient treatment services per week for juveniles.

"Interim maintenance treatment" means withdrawal management for a period of more than 30 days but not in excess of 180 days.

"Level of care" or *"level of service"* means the different ASAM criteria service options. "Level of care" also means certain licensed program services under these rules.

"Licensed program services" means the services a licensee may be authorized to provide under these rules.

"Licensee" means a program licensed by the department pursuant to these rules.

"Licensure" means the issuance of a license by the department pursuant to these rules that validates the licensee's compliance with these rules and authorizes the licensee to operate a program in the state of Iowa.

"Licensure weighting report" means the department's report that is used to determine an applicant's level of compliance with these rules and the length of time a license will be in effect.

"Maintenance" means the prolonged, scheduled administration of an opiate agonist medication such as buprenorphine or methadone by an opioid treatment program in accordance with federal and state laws, rules and regulations.

"Maintenance treatment" means the dispensing of a medication for opioid use disorder (MOUD) at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

"Management of care" means the ongoing application of the ASAM criteria and the coordination of care to ensure the appropriate provision of licensed program services to a patient.

"Medical and rehabilitative services" means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement) that are intended to help patients in opioid treatment programs become or remain productive members of society.

"Medical director" means a physician who is licensed to practice medicine in accordance with Iowa Code chapter 148 and who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.

"Medically managed" means that the inpatient program services that involve daily medical care in a hospital setting are directed by a prescriber.

"Medically managed intensive inpatient treatment" means the ASAM criteria level of care for medically managed inpatient treatment services.

"Medically monitored" means that the program services are directed by addictive disorder professionals with medical oversight by a prescriber.

"Medically monitored intensive inpatient treatment" means the ASAM criteria level of care for medically monitored subacute inpatient treatment services.

"Medication-assisted treatment" means the medically monitored use of certain substance use disorder medications in combination with other treatment services.

"Medication unit" means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit.

"Opioid addiction" means a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opioids despite significant opiate-induced problems. Opioid dependence is characterized by an individual's repeated self-administration of opioids that usually results in opioid tolerance, withdrawal symptoms, and compulsive drug-taking. Dependency may occur with or without the physiological symptoms of tolerance and withdrawal.

"Opioid agonist treatment medication" means any opioid agonist drug that is approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 as amended to August 1, 2025) for use in the treatment of opiate addiction.

"Opioid drug" means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

"Opioid treatment program" or *"OTP"* means a substance use disorder treatment program or a substance use disorder and problem gambling treatment program licensed to provide opioid treatment services in accordance with Iowa Code section 125.21 and rules 641—155.2(125,135) and 641—155.35(125,135).

"Opioid treatment services" means medically monitored outpatient maintenance services provided in accordance with federal and state laws, rules and regulations.

"Opioid use disorder treatment" or *"OUD treatment"* means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based

on an individualized assessment and a mutually agreed-upon care plan, to an individual to alleviate the combination of adverse medical, psychological, or physical effects associated with an OUD.

"Outpatient" means non-24-hour licensed program services.

"Outpatient treatment" means the ASAM criteria level of care totaling less than nine hours of clinically managed outpatient treatment services per week for adults and less than six hours of clinically managed outpatient treatment services per week for juveniles.

"OWI evaluation" means an assessment completed solely for the purpose of compliance with the substance abuse evaluation requirements of Iowa Code chapter 321J.

"Partial/day treatment" means the ASAM criteria level of care totaling 20 or more hours of clinically managed outpatient treatment services per week.

"Patient" means an individual who participates in licensed program services.

"Placement" means selection of an appropriate licensed program service, based on ongoing assessment.

"Prescriber" means a licensed health care professional with the authority to prescribe medication in accordance with Iowa law.

"Prevention" means activities aimed at minimizing the use of potentially addictive substances, lowering risk in at-risk individuals, or minimizing potential adverse consequences of substance use or gambling.

"Prime programming time" means any period of the day, as determined by a program treating juveniles, when special attention or supervision is necessary.

"Problem gambling" means a gambling disorder that results in a functional impairment of sufficient impact and duration to meet diagnostic criteria specified within the DSM.

"Program" means a person, facility, institution, building, agency or legal entity that provides one or more of the services stated in subrule 155.2(2) and is required to be licensed under these rules.

"Program sponsor" means the person responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

"Quality improvement" means the process of objectively and systematically monitoring and evaluating the quality and appropriateness of patient care and program services and operations to resolve identified problems and to make continued improvements.

"Recovery" means the process of addressing an addictive disorder and working toward personally defined health and well-being.

"Recovery supports" means the broad range of nontreatment services, such as transportation, that assists patients in their recovery efforts.

"Rehabilitation" means the restoration of an optimal state of health by medical, psychological, and social means, including peer group support.

"Residential" means clinically managed inpatient treatment services.

"Screening" means the brief review of a patient's or potential patient's current risk factors for an addictive disorder or medical or mental health condition to determine if they indicate a need for immediate admission or referral. Screening is not an assessment and is not sufficient to develop a treatment plan, rule out an addictive disorder, or determine that admission to treatment or referral to other services is not indicated.

"Short-term withdrawal management treatment" means withdrawal management treatment for a period not in excess of 30 days.

"Self-administration of medication" means the process whereby a properly trained and qualified staff person observes a patient take medication prescribed by a prescriber.

"Staff" means any individual who conducts an activity on behalf of a program as an employee, agent, consultant, contractor, volunteer or other status.

"Standards category" means the grouping of standards, such as clinical, administrative or programming, in the licensure weighting report.

"State authority" means the department, which regulates the treatment of opioid addiction with opioid drugs.

"Subacute" means medically monitored inpatient services for individuals who require management, supervision and treatment to reduce immediate risk of danger to self or others or severe disability or complication of an addictive disorder or an addictive disorder and a medical or mental health condition.

"Substance abuse treatment and rehabilitation facility" or *"substance abuse treatment program"* means a program required to be licensed under these rules.

"Substance use disorder" means a substance use disorder that results in a functional impairment of sufficient impact and duration to meet diagnostic criteria specified within the DSM.

"Telehealth" means the same as defined in Iowa Code section 514C.34(1).

"Time frames" means the periods of time specified throughout the standards.

"Treatment" means the broad range of planned services to identify and change patterns of behavior that are maladaptive, destructive or injurious to health or to restore appropriate levels of physical, psychological or social functioning. Such services may include assessment; care coordination; crisis stabilization; withdrawal management; early intervention; health promotion; individual, group and family counseling; management of care; and medication administration, provided by addictive disorder professionals and a mix of medical, mental health and peer professionals as appropriate to the structure of the program.

"Treatment plan" means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and that specifies the services to be provided and the frequency and schedule for their provision.

"Treatment planning" means the process, based on ongoing assessment, by which a patient and qualified staff identify and rank problems, establish agreed-upon goals, and decide on the treatment services and resources to be utilized.

"Withdrawal management" means the safe management of intoxication states and withdrawal states in accordance with the ASAM criteria and accepted standards of practice.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.2(125,135) Licensing. In accordance with Iowa Code section 125.13, a person shall not maintain or conduct a substance use disorder program without having first obtained a license for the program from the department, and in accordance with Iowa Code section 135.150, a person shall not maintain or conduct a problem gambling treatment program funded by the department unless the person has obtained a license for the program from the department. The provision of treatment to a patient through any electronic means, regardless of the location of the program or facility, shall constitute the practice of treatment in the state of Iowa and shall be subject to regulation in accordance with Iowa Code chapter 125, Iowa Code section 135.150, and these rules. An applicant shall apply for one license only. The department will award one license only to an applicant or licensee.

155.2(1) *Program licenses.* The department will offer the following program licenses:

a. A substance use disorder assessment and OWI evaluation-only program license.

b. A substance use disorder treatment program license.

c. A problem gambling treatment program license.

d. A substance use disorder and problem gambling treatment program license.

155.2(2) *Licensed program services.* The license will delineate the licensed program service(s) the program is authorized to provide and will specify that each licensed program service is licensed for adults, juveniles, or adults and juveniles. Licensed program services are:

a. Substance use disorder assessment and OWI evaluation only, provided by a substance use disorder assessment and OWI evaluation-only program;

b. Outpatient treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;

c. Intensive outpatient treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;

d. Partial/day treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;

e. Clinically managed low-intensity residential treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;

f. Clinically managed medium-intensity residential treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;

g. Clinically managed high-intensity residential treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;

h. Medically monitored intensive inpatient treatment, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program;

i. Medically managed intensive inpatient treatment, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program;

j. Enhanced treatment services, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program;

k. Opioid treatment services, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program.

155.2(3) *Licensing body.* The department will consider and approve or deny all license applications, suspensions and revocations.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.3(125,135) Types of licenses.

155.3(1) The department may issue an initial license for 270 days to a new applicant scoring a minimum rating of 70 percent in each standards category on the licensure weighting report. An initial license shall expire in 270 days and shall not be extended or renewed.

155.3(2) The department may issue a license subsequent to an initial license for one, two, or three years based on the applicant's rating on the licensure weighting report.

a. An applicant achieving a rating of 95 percent or higher in each standards category may qualify for a three-year license.

b. An applicant achieving a rating of less than 95 percent but not less than 90 percent in each standards category may qualify for a two-year license.

c. An applicant achieving a rating of less than 90 percent but not less than 70 percent in each standards category may qualify for a one-year license.

d. A license for one, two, or three years shall expire on the date noted on the license and shall not be extended but may be renewed upon application.

155.3(3) The department may issue a license under deemed status to an applicant providing required documentation of accreditation by a recognized accreditation body. A deemed-status license will be effective for the same time frame as that of the accreditation granted by the accreditation body, up to three years.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.4(125,135) Nonassignability.

155.4(1) A license issued by the department for the operation of a program applies both to the licensee and the facility in which the program is operated. A license is not transferable.

155.4(2) A closing program is one that intends to cease providing licensed program services. The licensee shall notify the department 30 days before ceasing service provision. The licensee shall be responsible for the transition of patients to another program and for the preservation of all records. The licensee shall include in its notice to the department its plan to transition patients and locate records. When a program closes, the program's license is void on the date the program ceases providing licensed program services and the license shall be returned to the department.

155.4(3) A closed program is one that has ceased providing licensed program services. The licensee shall notify the department immediately of ceased service provision. The licensee shall be responsible for the transition of patients to another program and for the preservation of all records. The licensee shall

include in its notice to the department its plan to transition patients and locate records. When a program is closed, the program's license is void on the date the program ceased providing licensed program services and the license shall be returned to the department.

155.4(4) A person, facility or legal entity acquiring a licensed, closing or closed program for the purpose of operating a program shall apply for a license.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.5(125,135) Application procedures. The department will provide license application forms on its website and at its office. An applicant shall submit application materials to the department. The department will proceed with inspection of the applicant upon receipt of a complete application. To be complete, an application must include all required materials and be responsive to all licensure standards, as described in these rules.

155.5(1) *Application information.* An applicant shall submit application materials on the forms provided and in the required format. Application materials shall include but may not be limited to:

a. The name and address of the applicant and, if the applicant is part of a larger organization, the name and address of the larger organization.

b. The name and address of the applicant's executive director and, if the applicant is part of a larger organization, the name and address of the executive director of the larger organization.

c. The names, titles, dates of employment, education, and years of current job-related experience of the applicant's staff and the table of organization. If the applicant is part of a larger organization or has multiple organizational components and physical facilities, the relationships between the larger organization, organizational components and physical facilities must be shown on the table of organization, with the applicant and applicant's staff positions clearly delineated.

d. The names and addresses of members of the applicant's governing body, sponsors, and advisory boards and the current articles of incorporation and bylaws.

e. The names and addresses of individuals, facilities, organizations, and legal entities with which the applicant has a contractual or affiliation agreement pertaining to licensed program services.

f. A description of the licensed program services to be provided by the applicant and a calendar showing program services each week.

g. For each physical facility, copies of reports substantiating compliance with federal, state and local laws, rules and regulations, to include appropriate department of inspections, appeals, and licensing rules; state fire marshal rules and fire ordinances; and local health, fire, occupancy, and safety regulations.

h. Information required for programs admitting juveniles as described under Iowa Code section 125.14A.

i. Fiscal management information, to include a recent audit or opinion of auditor and program board minutes to reflect approval of the program's budget and insurance.

j. Insurance coverage related to professional and general liability; building, if the applicant has a physical location; and workers' compensation and fidelity bond, if the applicant has employees.

k. The address of each physical facility, if applicable.

l. The written policies and procedures manual that covers all the requirements of these rules.

155.5(2) *Application time frame.* An applicant seeking to be licensed subsequent to a 270-day initial license or a licensee seeking to renew a one-, two-, or three-year license or to significantly change a currently licensed program shall submit an application at least 90 days before expiration of the current license or before the program change.

155.5(3) *License under deemed status.* An organization seeking to be licensed under deemed status shall submit an application.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.6(125,135) Technical assistance. The department may provide technical assistance to an applicant or licensee.

155.6(1) An applicant may request technical assistance regarding these rules and the licensure process.

155.6(2) A licensee may request technical assistance regarding these rules and the licensure process or to bring areas of noncompliance with these rules into compliance.

155.6(3) The department may require a licensee to receive technical assistance to bring areas of noncompliance with these rules into compliance.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.7(125,135) Inspection of applicants.

155.7(1) *Inspection of applicants.* The department will inspect each applicant. Inspection will include review of the complete application and may include but may not be limited to review of patient records, review of applicant data reporting, and interviews with staff and patients. Inspection will include on-site inspection unless specifically waived as allowed under these rules. The department will send the applicant a report of inspection findings within 30 business days of the inspection.

155.7(2) *On-site inspection.* The department will schedule an on-site inspection of an applicant within 60 business days of receipt of the applicant's complete application.

a. The department may waive on-site inspection of an applicant that is:

(1) A licensee applying to renew a license when the applicant's licensed program services are limited to substance use disorder assessment and OWI evaluation services only, outpatient treatment, or intensive outpatient treatment.

(2) An applicant applying for a license under deemed status.

b. The department is not required to provide advance notice of the on-site inspection to the applicant.

c. The on-site inspection team will consist of designated employees or agents of the department.

d. The on-site inspection team will inspect the applicant to verify application information and determine compliance with all laws, rules and regulations.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.8(125,135) License—approval. The department will issue a license upon approval of an application. The license will be effective upon approval.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.9(125,135) Written corrective action plan.

155.9(1) A program approved for a license shall submit a written corrective action plan to the department within 30 days following approval to bring any area of noncompliance with these rules into compliance.

155.9(2) The written corrective action plan shall include but may not be limited to:

a. Any area of noncompliance specified in the inspection findings report;

b. The corrective measures to be taken by the program for each area of noncompliance; and

c. The completion date for each corrective measure.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.10(125,135) Grounds for denial of license. The department may deny an application for a license for any of the following reasons:

155.10(1) The application is not complete, is not timely or otherwise does not meet the requirements of these rules.

155.10(2) The applicant fails to achieve the minimum licensure weighting report rating required for a 270-day initial license or a one-, two- or three-year license.

155.10(3) Lack of patients or patient records for review.

155.10(4) Violation of any of the following grounds for discipline:

a. Submission of fraudulent or misleading information.

b. Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

c. Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.

d. Sanction, modification, termination, withdrawal, refused renewal, suspension, or revocation of accreditation by an accreditation body.

e. Sanction, modification, termination, withdrawal, refused renewal, suspension, revocation, or refused issuance of a federal registration to distribute or dispense controlled substances.

f. Commission of or permitting, aiding or abetting commission of an unlawful act.

g. Conviction of a member of the governing body, a director, administrator, chief executive officer, or other managing staff person of a felony or misdemeanor related to the management, operation or integrity of the program.

h. Use of untruthful or improbable statements in advertising.

i. Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

j. Violation of a patient's confidentiality or willful, substantial, or repeated violation of a patient's rights.

k. Defrauding a patient, potential patient, concerned person, visitor, staff or third-party payor.

l. Inappropriate conduct by staff, including sexual or other harassment or exploitation of a patient, potential patient, concerned person, visitor or staff.

m. Utilization of treatment techniques that endanger the health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

n. Discrimination or retaliation against a patient, potential patient, concerned person, visitor, staff, or member of the public who has submitted a complaint or information to the department.

o. Failure to allow an employee or agent of the department access to the program or facility for the purpose of inspection, investigation, or other activity necessary to the performance of the department's duties.

p. Failure to submit an acceptable written corrective action plan or failure to comply with a corrective action plan issued pursuant to rule 641—155.9(125,135) or 641—155.16(125,135).

q. Violation of an order of the department or violating the terms or conditions of a consent agreement or informal settlement between a program and the department.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.11(125,135) Denial, suspension or revocation of a license. The department may deny an application for a license. The department may suspend or revoke a license for any of the grounds for discipline pursuant to subrule 155.10(4).

155.11(1) *Initial notice from the department.* When the department determines to deny, suspend or revoke a one-, two-, or three-year license or a license under deemed status, the department will notify the applicant or licensee by certified mail, return receipt requested, in accordance with 441—Chapter 16. Such notice will provide the applicant or licensee the opportunity to submit a written corrective action plan or written objections to the department.

155.11(2) *Submission of corrective action plan or objections.* An applicant notified of denial of a one-, two-, or three-year license or a license under deemed status or a licensee notified of suspension or revocation of a license may submit a written corrective action plan or written objections to the department within 20 days after receipt of the notice.

a. Written corrective action plan. The written corrective action plan must meet the requirements of paragraphs 155.9(1)*"a"* through *"c."* If the applicant or licensee submits a written corrective action plan, the applicant or licensee shall have 90 days from the date of submission within which to show compliance with the plan. The applicant or licensee shall submit any information to the department that the department requests or that the applicant or licensee deems pertinent to show compliance with the plan. The department may inspect the licensee, including on-site inspection, to review the implemented corrective measures.

b. Objections. If the applicant or licensee submits written objections, the applicant or licensee shall submit to the department any information that the department or the applicant or licensee deems pertinent to support the applicant's or licensee's defense.

155.11(3) *Decision of department.* Following receipt of a written corrective action plan and expiration of the 90-day compliance period, or following receipt of written objections, or when a written corrective

action plan or written objections have not been received within the 20-day time period, the department will determine whether to proceed with the denial, suspension or revocation.

155.11(4) *Notice of decision and opportunity for contested case hearing.*

a. When the department determines to deny, suspend, or revoke a license, the applicant or licensee shall be given written notice by restricted certified mail pursuant to 441—Chapter 16.

b. The applicant or licensee may request a hearing on the determination. The request must be in writing and sent to the department's address within 30 days of the notice issued by the department. Failure to request a hearing will result in final action by the department.

155.11(5) *Summary suspension.* If the department finds that the health, safety or welfare of the public is endangered by continued operation of a program, the department may order summary suspension of a license, pursuant to Iowa Code sections 17A.18 and 125.15A, pending proceedings for revocation or other actions in accordance with Iowa Code sections 17A.18A and 125.15A and 441—Chapter 2506. These proceedings shall be promptly instituted and determined.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25; Editorial change: IAC Supplement 6/10/26]

641—155.12 to **155.14** Reserved.

641—155.15(125,135) Issuance of a license after denial, suspension or revocation. After denial, suspension, or revocation of a license, the former applicant or licensee shall not have a license issued within one year of the effective date of the denial, suspension or revocation. After one year, the former applicant or licensee may submit an application for a 270-day initial license. For purposes of this rule, "former applicant or licensee" includes any director, officer, administrator, chief executive officer, or other managing staff of the former applicant or licensee.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.16(125,135) Complaints and investigations.

155.16(1) *Complaints.* Any person may file a complaint with the department against any program licensed pursuant to this chapter. The complaint shall be made in writing and shall be emailed, mailed or delivered to the department. The complaint shall include the name and address of the complainant, the name of the program, and a concise statement of the allegations against the program, including the specific alleged violations of Iowa Code chapter 125 or this chapter, if known. A complaint may also be initiated by the department when an emergency exists that is deemed to endanger the health, safety or welfare of a patient, potential patient, concerned person, visitor, staff or the public, pursuant to evidence received by the department. Timely filing of complaints is required to ensure the availability of witnesses and to avoid initiation of an investigation under conditions that may have been significantly altered during the period of delay.

155.16(2) *Evaluation and investigation.* Upon receipt of a complaint, the department will make a preliminary review of the allegations contained in the complaint. The department may request that the complainant submit the complaint to the program's grievance process. Unless the department concludes that the complaint is intended solely to harass a program or lacks a reasonable basis, or is more reasonably addressed through the program's grievance process, the department will conduct an investigation of the program that is the subject of the complaint as soon as is practicable. The program that is the subject of the complaint will be given an opportunity to informally respond to the allegations contained in the complaint either in writing or through a personal interview or conference with department staff.

155.16(3) *Investigative report.* Within 30 days after completion of the investigation, the department will prepare a written investigative report and submit it to the executive director of the program and the chairperson of the governing body of the program. This report will include the nature of the complaint and shall indicate if the complaint allegations were substantiated, unsubstantiated, or undetermined; the basis for the finding; the specific statutes or rules at issue; a response from the program, if received; and a recommendation for action.

155.16(4) *Review of investigations.* The department will review the investigative report and determine appropriate action.

a. Closure. If the department determines that the allegations contained in the complaint are unsubstantiated, the department will close the case and promptly notify the complainant and the program by letter.

b. Further investigation. The department may determine that the complaint warrants further investigation and may conduct an additional investigation.

c. Written corrective action plan. If the department determines that the allegations contained in the complaint are substantiated and corrective action is warranted, the department may require the program to submit and comply with a written corrective action plan. A program shall submit a written corrective action plan to the department within 20 business days after receiving a request for such plan. The written corrective action plan shall include a plan for correcting areas of noncompliance as required by the department and a time frame within which such plan shall be implemented. The plan is subject to department approval. Requiring a written corrective action plan is not formal disciplinary action. Failure to submit or comply with a written corrective action plan may result in formal disciplinary action against the program.

d. Disciplinary action. If the department determines the allegations contained in the complaint are substantiated and disciplinary action is warranted, the department may proceed with such action in accordance with rule 641—155.11(125,135).

155.16(5) *Confidential information and public information.* Information contained in a complaint may be confidential pursuant to Iowa Code section 22.7(2), 22.7(18), or 125.37 or any other provision of state or federal law. Investigative reports, written corrective action plans, and all notices and orders issued pursuant to rule 641—155.11(125,135) shall refer to patients by number and shall not include patient identifying information. Investigative reports, written corrective action plans, and all notices and orders issued pursuant to rule 641—155.11(125,135) shall be available to the public as open records pursuant to Iowa Code chapter 22.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.17(125,135) License revision. A licensee shall submit a written request to the department to revise a license at least 30 days prior to any change of address, executive director, clinical oversight staff, facility, or licensed program service. The department will determine if the requested revision can be approved or if the change is significant enough to require the submission of an application for license renewal by the licensee.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.18(125,135) Deemed status.

155.18(1) *Accreditation.* The department will approve a license under deemed status for an applicant accredited by a recognized national accreditation body when it determines that the accreditation is for the same licensed program services as those addressed by these rules and when such accreditation is consistent with these rules.

a. An applicant for a license under deemed status shall submit a copy of the entire accreditation body survey or inspection report, certificate of accreditation, accreditation conditions, and corrective action requirements and plans with the applicant's application.

b. The department may review and accept an accreditation body's survey or inspection report, certificate of accreditation, and conditions or corrective action plans as meeting the requirements for inspection for those licensed program services described in these rules.

c. An applicant for a license under deemed status shall be licensed only for licensed program services that are described in these rules.

d. A program licensed under deemed status shall be licensed for the same period of time as that for which the program is accredited, up to three years.

155.18(2) *National accreditation bodies.* The national accreditation bodies recognized for the purposes of licensure under deemed status are:

a. The Joint Commission.

b. The Council on Accreditation of Rehabilitation Facilities (CARF).

c. The Council on Accreditation (COA).

d. The American Osteopathic Association (AOA).

155.18(3) *Credentials and expectations of accreditation bodies.* The accreditation credentials of an accreditation body shall specify the types of organizations, programs and services the body accredits.

155.18(4) *Responsibilities of programs licensed under deemed status.*

a. A program licensed under deemed status shall meet all requirements of these rules and all applicable laws and regulations.

b. A program licensed under deemed status may submit an application for licensure of licensed program services covered by these rules that are not covered by the accreditation.

155.18(5) *Rights and responsibilities of department.* The department retains the following responsibilities and rights for deemed status applicants and licensees:

a. The department may inspect the applicant or licensee.

b. The department will investigate complaints in accordance with these rules and recommend and require corrective action or other sanctions. Complaints, findings, and required corrective action may be reported to the accreditation body.

c. The department will review and act upon a license under deemed status when complaints have been founded, when the national accreditation body identifies noncompliance with accreditation, when accreditation expires without renewal, or when accreditation is sanctioned, modified, terminated, withdrawn, suspended or revoked.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.19(125,135) Funding. The issuance of a license shall not be construed as a commitment on the part of either the state or federal government to provide funds to such licensee.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.20(125,135) Inspection. An applicant or licensee agrees as a condition of licensure:

155.20(1) To permit properly designated representatives of the department to enter into and inspect any and all programs and facilities for which a license has been applied or issued to verify information contained in the application or to ensure compliance with all laws, rules, and regulations relating thereto, during all hours of operation of said applicant or licensee and at any other reasonable hour.

155.20(2) To permit properly designated representatives of the department to audit and collect statistical data from all records maintained by the applicant or licensee. An applicant or licensee that does not permit inspection by the department or examination of all records, including financial records, records pertaining to methods of administration, general and special dietary programs, and the disbursement of medications and methods of supply, and any other records the department deems relevant, will not be licensed.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.21(125,135) General standards for all programs. The following standards apply to all programs. For programs for which both the general standards and specific standards apply, both sets of standards shall be met.

155.21(1) *Governing body.* The program shall have a formally designated governing body that complies with Iowa Code chapter 504 and that is the ultimate authority for program operations.

a. The governing body shall develop and adopt written bylaws and policies that define the powers and duties of the governing body, its committees, its advisory groups, and the executive director. These bylaws and policies shall be reviewed and revised by the governing body as necessary.

b. The bylaws shall minimally specify the following:

(1) The type of membership;

(2) The term of appointment;

(3) The frequency of meetings;

(4) The attendance requirements; and

(5) The quorum necessary to transact business.

c. The governing body shall maintain minutes of all meetings, and the minutes shall be available for review by the department and shall include but not necessarily be limited to:

(1) Date of the meeting;
(2) Names of members attending;
(3) Topics discussed; and
(4) Decisions reached and actions taken.

d. The duties of the governing body shall include but not necessarily be limited to:

(1) Appointment of a qualified executive director, who shall have the responsibility and authority for the management of the program in accordance with the governing body's established policies;
(2) Establishment of effective controls to ensure that quality services are provided;
(3) Review and approval of the program's annual budget; and
(4) Approval of all contracts.

e. The governing body shall approve policies and procedures for the effective operation of the program.

f. The governing body shall be responsible for all funds, equipment, and supplies and the facility in which the program operates, if applicable. The governing body shall be responsible for the appropriateness and adequacy of services provided by the program.

g. The governing body shall at least annually prepare a report, which shall include but not necessarily be limited to:

(1) The name, address, occupation, and place of employment of each governing body member;
(2) Disclosure of any family relationship a member of the governing body has with a program staff member;
(3) The names and addresses of any owners or controlling parties, whether they are individuals, partnerships, a corporation body, or a subdivision of other bodies;
(4) Disclosure of any potential conflict of interest a member of the governing body may have.

h. The governing body shall ensure that the program has malpractice, liability and workers' compensation insurance for all staff and a fidelity bond that covers all staff, if applicable.

155.21(2) *Executive director.* The executive director shall have primary responsibility for program operations. The duties of the executive director shall be clearly defined in accordance with the policies established by the governing body.

155.21(3) *Clinical oversight.* The program shall designate a treatment supervisor to oversee provision of licensed program services.

155.21(4) *Policies and procedures manual.* The program shall maintain and implement a written policies and procedures manual that documents the program's compliance with these rules. The manual shall describe the program's licensed program services and related activities, specify the policies and procedures to be followed, and govern all staff.

a. The manual shall have a table of contents.

b. Revisions to the manual shall be entered with the date and with the name and title of the staff person making the revisions.

155.21(5) *Staff development and training.* The program's policies and procedures shall establish a staff development and training plan that encompasses all staff and all licensed program services, considers the professional continuing education requirements of certified and licensed staff, and is available to all staff.

a. The program shall designate a staff person responsible for the staff development and training plan.

b. The staff person responsible for the staff development and training plan shall conduct an annual needs assessment.

c. The staff development and training plan shall describe orientation for new staff that includes an overview of the program and licensed program services, confidentiality, tuberculosis and bloodborne pathogens, including HIV/AIDS, and culturally and environmentally specific information. Orientation shall also address the specific responsibilities of each staff person and community resources specific to the staff person's responsibilities.

d. The staff development and training plan shall address training when program operations or licensed program services change.

e. The staff development and training plan may include on-site training activities. The program shall maintain minutes of on-site training that include the name and date of the training, the training topic, the name and title of the trainer, and the names of staff attending the training.

155.21(6) *Data reporting.* The program's policies and procedures shall describe how the program reports required data to the department in accordance with department requirements and processes.

155.21(7) *Fiscal management.* The program's policies and procedures shall ensure proper fiscal management, which shall include:

a. The preparation and maintenance of an annual written budget, which shall be reviewed and approved by the governing body prior to the beginning of the budget year.

b. A fiscal management system maintained in accordance with generally accepted accounting principles, including internal controls to reasonably protect program assets. This shall be verified by an annual independent fiscal audit of the program by the state auditor's office or a certified public accountant based on an agreement entered into by the governing body. A program with an annual budget of $100,000 or less shall conduct a fiscal audit no less than every three years.

c. An insurance program that provides for the protection of the physical and financial resources of the program and provides coverage for all people, buildings, and equipment. The insurance program shall be reviewed annually by the governing body.

155.21(8) *Personnel.* The program shall have personnel policies and procedures.

a. Personnel policies and procedures shall address:

(1) Recruitment and selection of staff;
(2) Wage and salary administration;
(3) Promotions;
(4) Employee benefits;
(5) Working hours;
(6) Vacation and sick leave;
(7) Lines of authority;
(8) Rules of conduct;
(9) Disciplinary actions and termination;
(10) Methods for handling cases of inappropriate patient care;
(11) Work performance appraisal;
(12) Staff accidents and safety;
(13) Staff grievances;
(14) Prohibition of sexual harassment;
(15) Implementation of the Americans with Disabilities Act as amended to August 1, 2025;
(16) Implementation of the Drug-Free Workplace Act as amended to August 1, 2025;
(17) Use of social media; and
(18) Implementation of equal employment opportunity.

b. The program shall have for each position and each staff person a written job description that describes the duties of each position and staff and the qualifications required for each position.

(1) A staff person providing screening, OWI evaluation, assessment or treatment services in accordance with these rules shall be qualified as an addictive disorder professional by meeting at least one of the following conditions:

1. Be certified or licensed as a substance use disorder or problem gambling counselor by a national or state organization approved by the department.

2. Be licensed as a marital and family therapist or a mental health counselor under Iowa Code chapters 154D and 147, an independent social worker under Iowa Code chapters 154C and 147, or another independent professional authorized by the Iowa Code to diagnose and treat mental disorders as specified in the DSM.

3. Be licensed as a master social worker under Iowa Code chapters 154C and 147.

4. Be licensed as a bachelor social worker under Iowa Code chapters 154C and 147.

5. Be temporarily or provisionally certified or licensed as allowed under a certification or license acceptable to the department. Such staff person must meet all requirements of the temporary or provisional

certification or license, must be supervised by a staff person meeting one of the requirements of paragraphs "1" through "4" above, and must be fully certified or licensed within two years of the date on which the person began to provide licensed program services.

6. A staff person employed on and after July 1, 2010, who is not qualified as described in any of the paragraphs "1" through "5" above shall be deemed qualified while the person is in the process of being certified or licensed under a certification or license acceptable to the department. Such staff must meet the requirements of the certification or licensure process, must be supervised by a staff person meeting one of the requirements of paragraphs "1" through "4" above, and must be fully certified or licensed within two years of the date on which the person began to provide licensed program services. The two-year time frame is continuous from the person's date of first employment by the program, including if the person changes employment from one program to another.

7. A person employed before July 1, 2010, and continuously since that date at a program licensed pursuant to this chapter, who is not qualified as described in any of the paragraphs "1" through "5" above, shall be deemed qualified as long as such person remains employed by that program and that program remains licensed. Such staff shall maintain a minimum of 30 hours of training every two years, including a minimum of 3 hours of ethics training, and shall be supervised by a staff person meeting at least one of the conditions of paragraphs "1" through "4" above.

(2) The program shall review job descriptions annually and whenever there is a change in a position's duties or required qualifications.

(3) The program shall include job descriptions in the personnel section of the policies and procedures manual.

c. The program shall conduct a written evaluation of job performance with each staff person at least annually. The evaluation shall include the opportunity for the staff person to comment.

d. The program shall maintain a personnel record on each staff person. The record shall contain, as applicable:

(1) Verification of training, experience, qualifications, and professional credentials;

(2) Job performance evaluations;

(3) Incident reports;

(4) Disciplinary action taken; and

(5) Documentation of review of and agreement to adhere to confidentiality laws and regulations. This review and agreement shall occur prior to the staff person's assumption of duties.

e. The personnel policies and procedures shall ensure confidentiality of personnel records and shall specify staff authorized to have access to personnel information.

f. The program shall notify the department in writing within ten days of being informed that a staff person has been sanctioned or disciplined by a certifying or licensing body. Such notice shall include the sanction or discipline order.

155.21(9) *Child abuse, dependent adult abuse and criminal history background checks.* The program's policies and procedures shall address child abuse, dependent adult abuse and criminal history background checks.

a. The program shall prohibit mistreatment, neglect, or abuse of children and dependent adults and shall specify reporting and enforcement procedures. Alleged violations shall be reported immediately to the program's executive director and appropriate department personnel. Policies and procedures on reporting alleged violations shall be in compliance with subrule 155.21(10). A staff person found to be in violation of Iowa Code sections 232.67 through 232.70, as substantiated by a department investigation, shall be subject to the program's policies concerning termination.

b. For each staff person working with juveniles as set forth in Iowa Code section 125.14A or with dependent adults as set forth in Iowa Code chapter 235B, the personnel record shall contain:

(1) Documentation of a criminal history background check with the Iowa division of criminal investigation on all new staff applicants. The background check shall include asking whether the applicant has been convicted of a crime.

(2) A written, signed and dated statement furnished by a new staff applicant that discloses any substantiated report of child abuse, neglect or sexual abuse or dependent adult abuse.

(3) Documentation of a check prior to permanent acceptance of a person as staff, with the Iowa central registry for any substantiated reports of child abuse, neglect or sexual abuse pursuant to Iowa Code section 125.14A or substantiated reports of dependent adult abuse for all staff hired or accepted on or after July 1, 1994, pursuant to Iowa Code chapter 235B.

c. A person who has a record of a criminal conviction or founded child abuse report or founded dependent adult abuse report shall not be hired or accepted as staff unless an evaluation of the crime or founded child abuse or founded dependent adult abuse has been made by the department that concludes that the crime or founded child abuse or founded dependent adult abuse does not merit prohibition of employment. If a record of criminal conviction or founded child abuse or founded dependent adult abuse does exist, the person shall be offered the opportunity to complete and submit a Record Check Evaluation form. In its evaluation, the department will consider the nature and seriousness of the crime or founded abuse in relation to the position sought, the time elapsed since the commission of the crime or founded abuse, the circumstances under which the crime or founded abuse was committed, the degree of rehabilitation and the number of crimes or founded abuses committed by the person involved.

d. A staff person providing screening, OWI evaluation, assessment or treatment in accordance with this chapter shall complete the department's core training curriculum pursuant to Iowa Code sections 232.69 and 235B.16 within six months of initial employment or self-employment and every three years thereafter.

155.21(10) *Patient records.* The program's policies and procedures shall describe compilation, storage and dissemination of patient records and release or disclosure of information.

a. The policies and procedures shall ensure that:

(1) The program protects the patient record against loss, tampering or unauthorized disclosure of information;

(2) The content and format of patient records are uniform;

(3) All entries in the patient record are in chronological order, signed, dated and legible. When records are maintained electronically, a staff identification code number authorizing access shall be accepted in lieu of a signature;

(4) Each entry in the patient record is made in permanent ink, by typewriter, or by computer; and

(5) Entries in the patient record use language consistent with generally accepted standards of practice and do not include abstract terms, technical jargon or slang.

b. The program shall provide adequate physical facilities for the secure storage, processing and handling of patient records.

c. Appropriate patient records shall be readily accessible to staff as specifically authorized by program policy.

d. The program shall appropriately maintain and dispose of patient records. Patient records shall be maintained for not less than seven years from the date they are officially closed.

e. Each file cabinet or storage area containing patient records shall be locked.

f. The program shall release or disclose information on individuals seeking program services or on patients in strict accordance with the Health Insurance Portability and Accountability Act (HIPAA) as amended to August 1, 2025, and state and federal confidentiality laws, rules and regulations.

(1) The confidentiality of substance use disorder patient records and information is protected by HIPAA as amended to August 1, 2025, and the regulations on confidentiality of alcohol and drug abuse patient records, 42 CFR Part 2 as amended to August 1, 2025, which implement federal statutory provisions, 42 U.S.C. 290dd-2 applicable to alcohol abuse patient records, and 42 U.S.C. 290ee-3 both as amended to August 1, 2025, applicable to drug abuse patient records.

(2) The confidentiality of problem gambling patient records and information is protected by HIPAA as amended to August 1, 2025, Iowa Code chapter 228 and section 22.7(35).

g. A program that provides licensed program services via electronic means shall inform the patient of the limitations and risks associated with such services and shall document in the patient record that such notice has been provided.

h. Upon receipt of a properly executed written release of information or authorization to disclose signed by the patient, the program shall release patient records in a timely manner. A program shall

not refuse to release patient records related to continuation of care solely because payment has not been received. A program may refuse to release patient records that are unrelated to continuation of care if payment has not been received. A program may refuse to file the reporting form required by 641—subrule 157.3(1), "Notice Iowa Code 321J—Confidential Medical Record," reporting screening, evaluation, and treatment completion, if payment has not been received for such services.

155.21(11) *Assessment and admission.* The program's policies and procedures shall address screening, assessment, referral and admission and documentation of such activities in the patient record.

a. The program shall conduct an assessment with each patient prior to admission unless the patient's current risk factors indicate a need for immediate admission.

(1) If the program admits a patient based on a screening or initial assessment that indicates the patient requires immediate admission, that screening or initial assessment must be updated and expanded to a full assessment when the patient's current risk factors are stabilized.

(2) The assessment shall be documented in the patient record and shall be organized in a manner that supports development of a treatment plan by the program or by any program to which the patient is referred.

b. The program shall implement a uniform assessment process that describes:

(1) The information to be gathered;

(2) Procedures for accepting a referral from another program, agency or organization;

(3) Procedures for referring a patient to another program, agency or organization.

c. A substance use disorder treatment program, problem gambling treatment program, or substance use disorder and problem gambling treatment program shall update the assessment on an ongoing basis, when clinically indicated, and within the periods of time specified for each level of care in the management-of-care review process.

d. The results of each assessment shall be clearly explained to the patient, and to the patient's family when appropriate, and such explanation shall be documented in the patient record.

e. At the time of admission, a substance use disorder treatment program, problem gambling treatment program, or substance use disorder and problem gambling treatment program shall document that the patient has been informed of:

(1) The general nature and goals of the program;

(2) Rules governing patient conduct and infractions that can lead to disciplinary action or discharge from the program;

(3) The hours during which services are available;

(4) The costs to be borne by the patient;

(5) Patient rights and responsibilities;

(6) Confidentiality laws, rules and regulations; and

(7) Safety and emergency procedures.

155.21(12) *Treatment plans.* The policies and procedures for substance use disorder treatment programs, problem gambling treatment programs, and substance use disorder and problem gambling treatment programs shall describe the program's uniform process for developing individualized treatment plans based on ongoing assessment and documentation of such plans in the patient record.

a. Staff shall initiate development of the treatment plan as soon after the patient's admission as is clinically feasible and within the period of time between admission and the review date specified for that level of care in the management-of-care review process.

b. The treatment plan shall minimally contain:

(1) A summary of assessment findings;

(2) Patient short- and long-term goals;

(3) The type and frequency of planned treatment activities;

(4) The staff responsible for the patient's treatment; and

(5) Culturally and environmentally specific considerations.

c. Staff shall develop each treatment plan in partnership with the patient, with patient participation documented in the patient record. The treatment plan shall be written in a manner clearly understandable to the patient. Staff shall give the patient a copy of each treatment plan. The patient and staff shall review and

revise the treatment plan when clinically indicated and in accordance with the time frames specified in the management-of-care review process.

d. Treatment plan reviews shall be based on ongoing assessment and shall specify the indicated level of care and licensed program services and any revision of treatment plan goals. The date of the review and any revision of the treatment plan shall be documented in the patient record.

155.21(13) *Progress notes.* The policies and procedures for substance use disorder treatment programs, problem gambling treatment programs, and substance use disorder and problem gambling treatment programs shall describe the program's uniform process for reviewing a patient's current status and progress in meeting treatment plan goals and documenting such review in the patient record.

a. Progress notes shall include the date each service was provided or observation was made and the name and title of the staff person providing each service.

b. Staff shall enter a progress note following each individual counseling session.

c. Staff shall enter a summary progress note at least weekly for group counseling sessions.

d. Progress notes that involve subjective interpretations of a patient's status or progress should be supplemented with a description of the behavioral observations that were the basis for the interpretation.

155.21(14) *Patient record contents.* The program's policies and procedures shall require that a record be maintained for each patient and shall specify the contents of the patient record.

a. The patient record shall include:

(1) Any screening;

(2) Each assessment;

(3) Results of any physical examination or laboratory test;

(4) Admission information;

(5) Any report from a referring source or outside resource;

(6) Notes from any case conference, consultation, care coordination or case management;

(7) Any correspondence related to the patient, including letters, electronic communications and telephone conversations;

(8) Any treatment consent form;

(9) Any release of information or authorization to disclose;

(10) Notes on any service provided; and

(11) Any incident report.

b. For substance use disorder treatment programs, problem gambling treatment programs, and substance use disorder and problem gambling treatment programs, the patient record shall also include:

(1) Treatment plans;

(2) Management-of-care reviews;

(3) Medication records, which shall allow for the monitoring of all medications administered and self-administered and detection of adverse drug reactions;

(4) Progress notes;

(5) Discharge summaries completed within 30 days of discharge, which shall be sufficiently detailed to identify the types of services the patient received, action taken to address specific problems identified, and plans for services and referrals postdischarge.

c. For problem gambling treatment programs and substance use disorder and problem gambling treatment programs, the patient record shall also include documentation of financial counseling services that assist problem gambling patients in preparing a budget and addressing financial debt options, including restitution and bankruptcy.

155.21(15) *Drug screening.* The program's policies and procedures shall address collection of drug-screening specimens and utilization of drug-screening results. Such policies may state that the program does not conduct drug screening.

a. A specimen obtained from a patient shall be collected under direct supervision and analyzed in accordance with program policies, or the program shall have a policy in place to reduce the patient's ability to alter the drug screening.

b. Any laboratory used by the program for drug screening and analysis shall comply with federal and state requirements.

c. A program conducting on-site drug screening shall comply with the Clinical Laboratory Improvement Act regulations as amended to August 1, 2025.

d. The manner in which drug-screening results are utilized shall be documented in the patient record.

155.21(16) *Medical and mental health services.* The program's policies and procedures shall address patient medical and mental health conditions.

a. In addition to assessment of biomedical conditions and complications as described in the ASAM criteria, the program shall take a medical history and perform a physical examination and necessary laboratory tests as follows for patients admitted to the level of care specified:

(1) Medically managed intensive inpatient treatment and medically monitored intensive inpatient treatment: within 24 hours of admission.

(2) Clinically managed high-intensity residential treatment and clinically managed medium-intensity residential treatment: within seven days of admission.

(3) Clinically managed low-intensity residential treatment: within 21 days of admission.

(4) Crisis stabilization services and opioid treatment program services: within 24 hours of admission.

b. A program may accept a medical history or physical examination from a qualified source if the history or examination was completed no more than 90 days prior to the patient's current admission.

c. In addition to assessment of emotional, behavioral, and cognitive conditions and complications as described in the ASAM criteria, a program may accept a mental health history from a qualified source if the history was completed no more than three days prior to the patient's current admission.

155.21(17) *Emergency services.* The program's policies and procedures shall address the availability of emergency services for substance use disorders and medical and mental health conditions.

a. Emergency services shall be available 24 hours a day, seven days a week.

b. Emergency services may be provided by the program or by any other qualified individual, institution, facility, or other legal entity.

c. The program shall communicate the availability of emergency services by posting notice at facilities, having a recorded message on the program's telephone system, posting notice on the program's website and through program materials.

155.21(18) *Medication control.* The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

a. Staff authorized to administer medications shall be qualified, and a current list of such staff shall be maintained.

b. Medication shall be administered only in accordance with the instructions of the attending prescriber. The type and amount of the medication, the time and date, and the staff person administering the medication shall be documented in the patient record.

c. Self-administration of medication shall be observed by a staff person who has been oriented to the program's policies and procedures on self-administration. Self-administration of medication shall be permitted only when the patient's medication is clearly labeled. The policies and procedures on self-administration shall include:

(1) Medications are ordered or prescribed by a prescriber.

(2) The prescriber agrees that the patient can self-administer the medication.

(3) The medication taken and how and when the medication is taken are documented in the patient record.

d. Prescription medication shall not be administered to or self-administered by a patient without a written order signed by a prescriber. All prescribed medications shall be clearly labeled indicating the patient's full name, the prescriber's name, the prescription number, the name and strength of the medication, the dosage, the directions for use, and the date of issue and the name, address and telephone number of the pharmacy or prescriber issuing the medication. Medications shall be packaged and labeled according to state and federal guidelines.

e. If a medication the patient brings to the program is not used, it shall be packaged, sealed and stored. The sealed package of medication shall be returned to the patient, family or designee at the time of discharge.

f. Accountability and control of medications.

(1) There shall be a specific routine for medication administration, indicating dose schedules and standardization of abbreviations.

(2) There shall be specific methods for control and accountability of medication products throughout the program.

(3) The staff person in charge of medications shall provide for monthly inspection of all storage units.

(4) Prescription medication containers having soiled, damaged, illegible, or makeshift labels shall be returned to the issuing pharmacist, pharmacy, or prescriber for relabeling or disposal.

(5) Unused prescription medication prescribed for a patient who leaves a program without the patient's medication shall be destroyed by a staff person with a staff witness, and a notation shall be made in the patient record. When a patient is discharged or leaves the program, medication currently being administered shall be sent, in the original container, with the patient or with a responsible agent, as approved by a prescriber.

g. Medication storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All medication shall be maintained in locked storage. Controlled substances shall be maintained in a locked box within the locked cabinet.

(2) Medications requiring refrigeration shall be kept in a refrigerator and separated from food and other items.

(3) Disinfectants and medication for external use shall be stored separately from internal and injectable medications.

(4) The medication for each patient shall be stored in the original container.

(5) All poisonous or caustic medication shall be plainly labeled; stored separately from other medication in a specific well-illuminated cabinet, closet, or storeroom and made accessible only to authorized staff.

h. Prescription medication provided to a patient shall be dispensed only from a licensed pharmacy in the state of Iowa in accordance with the pharmacy laws in the Iowa Code, from a licensed pharmacy in another state according to the laws of that state, or by a licensed prescriber.

i. Prescription medication prescribed for one patient shall not be administered to or allowed to be in the possession of another patient.

j. Any unusual patient reaction to a medication shall be documented in the patient record and reported to the prescriber immediately.

k. Dilution or reconstitution and labeling of medication shall be done only by a licensed pharmacist.

155.21(19) *Management of care and discharge planning.* The program's policies and procedures shall use the ASAM criteria for assessment, admission, continued service and discharge decisions and shall describe management-of-care processes.

a. The program shall conduct care coordination to meet each patient's needs and promote effective outcomes.

b. The program shall conduct management-of-care activities at least minimally within the time frames specified for each level of care.

(1) Medically managed intensive inpatient treatment and medically monitored intensive inpatient treatment: daily.

(2) Clinically managed high-intensity residential treatment, clinically managed medium-intensity residential treatment, partial/day treatment, and intensive outpatient treatment: within seven days of the patient's admission.

(3) Clinically managed low-intensity residential treatment and outpatient treatment: within 30 days of the patient's admission.

c. The program shall coordinate patient care with other programs for any licensed program service for which the program is not licensed and with qualified individuals and organizations for any related

services the program does not provide, such as crisis stabilization, medical services, mental health services, and social services.

d. At the time of the patient's admission, the program shall initiate discharge planning that includes a determination of the patient's continued need for licensed program services and development of a plan to address ongoing patient needs postdischarge.

155.21(20) *Quality improvement.* The program's policies and procedures shall describe a written quality improvement plan that encompasses all licensed program services and related program operations.

a. The program shall designate a staff person responsible for the quality improvement plan.

b. The quality improvement plan shall describe and document monitoring, problem-solving and evaluation activities designed to systematically identify and resolve problems and make continued improvements.

(1) The quality improvement plan shall include specific goals, objectives, and methods.

(2) The quality improvement plan shall include objective criteria to measure its effectiveness.

c. The program shall document whether the quality of patient care and program operations are improved and identified problems are resolved.

d. The program shall communicate quality improvement plan activities and findings to all staff.

e. Quality improvement plan findings are used to detect trends, patterns of performance, and potential problems that affect patient care and program operations.

f. The program shall evaluate the effectiveness of the quality improvement plan at least annually and revise the plan as necessary.

155.21(21) *Facility safety and cleanliness.* The program's policies and procedures shall ensure that program physical facilities are clean, well-ventilated, heated, free from vermin, and appropriately furnished and are designed, constructed, equipped, and maintained in a manner that provides for the physical safety of patients, concerned persons, visitors and staff.

a. If required by local jurisdiction, the program shall maintain a certification of occupancy.

b. During all phases of construction or alterations of buildings, the level of life safety shall not be diminished in any occupied area. The construction shall be in compliance with all applicable federal, state, and local codes. New construction shall comply with Iowa Code chapter 104A and all applicable federal and local codes and provide for safe and convenient use by disabled individuals.

c. The program shall have specific policies and procedures for each of the following:

(1) Identification, development, implementation, maintenance and review of safety policies and procedures.

(2) Promotion and maintenance of an ongoing, facilitywide hazard surveillance program to detect and report all safety hazards.

(3) Safe and proper disposal of biohazardous waste.

(4) Stairways, halls, and aisles that shall be of substantial, nonslippery material, maintained in a good state of repair, adequately lighted and kept free from obstructions at all times. All stairways shall have handrails.

(5) Radiators, registers, and steam and hot water pipes, each of which shall have protective covering or insulation. Electrical outlets and switches shall have wall plates.

(6) For programs serving juveniles, fuse boxes that shall be under lock and key or six feet above the floor.

(7) Safe and proper handling and storage of hazardous materials.

(8) Prohibition against weapon possession; safe and proper removal of weapons.

(9) Swimming pools that shall conform to state and local health and safety rules and regulations. Adult supervision shall be provided at all times when juveniles are using the pool.

(10) Ponds, lakes, or any bodies of water located on or near the program and accessible to patients, concerned persons, visitors and staff.

(11) The written plan to be followed in the event of fire or tornado. The plan shall be conspicuously displayed at the facility.

155.21(22) *Therapeutic environment.* The program's policies and procedures shall provide for the establishment of an environment that preserves human dignity. Program facilities shall have adequate space for the program to provide licensed program services.

a. The program's policies and procedures shall include a description of how all licensed program services are accessible to people with disabilities or how the program provides accommodations for people with disabilities. All programs shall comply with the Americans with Disabilities Act as amended to August 1, 2025.

b. The waiting or reception areas shall be of adequate size and be located so as to ensure patient confidentiality.

c. Staff shall be available in waiting or reception areas to address the needs of the patients, potential patients, concerned persons, and visitors.

d. The program's policies and procedures shall include:

(1) Possession and use of chemical substances in the facility.

(2) Prohibition of smoking.

(3) Prohibition of the sale or other provision of any tobacco product.

(4) Informing patients of their legal and human rights at the time of admission.

(5) Patient communication, opinions, or grievances, with a mechanism for redress.

(6) Prohibition of sexual harassment.

(7) Patient right to privacy.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.22(125,135) Inpatient and residential program facilities. Specific standards apply for programs providing clinically managed low-intensity residential treatment, clinically managed medium-intensity residential treatment, clinically managed high-intensity residential treatment, medically monitored intensive inpatient treatment, and medically managed intensive inpatient treatment. The program's policies and procedures shall address each standard.

155.22(1) *Health and fire safety inspections.* Inpatient and residential programs shall comply with applicable department of inspections, appeals, and licensing rules; state fire marshal's rules and fire ordinances; and applicable local health, fire, occupancy, and safety regulations. The program shall maintain documentation of such compliance.

a. Inpatient and residential programs shall comply with standards for food service sanitation in accordance with rules promulgated by the department of inspections, appeals, and licensing pursuant to 481—Chapter 30 and Iowa Code chapter 137F.

b. The use of door locks or closed sections shall be documented in written policies and procedures approved by the fire marshal and governing body.

155.22(2) *Emergency preparedness.* Inpatient and residential programs shall have a written emergency preparedness plan for continuation of licensed program services during an emergency or disaster.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.23(125,135) Specific standards for inpatient and residential programs. The program's policies and procedures shall address each standard.

155.23(1) *Hours of operation.* Inpatient and residential programs shall operate seven days per week, 24 hours per day.

155.23(2) *Meals.* Inpatient and residential programs shall provide a minimum of three meals per day to each patient. A program where patients are not present during mealtime shall make provisions to make available the necessary meals. Menus shall be prepared in consultation with a dietitian. If patients are allowed to prepare meals, the program shall document conformity with all commonly accepted policies and procedures of state health rules and regulations and food hygiene.

155.23(3) *Consultation with counsel.* Patients shall have opportunity for and access to consultation with legal counsel at any reasonable time.

155.23(4) *Visitation with family and friends.*

a. Each patient shall have opportunities for continuing contact with family and friends. If such contact is clinically contraindicated, it may be restricted. Any restriction shall be approved by the treatment supervisor and the executive director. Justification for the restriction shall be documented in the patient record. Any restriction shall be reviewed within three calendar days by the treatment supervisor, who may continue or end the restriction. Continuation of a restriction shall be documented in the patient record and shall be reviewed by the treatment supervisor every three calendar days.

b. The program shall establish visiting hours, which shall be conspicuously displayed at the facility in such a manner to be visible to those entering the facility.

155.23(5) *Telephone use.*

a. Each patient shall have opportunities to conduct private telephone conversations. If such conversations are clinically contraindicated, they may be restricted. Any restriction shall be approved by the treatment supervisor and the executive director. Justification for the restriction shall be documented in the patient record. Any restriction shall be reviewed within three calendar days by the treatment supervisor, who may continue or end the restriction. Continuation of a restriction shall be documented in the patient record and shall be reviewed by the treatment supervisor every three calendar days.

b. The program shall establish telephone hours. Emergency telephone conversations may be received at the time of the call or made when necessary.

155.23(6) *Written communication.*

a. Each patient shall have opportunities to conduct private written communications. If such communications are clinically contraindicated, they may be restricted. Any restriction shall be approved by the treatment supervisor and the executive director. Justification for the restriction shall be documented in the patient record. Any restriction shall be reviewed within three calendar days by the treatment supervisor, who may continue or end the restriction. Continuation of a restriction shall be documented in the patient record and shall be reviewed by the treatment supervisor every three calendar days.

b. The program shall establish access to written communications. The program shall not intercept, read, or censor the U.S. mail.

155.23(7) *Facility.* Inpatient and residential program facilities shall be appropriate for 24-hour occupancy.

a. Patient bedrooms shall include:

(1) A sturdily constructed bed;

(2) A clean mattress protected with a clean mattress pad;

(3) A designated space for personal possessions and for hanging clothing in proximity to the sleeping area; and

(4) Curtains or window blinds on any windows.

b. Sleeping areas.

(1) Sleeping areas shall include doors for privacy.

(2) Sleeping areas shall include partitioning or placement of furniture to provide privacy for all patients.

(3) The number of patients in a room shall be appropriate to the goals of the facility and to the ages, developmental levels, and clinical needs of the patients.

(4) Patients will be allowed to keep and display personal belongings and add personal touches to the decoration of their rooms in accordance with program policy.

(5) Staff shall respect the patient’s right to privacy by knocking on the door of the patient’s room before entering.

c. Clean linen, towels and washcloths shall be available minimally on a weekly basis and more often as needed.

d. Bathrooms.

(1) Bathrooms shall provide the facilities necessary for patients’ personal hygiene and personal privacy, including:

1. A safe supply of hot and cold running potable water;
2. Clean towels, electric hand dryers or paper towel dispensers, toilet paper and soap;
3. Natural or mechanical ventilation capable of removing odors;

4. Tubs or showers that have slip-proof surfaces;

5. Partitions with doors that provide privacy if a bathroom has multiple toilet stools; and

6. Toilets, wash basins, and other plumbing or sanitary facilities that shall at all times be maintained in good operating condition.

(2) The ratio of bathroom facilities to inpatient and residential patients shall be one tub or shower head per 12 patients, one wash basin per 12 patients and one toilet per 8 patients.

(3) If the facility is coeducational, the program shall designate and so identify separate bathrooms for male and female patients.

e. The written plan to be followed in the event of fire or tornado shall be conspicuously displayed on each floor or in each area that patients, concerned persons, staff or visitors occupy at the facility and shall be explained to all inpatient and residential patients as a part of their orientation to the program. Fire drills shall be conducted at least monthly, and tornado drills shall be conducted monthly from April through October.

f. Written reports of annual inspections by state or local fire safety officials or private fire protection companies approved by the department shall be maintained with records of corrective action taken by the program based on recommendations articulated in such reports.

g. Every facility shall have an adequate water supply from an approved source. A municipal water system shall meet this requirement. Private water sources shall be tested annually.

h. The facility shall allow for the following:

(1) Areas in which a patient may be alone when appropriate; and

(2) Areas for private conversations with others.

i. Articles of grooming and personal hygiene that are appropriate to the patient's age, developmental level, and clinical state shall be readily available in a space reserved near the patient's sleeping area. If access to such articles is clinically contraindicated as approved by the treatment supervisor, a patient's personal articles may be kept under lock and key by staff. Staff shall explain to the patient the conditions under which the articles may be used. Justification for this restriction shall be documented in the patient record.

j. If patients maintain their own living quarters or perform day-to-day housekeeping activities, these responsibilities shall be clearly defined in writing and be a part of the patient orientation program. Staff assistance and equipment shall be provided as needed.

k. Patients shall be allowed to wear their own clothing in accordance with program rules. If clothing is provided by programs, it shall be suited to the climate and appropriate. A laundry room shall be accessible so patients may wash their clothing.

l. The program shall ensure that the use and location of noise-producing equipment and appliances, such as television sets, radios, computers, and CD players, do not interfere with clinical and therapeutic activities.

m. The program shall provide recreation and outdoor activities unless clinically contraindicated.

155.23(8) *Religion-culture.* Program policies and procedures shall include a written description of any religious orientation, religious practice, or religious restrictions. For juvenile patients, this description shall be provided to the patient, parent(s) or guardian, and placing agency at the time of admission in compliance with HIPAA as amended to August 1, 2025, and U.S. Department of Health and Human Services (DHHS), 42 CFR Part 2 as amended to August 1, 2025, regulations on the confidentiality of alcohol and drug abuse patient records. For adult patients, this information shall be available during orientation. The patient shall have the opportunity to participate in religious activities and services in accordance with the patient's faith or that of a patient's parent(s) or guardian if the patient is a minor. The program shall, when necessary and reasonable, arrange transportation to religious activities.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.24(125,135) Specific standards for inpatient and residential programs licensed to provide services to juveniles. Inpatient and residential programs that provide services to juveniles under the age of 18 shall also comply with the following standards. The program's policies and procedures shall address each standard.

155.24(1) *Personal possessions.* A program shall allow a patient to bring personal belongings. The program may limit or supervise the use of these items. The program shall ensure that each patient has adequate, clean, well-fitting, attractive, and seasonable clothing as required for health, comfort, and physical well-being. The clothes should be appropriate to the patient's individual needs, age, and sex.

155.24(2) *Family involvement.* The program shall encourage family involvement.

155.24(3) *Money.* Money earned or received as a gift or as an allowance by a patient shall be that patient's personal property. The program shall maintain a separate accounting system for patient money and shall address the patient's use of funds.

155.24(4) *Discipline.* The program's methods for control and discipline of juveniles shall be available to all staff and to the juvenile's family. Staff shall be in control of and responsible for discipline at all times. Discipline shall not include withholding basic necessities such as food, clothing, or sleep.

a. The program shall prohibit staff or patients from utilizing corporal punishment as a method of disciplining or correcting patients. This policy shall be communicated in writing to all staff.

b. The program's written policies on behavior expectations shall be made available to the patient and the patient's parent(s) or guardian, including:

(1) The general expectations of behavior, including the program's rules and practices.

(2) The range of reasonable consequences that may be used to deal with inappropriate behavior.

155.24(5) *Number of staff.* The program shall have staff coverage seven days per week, 24 hours per day. The number and qualifications of the staff will vary depending on the needs of the patients.

a. The program shall have a 24-hour supervisory consultation on-call system. During prime programming time, there shall be at least a one-to-eight staff-to-patient ratio.

b. Comprehensive residential facilities, as defined in 441—Chapter 115, shall have at least a one-to-five staff-to-patient ratio during prime programming time. A staff person shall be in each living unit at all times when juveniles are in residence, and there shall be a minimum of three nighttime checks between the hours of 12 midnight and 6 a.m. These checks shall be logged. The program's policies and procedures shall address nighttime checks.

c. The program shall define its prime programming time.

155.24(6) *Illness, accident, death, or absence from the inpatient or residential program.* The program shall notify the patient's parent(s), guardian, and responsible agency of any serious illness, incident involving serious bodily injury, absence, or removal of the juvenile from the facility in compliance with HIPAA as amended to August 1, 2025, and DHHS, 42 CFR Part 2 as amended to August 1, 2025, regulations on the confidentiality of alcohol and drug abuse patient records. In the event of the death of a patient, the program shall immediately notify the prescriber, the patient's parent(s) or guardian, the placing agency, and the appropriate state authority.

155.24(7) *Educational services.* The program's educational program shall meet the requirements of the department of education and shall be available for each patient in accordance with abilities and needs.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.25(125,135) Specific standards for substance use assessment and OWI evaluation-only programs. Programs that provide substance use assessment and OWI evaluation-only services shall also comply with the following standards. The program's policies and procedures shall address each standard.

155.25(1) A program conducting OWI evaluations on persons convicted of operating a motor vehicle while intoxicated (OWI) pursuant to Iowa Code section 321J.2 and on persons whose driver's license or nonresident operating privileges are revoked under Iowa Code chapter 321J shall do so in accordance with 641—Chapter 157.

155.25(2) The program shall make its fees public and shall inform potential patients of the fee at the time the assessment or evaluation is scheduled.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.26 to **155.33** Reserved.

641—155.34(125,135) Specific standards for enhanced treatment services.

155.34(1) *Standards.* Substance use disorder and problem gambling treatment programs licensed to provide enhanced treatment services shall also comply with the following standards. The program's policies and procedures shall address each standard.

155.34(2) *Personnel.* The program shall meet the requirements in subrule 155.21(8). In addition:

a. The program's policies and procedures shall include job descriptions for positions that provide prevention services for substance use disorders and problem gambling, treatment for substance use disorders and problem gambling, services for medical conditions, and services for mental health conditions.

b. The program shall have staff on site who are qualified to provide prevention and early intervention services for substance use disorders and problem gambling, treatment for substance use disorders and problem gambling, services for medical conditions, and services for mental health conditions.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.35(125,135) Specific standards for opioid treatment programs. All programs that use methadone or other medications approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 as amended to August 1, 2025) and by the state of Iowa for use in the treatment of opioid addiction shall comply with this rule; HIPAA, as amended to August 1, 2025; and Part II, DHHS, Substance Abuse and Mental Health Services Administration, 42 CFR Part 8, Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction, effective February 2, 2024, and as amended to August 1, 2025.

155.35(1) *Required approvals.* All opioid treatment programs shall be licensed or approved by the department and shall maintain all other approvals required by the federal Drug Enforcement Administration, SAMHSA and the Iowa board of pharmacy in order to provide services.

155.35(2) *Central registry system.* To prevent simultaneous enrollment of a patient in more than one program, all opioid treatment programs shall participate in a central registry as established by the department.

Prior to admission of an applicant to an opioid treatment program, the program shall submit to the registry the applicant's name, birth date, and date of intended admission, and any other information required for the clearance procedure. No person shall be admitted to a program who is found by the registry to be participating in another such program. All opioid treatment programs shall report all admissions, discharges, and transfers to the registry immediately. All information reported to the registry from the programs and all information reported to the programs from the registry shall be treated as confidential in accordance with HIPAA as amended to August 1, 2025, and regulations on the confidentiality of alcohol and drug abuse patient records, DHHS, 42 CFR Part 2 as amended to August 1, 2025.

a. Definitions. For purposes of this subrule:

"Central registry" means the system through which the department obtains patient identifying information about individuals applying for maintenance treatment for the purpose of preventing an individual's concurrent enrollment in more than one such program.

"Opioid treatment program" means a withdrawal management or maintenance treatment program that is required to report patient identifying information to the central registry and that is located in the state.

b. Restrictions on disclosure.

(1) A program may disclose patient identifying information to a central registry for the purpose of preventing the multiple enrollment of a patient only if:

1. The disclosure is made when:
- The patient is admitted for treatment; or
- The treatment is interrupted, resumed or terminated.

2. The disclosure is limited to:
- Patient identifying information; and
- Relevant dates of admission.

(2) The program shall inform the patient of the required disclosure prior to admission.

c. Use of information limited to prevention of multiple enrollments. Any information disclosed to the central registry to prevent multiple enrollments shall not be redisclosed by the registry nor shall such information be used for any other purpose than the prevention of multiple enrollments unless so authorized

by court order in accordance with HIPAA as amended to August 1, 2025, and 42 CFR Part 2 as amended to August 1, 2025.

d. *Permitted disclosure by the central registry to prevent a multiple enrollment.* If a program petitions the central registry and an identified patient is enrolled in another program, the registry may disclose:

(1) The name, address, and telephone number of the program in which the patient is currently enrolled to the inquiring program; and

(2) The name, address, and telephone number of the inquiring program to the program in which the patient is currently enrolled. The programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

155.35(3) *Admission requirements.*

a. Prior to or at the time of a patient's admission to an opioid treatment program, the program shall conduct a comprehensive assessment so as to determine appropriateness for admission.

b. The program shall verify, to the extent possible, the patient's name, address, and date of birth.

c. Determination and documentation.

(1) An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that:

1. The person meets diagnostic criteria for a moderate to severe OUD; or

2. The individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose.

(2) Such decisions must be appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD, that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

(3) When physiological addiction cannot be clearly documented, the program physician or an appropriately trained staff member designated and supervised by the physician shall record in the patient's record the criteria used to determine the patient's current physiologic dependence and history of addiction. In the latter circumstance, the program physician shall review, date, and countersign the supervised staff member's evaluation to demonstrate the physician's agreement with the evaluation. The program physician shall make the final determination concerning a patient's physiologic dependence and history of addiction.

(4) When a patient has voluntarily left an opioid treatment program in good standing and seeks readmission within two years of discharge, the program shall document the following information about the patient:

1. Prior opioid treatment of six months or more; and

2. That in the physician's medical judgment, treatment of the patient is warranted. Such documentation shall be entered in the patient's record by the program physician.

d. The program shall collect a drug screening sample for analysis. Where dependence is substantially verified through other indicators, a negative drug screen will not necessarily preclude admission to the program.

e. Prior to a patient's admission, the program shall confirm with the central registry that the patient is not currently enrolled in another opioid treatment program.

f. If a potential patient has previously been enrolled in another program, the admitting program shall request from the previous program a copy of the patient's assessment data, treatment plan, and discharge summary including the type of or reason for discharge. All programs subject to these rules shall promptly respond to such a request upon receipt of a valid release of information.

g. A person under the age of 18 is required to have had two documented attempts at short-term withdrawal management or drug-free treatment to be eligible for maintenance treatment. A one-week waiting period is required after such a short-term withdrawal management attempt, however, before an attempt is repeated. The program physician shall document in the patient's record that the patient continues to be, or is again, physiologically dependent on narcotic drugs. No person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.

h. Program staff shall ensure that a patient is voluntarily participating in the program, and the patient shall sign a Consent to Treatment Form.

i. Pregnant patients may be admitted to opioid treatment in accordance with the following provisions:

(1) Evidence of current physiological dependency is not needed if the program physician certifies the pregnancy and, in the physician's reasonable judgment, finds treatment to be justified. Documentation of all findings and justifications for admission shall be documented in the patient's record by the program physician prior to the administration of the initial dose of medication.

(2) Pregnant patients shall be offered comprehensive prenatal care. If the program cannot provide prenatal services, the program shall assist the patient in obtaining such services and shall coordinate ongoing care with the collateral provider.

(3) The program physician shall document that the patient has been informed of the possible risks to the unborn child from the use of medication and the risks of continued use of illicit substances.

(4) Should a program have a waiting list for admission to the program, pregnant patients shall be given priority.

155.35(4) *Placement, admission and assessment.* The program shall have written criteria for considering an individual for placement and admission. In addition, the program shall maintain current procedures to ensure that patients are admitted to maintenance treatment by qualified staff who have determined by using accepted medical criteria, such as those outlined in the DSM.

a. The program shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts:

(1) A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD; and

(2) A full history and examination to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude the patient from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

b. Assuming there are no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP and verified by an OTP practitioner.

c. A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full examination can be completed by a non-OTP practitioner if the examination is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

d. Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination.

e. The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone if a practitioner or primary care provider determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply:

(1) In evaluating patients for treatment with Schedule II medications (such as methadone), audiovisual telehealth platforms must be used, except when not available to the patient, in which case, it is acceptable to use audio-only devices but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(2) In evaluating patients for treatment with Schedule III medications or medications not classified as a controlled medication, audiovisual or audio-only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

f. The medical evaluation of the patient shall include but not be limited to:

(1) A complete medical history;

(2) An assessment of the patient's current psychological and mental status;

(3) A physical examination, including examination for:

1. Pulmonary, liver, or cardiac abnormalities;
2. Infectious disease; and
3. Dermatologic sequela of addiction;

(4) Laboratory tests, including:

1. Serological test for syphilis; and
2. Urine screening for drugs;

(5) An intradermal PPD (tuberculosis skin test) and review of tetanus immunization status; and

(6) When indicated, an EKG, chest X-ray, pap smear, pregnancy test, sickle cell screening, complete blood count and white cell differential, multiphasic chemistry profile, routine and microscopic urinalysis, or other tests indicated by the patient's condition. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude the patient from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

155.35(5) *Treatment plans.* Based upon the initial assessment, an individualized written treatment plan shall be developed and recorded in the patient's case record.

a. A treatment plan shall be developed and shall delineate the patient's immediate needs and the actions required to meet these needs.

b. The treatment plan shall be developed as soon after the patient's admission as is clinically feasible but no later than 30 days following the patient's admission to an outpatient opioid maintenance treatment program.

c. Treatment plans shall be developed in partnership with the patient. Comprehensive treatment plans shall be reviewed by the primary counselor and the patient as often as necessary but no less than every 90 days during the first year and semiannually each subsequent year for opioid treatment modalities. Treatment plans shall be reviewed by the program physician on an annual basis.

155.35(6) *Rehabilitative services.*

a. OTPs must provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed upon, including harm reduction education and recovery-oriented counseling. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients and engage with patients, to contribute to the appropriate care plan for the patient and to monitor and update patient progress. Patient refusal of counseling shall not preclude the patient from receiving MOUD.

b. OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from an initial or periodic medical examination.

c. OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed upon as beneficial by the patient and program staff.

155.35(7) *Medication administration.*

a. The program physician shall determine the patient's initial and subsequent dose of medication and on-site dosing schedule and shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each patient's case record each change in the dosage schedule. The physician shall directly communicate orders to the pharmacy or registered or licensed personnel

supervising medication administration. The program physician may communicate such orders verbally; however, orders shall be reduced to writing and countersigned within 72 hours by the program physician.

b. For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's OUD, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

(1) Medication shall be administered by a professional authorized by law.

(2) No medication shall be administered until the patient has completed admission procedures unless the patient enters the program on a weekend and the central registry cannot be contacted. If, in the clinical judgment of the program physician, a patient is experiencing an emergency situation, the admission procedures may be completed on the following workday.

c. Administration.

(1) Take-home medication shall be labeled in accordance with state and federal law and have childproof caps.

(2) A medication administration log shall be kept in the dosing area and in the patient's case record. The amount of medication administered and the signature of the staff member authorized to administer the medication shall also be included in the patient's case record. No dose shall be administered until the patient has been positively identified and the dosage amount has been compared with the currently ordered and documented dosage level.

(3) Ingestion shall be observed and verified by the staff person authorized to administer the medication.

(4) The program physician shall record, date, and sign in each patient's case record each change in the dosage schedule. Daily dosages of medications in excess of 100 milligrams shall be dispensed only with the approval of the program physician and shall be documented and justified in the patient's case record.

155.35(8) *Take-home or unsupervised medication use.*

a. Unsupervised (take-home) medication doses may be provided under the following circumstances:

(1) Any patient in comprehensive treatment may receive individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and state and federal holidays, no matter the patient's length of time in treatment.

(2) OTP decisions on dispensing MOUD to patients for unsupervised use shall be determined by an appropriately licensed OTP medical practitioner or the medical director. In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

1. Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;
2. Regularity of attendance for supervised medication administration;
3. Absence of serious behavioral problems that endanger the patient, the public or others;
4. Absence of known recent diversion activity;
5. Whether take-home medication can be safely transported and stored; and
6. Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined shall be documented in the patient's medical record. If it is determined that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in this rule apply. The dispensing restrictions set forth in this rule do not apply to buprenorphine and buprenorphine products listed in this rule.

1. During the first 14 days of treatment, the take-home supply is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to seven days, but decisions must be based on the criteria listed in this rule. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

2. From 15 days of treatment, the take-home supply is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in this rule. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

3. From 31 days of treatment, the take-home supply provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in this subrule. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

(4) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers. Programs must provide education to each patient on the following: safely transporting medication from the OTP to the patient's place of residence and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

b. If a patient is unable to conform to the applicable mandatory schedule, a revised schedule may be permitted provided that the program receives an exception to these rules from the department and SAMHSA, when applicable. A copy of the written exception shall be placed in the patient's case record. The department will consider exceptions only in unusual circumstances. When a program is applying for less frequent pickups for patients, approval will be based on considerations in addition to distance if another program exists within 25 miles of the patient's residence.

c. Should a patient receiving take-home medication provide a drug screen that is confirmed either positive for substances or negative for the prescribed medication, the program shall ensure that, when test results are used, presumptive laboratory results are distinguished from results that are definitive.

155.35(9) *Drug testing.* Each program shall establish policies and procedures for the collection of drug-screening specimens and utilization of results.

a. The program shall ensure that an initial drug-screening test or analysis is completed for each prospective patient and that at least eight additional random tests or analyses are performed on each patient during the patient's first year in maintenance treatment and that at least quarterly random tests or analyses are performed on each patient in maintenance treatment for each subsequent year. When a sample is collected from each patient for such a test or analysis, it shall be done in a manner that minimizes opportunity for falsification. Each test or analysis shall be analyzed for opioids, methadone, amphetamines, cocaine, and barbiturates. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must be analyzed for any of those drugs as well. Any laboratory that performs the testing required under this rule shall be in compliance with all applicable federal proficiency testing and licensing standards and all applicable state standards.

b. The program shall ensure that test results are not used as the sole criterion to force a patient out of treatment but are used as a guide to change treatment approaches. The program shall also ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

155.35(10) *Diversion prevention plan.*

a. The program shall develop a diversion identification and prevention plan that:

(1) Outlines the methods by which the program shall detect possible diversion of take-home medication; and

(2) Describes the actions to be taken when diversion is identified or suspected.

b. The program shall establish and implement proactive procedures to reduce the likelihood or possibility of diversion.

155.35(11) *Interim maintenance treatment.*

a. An approved program may offer interim maintenance treatment when, due to capacity, the program cannot place the patient in a program offering comprehensive services within 14 days of the patient's application for admission.

b. An approved program may provide interim maintenance treatment only if the program also provides comprehensive maintenance treatment to which interim maintenance treatment patients may be transferred.

c. Interim maintenance treatment program approval.

(1) Before a public or nonprofit private narcotic treatment program may provide interim maintenance treatment:

1. The program must receive approval of both the U.S. Food and Drug Administration and the department; and

2. The program director must certify that the program seeking such authorization is unable to place patients in a public or private nonprofit program within a reasonable geographic area within 14 days of the patient's application for admission and that interim maintenance treatment will not reduce the capacity of the program's comprehensive maintenance treatment.

(2) Patients admitted to interim maintenance treatment shall be transferred to comprehensive maintenance treatment within 120 days of admission.

d. Minimum standards for interim maintenance treatment. The program may admit a patient who is eligible for comprehensive maintenance treatment to interim maintenance treatment if the patient cannot be placed in a public or private nonprofit comprehensive program within a reasonable geographic area and within 14 days of application for services. An initial drug screen and at least two other drug screens shall be taken from the patient during the maximum admission period of 120 days. A program shall establish and follow reasonable criteria for determining the transfer of patients to comprehensive maintenance treatment. These transfer criteria shall be in writing and available for inspection and shall include at a minimum a preference for the transfer of pregnant patients. Interim maintenance shall be conducted in accordance with all applicable federal regulations and state rules. The program shall notify the department when a patient begins interim treatment, when a patient leaves interim treatment, and when a patient transfers to comprehensive maintenance treatment. Such notifications shall be documented by the program in the patient's case record. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment, with the following exceptions:

(1) The medication is required to be administered daily under observation;

(2) Take-home medication is not allowed;

(3) Initial and comprehensive treatment plans are not required;

(4) A primary counselor is not required to be assigned to the patient; and

(5) Interim maintenance treatment cannot be provided for longer than 120 days in any 12-month period.

155.35(12) *Accreditation.* All opioid treatment programs shall obtain and retain accreditation by a recognized national accreditation organization. The national accreditation bodies currently recognized as meeting committee criteria are:

a. The Joint Commission.

b. The Council on Accreditation of Rehabilitation Facilities (CARF).

c. The Council on Accreditation (COA).

d. The American Osteopathic Association (AOA).

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

TUBERCULOSIS (TB) SCREENING: HEALTH CARE WORKERS AND RESIDENTS

641—155.36 Reserved.

641—155.37(125,135) Definitions. For the purpose of these rules, the following definitions shall apply:

"Bacille Calmette-Guerin vaccination" or *"BCG vaccination"* means a vaccine for tuberculosis (TB). BCG is used in many countries with a high prevalence of TB to prevent childhood tuberculosis meningitis

and military disease. BCG is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis*, the variable effectiveness of the vaccine against adult pulmonary TB, and the vaccine's potential interference with tuberculin skin test reactivity.

"Baseline TB screening" means the screening of staff and residents for latent tuberculosis infection (LTBI) and TB disease at the beginning of employment or upon admission to a facility. Baseline TB screening includes a symptom screen for all staff and residents and tuberculin skin tests (TSTs) or interferon-gamma release assay (IGRA) for *Mycobacterium tuberculosis* for those staff and residents with previous negative test results for *M. tuberculosis* infection.

"Baseline TST" or *"baseline IGRA"* means the TST or IGRA, respectively, that is administered at the beginning of employment to newly hired staff or upon admission to residents of facilities.

"Boosting" means a phenomenon in which a person has a negative TST (i.e., false-negative) result years after infection with *M. tuberculosis* and then a positive subsequent TST result. The positive TST result is caused by a boosted immune response of previous sensitivity rather than by a new infection (false-positive TST conversion). Two-step testing reduces the likelihood of mistaking a boosted reaction for a new infection.

"Extrapulmonary TB" means TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes).

"Interferon-gamma release assay" or *"IGRA"* means a whole-blood test that can aid in diagnosing *Mycobacterium tuberculosis* infection.

"Laryngeal TB" means a form of TB disease that involves the larynx and may be highly infectious.

"Latent TB infection" or *"LTBI"* means infection with *M. tuberculosis* without symptoms or signs of disease having manifested.

"Mantoux method" means a skin test performed by intradermally injecting 0.1 mL of purified protein derivative (PPD) tuberculin solution into the volar or dorsal surface of the forearm.

"Pulmonary TB" means TB disease that occurs in the lung parenchyma, usually producing a cough that lasts three weeks or longer. Pulmonary TB is usually infectious.

"Purified protein derivative (PPD) tuberculin" means a material used in diagnostic tests for detecting infection with *M. tuberculosis*.

"Risk classification" means the category on which the infection control team, or designated other, determines the setting's TB risk classification is based as a result of the TB risk assessment.

"Serial screening" refers to TB screening performed at regular intervals following baseline TB screening. Serial TB screening, also called annual or ongoing TB testing, consists of two components: (1) assessing for current symptoms of active TB disease and (2) testing for the presence of infection with *M. tuberculosis* by administering either a TST or single IGRA.

"Symptom screen" means a procedure used during a clinical evaluation in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).

"TB patient" means a person who had undiagnosed infectious pulmonary or laryngeal TB while in the facility during the preceding year. "TB patient" does not include persons with LTBI (treated or untreated), extrapulmonary TB disease, pulmonary, or laryngeal TB who have met criteria for noninfectiousness.

"TB risk assessment" means an initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* in a particular health care setting.

"TB screening" means an administrative control measure in which evaluation for LTBI and TB disease is performed through baseline and serial screening of staff and residents of facilities.

"TB screening plan" means a plan that facilities develop and implement that comprises four major components: (1) baseline testing for *M. tuberculosis* infection, (2) serial testing for *M. tuberculosis* infection, (3) serial screening for signs or symptoms of TB disease, and (4) TB training and education.

"Treatment for LTBI" means treatment that prevents the progression of *M. tuberculosis* infection into TB disease.

"Tuberculin skin test" or *"TST"* means a diagnostic aid for finding *M. tuberculosis* infection. The Mantoux method is the recommended method to be used for the TST.

"Tuberculosis" or *"TB"* means the namesake member organism of *M. tuberculosis* complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name refers to the entire *M. tuberculosis* complex, which includes *M. bovis* and *M. africanum*, *M. microti*, *M. canetti*, *M. caprae*, and *M. pinnipedii*.

"Tuberculosis disease" or *"TB disease"* means a condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early stage of disease in which signs or symptoms are not present but other indications of disease activity are present) illness.

"Two-step tuberculin skin test" or *"two-step TST"* means the procedure used for the baseline skin testing of persons who will receive serial TSTs to reduce the likelihood of mistaking a boosted reaction for a new infection.

[**ARC 9499C**, IAB 8/20/25, effective 10/1/25]

641—155.38(125,135) Tuberculosis screening of staff and residents.

155.38(1) *TB risk assessment.* Annually, each facility shall conduct a TB risk assessment to evaluate the risk for transmission of *M. tuberculosis*, regardless of whether a person with suspected or confirmed TB disease is expected to be encountered in the facility. The TB risk assessment shall be utilized to determine the types of administrative, environmental, and respiratory protection controls needed and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection control measures. The risk assessment shall include:

a. The community rate of TB,

b. The number of persons with infectious TB encountered in the facility, and

c. The speed with which persons with infectious TB are suspected, isolated, and evaluated to determine if persons with infectious TB exposed staff or others in the facility. TB cases include persons who had undiagnosed infectious pulmonary or laryngeal TB while in the facility during the preceding year. This does not include persons with LTBI (treated or untreated), persons with extrapulmonary TB disease, or persons with pulmonary or laryngeal TB who have met criteria for noninfectiousness.

155.38(2) *Facility risk classification.* The infection control team or designated staff in a facility is responsible for determining the type of risk classification of the facility. The facility risk classification is used to determine the frequency of TB screening. The facility risk classification may change due to an increase or decrease in the number of TB cases during the preceding year.

a. Types of risk classifications.

(1) "Low risk" means that a facility is one in which persons with active TB disease are not expected to be encountered and in which exposure to TB is unlikely.

(2) "Medium risk" means that a facility is one in which health care workers will or might be exposed to persons with active TB disease or to clinical specimens that might contain *M. tuberculosis*.

(3) "Potential ongoing transmission" means that a facility is one in which there is evidence of person-to-person transmission of *M. tuberculosis*. This classification is a temporary classification. If it is determined that this classification applies to a facility, the facility shall consult with the department's TB control program.

b. Classification criteria—low risk.

(1) Inpatient settings with 200 or more beds. If a facility has fewer than six TB patients for the preceding year, the facility will be classified as low risk.

(2) Inpatient settings with fewer than 200 beds. If a facility has fewer than three TB patients for the preceding year, the facility will be classified as low risk.

(3) Outpatient, outreach, and home-based health care settings. If a facility has fewer than three TB patients for the preceding year, the facility will be classified as low risk.

c. Classification criteria—medium risk.

(1) Inpatient settings with 200 or more beds. If a facility has six or more TB patients for the preceding year, the facility will be classified as medium risk.

(2) Inpatient settings with fewer than 200 beds. If a facility has three or more TB patients for the preceding year, the facility will be classified as medium risk.

(3) Outpatient, outreach, and home-based health care settings. If a facility has three or more TB patients for the preceding year, the facility will be classified as medium risk.

d. Classification criteria—potential ongoing transmission. If evidence of ongoing *M. tuberculosis* transmission exists at a facility, the facility will be classified as potential ongoing transmission, regardless of the facility's previous classification.

155.38(3) *Baseline TB screening procedures for facilities.*

a. All facility staff members shall receive baseline TB screening upon hire. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using a two-step TST or a single IGRA to test for infection with *M. tuberculosis*.

b. A staff member may begin working with patients after a negative TB symptom screen (i.e., no symptoms of active TB disease) and a negative TST (i.e., first step) or a negative IGRA. The second TST may be performed after the staff member starts working with patients.

c. A staff member with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician. Treatment for LTBI should be considered in accordance with CDC guidelines.

d. A staff member with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, does not need another chest radiograph at the time of hire.

e. TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for staff with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., interferon-gamma (IFN-g)). All other staff should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

f. A second TST is not needed if the staff member has a documented TST result from any time during the previous 12 months. If a newly employed staff member has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

g. Previous BCG vaccination is not a contraindication to having an IGRA, a TST or two-step skin testing administered. Health care workers with previous BCG vaccination should receive baseline and serial testing in the same manner as those without BCG vaccination. Evaluation of TST reactions in persons vaccinated with BCG should be interpreted using the same criteria for those not BCG-vaccinated. A health care worker's history of BCG vaccination should be disregarded when administering and interpreting TST results. Previous BCG vaccination does not cause a false-positive IGRA test result.

155.38(4) *Serial TB screening procedures for facilities.*

a. Facilities classified as low risk. After baseline testing of staff for infection with *M. tuberculosis*, additional TB screening of staff is not necessary unless an exposure to *M. tuberculosis* occurs.

b. Facilities classified as medium risk.

(1) After undergoing baseline testing for infection with *M. tuberculosis*, staff should receive TB screening annually (i.e., symptom screen for all staff members and testing for infection with *M. tuberculosis* for staff members with baseline negative test results).

(2) Staff members with a baseline positive or new positive test result for *M. tuberculosis* infection or documentation of previous treatment for LTBI or TB disease shall receive one chest radiograph result to exclude TB disease. Instead of participating in serial testing, staff should receive a symptom screen annually. This screen should be accomplished by educating the staff about symptoms of TB disease and instructing the staff members to report any such symptoms immediately to the occupational health unit. Treatment for LTBI should be considered in accordance with CDC guidelines.

c. Facilities classified as potential ongoing transmission. Testing for infection with *M. tuberculosis* may need to be performed every eight to ten weeks until lapses in infection control have been corrected and no additional evidence of ongoing transmission is apparent. The potential ongoing transmission classification should be used only as a temporary classification. This classification warrants immediate investigation and corrective steps. After a determination that ongoing transmission has ceased, the setting will be reclassified as medium risk for a minimum of one year.

155.38(5) *Screening of staff who transfer to other facilities.*

a. Staff transferring from a low-risk facility to another low-risk facility. After a baseline result for infection with *M. tuberculosis* is established and documented, serial testing for *M. tuberculosis* infection is not necessary for staff transferring from a low-risk facility to another low-risk facility.

b. Staff transferring from a low-risk facility to a medium-risk facility. After a baseline result for infection with *M. tuberculosis* is established and documented, annual TB screening, including a symptom screen and TST or IGRA for persons with previously negative test results, should be performed for staff transferring from a low-risk facility to a medium-risk facility.

155.38(6) *Baseline TB screening procedures for residents of residential, inpatient, and halfway house facilities.*

a. TB screening is a formal procedure to evaluate residents for LTBI and TB disease. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using a two-step TST or a single IGRA to test for infection with *M. tuberculosis.*

b. All residents shall be assessed for current symptoms of active TB disease upon admission. Within 72 hours of a resident's admission, baseline TB testing for infection shall be initiated unless baseline TB testing occurred within three months prior to the resident's admission.

c. Residents with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician.

d. Residents with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, do not need another chest radiograph at the time of admission.

e. TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for residents with a documented history of TB disease, a documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., IFN-g). All other residents should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

f. A second TST is not needed if the resident has a documented TST result from any time during the previous 12 months. If a new resident has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

g. After baseline TB screening is accomplished, serial TB screening of the residents is not recommended.

155.38(7) *Serial TB screening procedures for residents of residential, inpatient, and halfway house facilities.*

a. If a resident is discharged and readmitted to a facility and less than 12 months have passed since the last TB screening, residents should receive a symptom screen upon readmittance. This screen should be accomplished by educating the resident about symptoms of TB disease and instructing the resident to report any such symptoms immediately to the infection control team or designated other staff. If symptoms or signs of TB disease are documented, then a medical evaluation to include a chest X-ray to rule out TB disease is required.

b. If a resident is discharged and readmitted to a facility and more than 12 months have passed since the last TB screening, baseline TB screening should be repeated as outlined in subrule 155.38(6).

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[1] Effective date of Ch 3 delayed by the Administrative Rules Review Committee 70 days from 8/2/78. Delay suspended by the Administrative Rules Review Committee at their meeting held on 9/11/78.

[2] Effective date of 643—3.35(125) delayed 70 days by the Administrative Rules Review Committee at its meeting held April 11, 1994; on June 15, 1994, the Committee voted to delay the rule until adjournment of the 1995 General Assembly.

CHAPTER 156
CONSUMABLE HEMP PRODUCTS

[Prior to 6/14/23, see Inspections and Appeals Department[481] Ch 32]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/17/29

641—156.1(204) Definitions. For the purpose of these rules, the following terms have the meanings indicated in this chapter. The definitions set out in Iowa Code section 204.2 are incorporated verbatim herein.

"Accredited laboratory" means a laboratory accredited in accordance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Standard 17025:2017 (July 17, 2024) by an International Laboratory Accreditation Cooperation (ILAC)-recognized accreditation body for the analyses performed on consumable hemp products.

"Adulterated" means the same as in 21 U.S.C. Section 342(a)(4) (as amended to July 17, 2024), except that a consumable hemp product is not deemed "adulterated" pursuant to this chapter solely because it contains a hemp product not generally recognized as safe (GRAS) by the federal Food and Drug Administration.

"Approved hemp source" means a manufacturer of a consumable hemp product that is engaged in the wholesale or retail sale of the product and that is:

1. Located in this state and manufactures the consumable hemp product in compliance with Iowa Code chapter 204 and these rules; or
2. Located in a state that has a state hemp plan approved by the United States Department of Agriculture under 7 U.S.C. Chapter 38, Subchapter VII (as amended to July 17, 2024).

"Batch" means a specific quantity of a consumable hemp product that contains a lot number; is uniform and intended to meet specifications for identity, strength, purity, and composition; and is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

"Cannabidiol" or *"CBD"* means the specific chemical compound with the Chemical Abstracts Service number 13956-29-1.

"Certificate of analysis" or *"COA"* means an official document released by an accredited laboratory following an analysis of a consumable hemp product. The certificate of analysis contains all of the concentrations of cannabinoids, pesticides, residual solvents, metals, harmful pathogens, toxicants, and synthetic or semisynthetic cannabinoids, including data on levels of total delta-9 tetrahydrocannabinol content concentration and whether a sample passed or failed any limits related to these analyses.

"Certificate of free sale" means a government certification that products such as food, drugs, medicine, or cosmetics are approved for unrestricted sale in the jurisdiction in which they originate.

"Consumable hemp establishment" means an individual or entity engaged in manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp product in Iowa or to purchasers located in Iowa. A consumable hemp establishment does not include an individual or entity manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp product containing only hemp seed or hemp seed-derived food ingredients GRAS under the conditions of use by the federal Food and Drug Administration.

"Consumable hemp manufacturer" means a consumable hemp establishment engaged in manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp product on a wholesale basis. A consumable hemp manufacturer includes individuals and entities outside of Iowa that distribute consumable hemp products in Iowa. A consumable hemp manufacturer does not include individuals or entities exclusively engaged in the harvesting, storage, or distribution of raw hemp.

"Consumable hemp retailer" means a consumable hemp establishment selling consumable hemp product to consumers on a retail basis. A consumable hemp retailer includes an establishment selling consumable hemp products online.

"Container" means the object that holds one or more servings of a consumable hemp product.

"Delta-9 tetrahydrocannabinol" or *"THC"* means the specific chemical compound with the Chemical Abstracts Service number 1972-08-3.

"Expiration date" means the month and year as determined by the manufacturer, packer, or distributor on the basis of tests showing that the product, until that date, under the conditions of handling, storage, preparation, and use per label directions, will, when consumed, contain not less than the quantity of each ingredient as set forth on its label.

"Food" means the same as defined in Iowa Code section 137F.1. Food includes human dietary supplements and alcoholic beverages.

"Harvesting" applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in Section 201(gg) of the federal Food, Drug, and Cosmetic Act (as amended to July 17, 2024).

"Jurisdiction of origin" means the federal, state, or local regulatory jurisdiction that has the authority to conduct inspections of the facility in which a consumable hemp product was most recently subject to a manufacturing/processing activity.

"Lot number" means a specific quantity of raw hemp or processed hemp product that is uniform and intended to meet specifications for identity, strength, purity, and composition that contains the manufacturer's, processor's, or distributor's number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of consumable hemp products.

"Manufacturing/processing" means making food from one or more ingredients or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

"Misbranded" means a food that violates 21 U.S.C. Section 343 (as amended to July 17, 2024).

"QR code" means a quick response machine-readable code that can be read by a camera, consisting of an array of black and white squares used for storing information or directing or leading a user to product information regarding manufacturer data and accredited laboratory certificates of analysis.

"Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

"Raw hemp" means an unprocessed hemp plant, or any part of the hemp plant, in its raw or natural state. Raw hemp is a raw agricultural commodity.

"Serving" means the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in table 2 of 21 CFR 101.12 (as amended to July 17, 2024). If a solid consumable hemp product is packaged in a manner that includes more than a single serving, each serving must be clearly identified and severable from the other servings in the container. If a liquid consumable hemp product is packaged in a manner that includes more than a single serving, the number of servings must be conspicuously labeled. Liquid consumable hemp products shall be packaged in a container that holds a minimum of 12 fluid ounces.

"Synthetic consumable hemp products" means products containing synthetic or semisynthetic cannabinoids. Synthetic and semisynthetic cannabinoids refer to a class of cannabinoids that are created through a chemical process and are structurally similar to naturally occurring cannabinoids or cannabinoids that may occur in very small amounts naturally. Examples of synthetic consumable hemp products include but may not be limited to delta-8 tetrahydrocannabinol, delta-10 tetrahydrocannabinol, hexahydrocannabinol (HHC), tetrahydrocannabiphorol (THC-P), and tetrahydrocannabinol-O-acetate (THC-O).

"Tetrahydrocannabinolic acid" or *"THCA"* means the specific chemical compound with the Chemical Abstracts Service number 23978-85-0.

"Total delta-9 tetrahydrocannabinol" or *"total THC"* means 87.7 percent of the amount of tetrahydrocannabinolic acid plus the amount of delta-9 tetrahydrocannabinol.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.2(204) Registration and posting. A consumable hemp establishment shall not engage in manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp product in Iowa or to purchasers located in Iowa until it has submitted a consumable hemp registration that is approved by the department.

156.2(1) *Consumable hemp manufactures/distributors.* At least 30 days prior to manufacturing, processing, packing, holding, preparing, distributing, or selling any consumable hemp product in Iowa or to purchasers located in Iowa, a consumable hemp manufacturer shall:

a. Complete the online registration form prescribed by the department;

b. Remit the registration fee set by the department in accordance with Iowa Code section 204.7; and

c. Submit a complete list of all consumable hemp products the consumable hemp manufacturer intends to manufacture, process, pack, hold, prepare, distribute, or sell, along with documentation of the jurisdiction of origin for each consumable hemp product.

156.2(2) *Consumable hemp retailers.* At least 30 days prior to selling any consumable hemp product in Iowa or to purchasers located in Iowa, a consumable hemp retailer shall register with the department by doing the following:

a. Complete the online registration form prescribed by the department;

b. Remit the registration fee set by the department in accordance with Iowa Code section 204.7; and

c. Submit a complete list of all consumable hemp products the consumable hemp retailer intends to sell, along with documentation of the jurisdiction of origin for each consumable hemp product.

156.2(3) *Combined consumable hemp manufacturers and retailers.* A consumable hemp establishment engaged in activities of a consumable hemp manufacturer and a consumable hemp retailer shall register separately for each activity. A registered consumable hemp manufacturer that exclusively sells consumable hemp products it has manufactured to consumers on a retail basis is not mandated to register as a consumable hemp retailer.

156.2(4) *Physical location.* A consumable hemp establishment's registration is valid for one physical location. A consumable hemp establishment that manufactures, processes, packs, holds, prepares, distributes, or sells a consumable hemp product at more than one physical location shall separately register each physical location.

156.2(5) *Expiration and renewal.* A consumable hemp registration, unless sooner suspended or revoked, expires one year after the registration is approved by the department. A consumable hemp registration may be renewed annually through the department's online registration system, accompanied by the registration fee, at least 30 days prior to expiration. Consumable hemp registrations that are expired more than 60 days will be revoked without notice.

156.2(6) *Transferability.* A consumable hemp registration is not transferable to a new owner or new physical location.

156.2(7) *Posting of registrations.* A valid registration shall be posted on the premises of the consumable hemp establishment in a location that is visible to the public. An image of the valid registration must also be posted on any website or online point of sale in a location that is visible to the public prior to payment.

156.2(8) *Returned payments.* The department will attempt to redeem a payment submitted for a consumable hemp registration that is not honored by the bank on which it is drafted. The department will notify the applicant of the need to provide sufficient payment. An additional fee of $25 shall be assessed for each dishonored payment. If the department does not receive payment, the establishment will be operating without a valid registration and is subject to penalties set forth in rule 641—156.7(204).

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.3(204) Testing requirements and documentation.

156.3(1) *Approved hemp source; certificate of analysis.* A consumable hemp product cannot be distributed or sold unless:

a. The consumable hemp product is from an approved hemp source and is accompanied by documentation that identifies the jurisdiction of origin. Documentation that identifies the jurisdiction of origin includes:

(1) Certificate of free sale issued by the jurisdiction of origin;

(2) Product label statements, provided the product label identifies the jurisdiction of origin; or

(3) Other documentation that identifies the jurisdiction of origin and also identifies the following:

1. Brand name;
2. Product name;
3. Serving and container size in terms of net quantity of contents; and
4. Lot number for the batch.

b. The consumable hemp product has a certificate of analysis issued within the last year by an independent accredited laboratory that verifies and states:

(1) The consumable hemp product is from a batch that has been tested by the independent accredited laboratory consistent with generally accepted industry standards for herbal and botanical substances;

(2) The presence and concentration of cannabinoids, including delta-9 tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and any other cannabinoids for which the product is being marketed;

(3) The consumable hemp product is from a batch that contained a total delta-9 tetrahydrocannabinol concentration that did not exceed 0.3 percent on a dry weight basis as calculated pursuant to an official postdecarboxylation analysis, as provided in Iowa Code section 204.8;

(4) The consumable hemp product is from a batch that has been tested for, and does not contain more than trace amounts of, pesticides, residual solvents, metals, harmful pathogens, and toxicants; and

(5) The batch does not contain synthetic or semisynthetic cannabinoids as described in these rules.

156.3(2) *Toxicant limits.* If a testing sample is found to contain greater than trace amounts of any pesticide, residual solvent, metal, harmful pathogen, or toxicants, the product is considered adulterated and cannot enter commerce.

156.3(3) *Examination of records.* All documentation mandated by this rule shall be maintained by the consumable hemp establishment and provided to the department or other regulatory authority immediately upon request.

156.3(4) *Independent accredited laboratory.* A consumable hemp establishment cannot utilize an accredited laboratory in which it has an ownership interest unless the consumable hemp establishment holds less than a 10 percent ownership interest in the accredited laboratory if the accredited laboratory is a publicly traded company. All testing of consumable hemp products under this rule must be conducted by an independent accredited testing laboratory.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.4(204) Packaging and labeling.

156.4(1) *Contents.* Each consumable hemp product intended for individual retail sale is labeled such that a reasonable consumer would plainly identify the product as a consumable hemp product and contains the following information:

a. Lot number for the batch;

b. Expiration date;

c. Brand name;

d. Product name;

e. List of ingredients;

f. Name, telephone number, and email address of the product manufacturer. If the registered manufacturer uses a contracted third-party or white-label manufacturer, the name of that entity must also be included on the container or label and is not proprietary or confidential under Iowa Code section 22.7;

g. If specific cannabinoids are contained within or marketed for the product, the number of milligrams of each cannabinoid per serving and serving size;

h. A certificate of analysis that the batch contained a total THC concentration that did not exceed 0.3 percent on a dry weight basis as calculated pursuant to an official test as provided in Iowa Code section 204.8;

i. A declaration of the net quantity of contents indicating the number of servings and total THC per serving and per container in compliance with Iowa Code section 204.2; and

j. A warning label containing the following or substantially similar language, in addition to any other warning language necessitated by the specific product. This warning label may be divided into multiple

sections on a label, provided that all the information is included in a prominent and conspicuous manner as compared to other words, statements, or designs on the container label:

(1) A statement that the product has not been evaluated or approved by the United States Food and Drug Administration (unless such approval has been secured);

(2) The potential for the product to cause the consumer to fail a drug test for THC;

(3) A statement that products containing THC may cause impairment and impact a consumer's ability to operate a vehicle;

(4) A statement that the product is not recommended for use by pregnant or breastfeeding women;

(5) A statement that product use may result in health risks and medication interactions; and

(6) A statement in capital letters to KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

The labeling must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies unless the claim has been approved by the federal Food and Drug Administration.

156.4(2) *Form.* The labeling mandated in paragraphs 156.4(1)*"f"* and *"h"* may be in the form of:

a. A uniform resource locator (URL) for the manufacturer's internet website that provides or links to the information mandated by this rule; or

b. A QR code or other bar code that may be scanned and that leads to the information required on the label.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.5(204) Applicability of other laws and regulations.

156.5(1) A consumable hemp establishment shall comply with all relevant Iowa laws and regulations applicable to the manufacturing, processing, storage, distribution, and sale of food, including but not limited to Iowa Code chapter 137F, Iowa Code chapter 137D, and regulations promulgated under those chapters.

156.5(2) An individual or entity subject to Iowa Code chapter 123 shall not introduce any consumable hemp product into the alcoholic beverage product for which the individual or entity is subject to Iowa Code chapter 123 unless the consumable hemp product is GRAS by the federal Food and Drug Administration and is thus not deemed adulterated.

156.5(3) An individual or entity subject to Iowa Code chapter 189A shall not introduce any consumable hemp product into the meat or poultry product for which the individual or entity is subject to Iowa Code chapter 189A unless the consumable hemp product is GRAS by the federal Food and Drug Administration and is thus not deemed adulterated. A consumable hemp retailer may introduce any consumable hemp product into meat or poultry sold to consumers on a retail basis in intrastate commerce.

156.5(4) An individual or entity subject to Iowa Code chapters 190 through 192 shall not introduce any consumable hemp product into the dairy product for which the individual or entity is subject to Iowa Code chapters 190 through 192 unless the consumable hemp product is GRAS by the federal Food and Drug Administration and is thus not deemed adulterated. A consumable hemp retailer may introduce any consumable hemp products into dairy products sold to consumers on a retail basis in intrastate commerce.

156.5(5) Consumable hemp products in interstate commerce are subject to federal law. Compliance with Iowa Code chapter 204 and this chapter does not represent compliance with federal law.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.6(204) Prohibitions.

156.6(1) A consumable hemp establishment cannot manufacture, process, pack, hold, prepare, distribute, or sell consumable hemp products:

a. On the premises of a private residence, except a portion of a private residence that is distinctly separate from any living space, that is dedicated to the production or sale of food, and that meets all applicable state and local regulations;

b. On the premises of a temporary location, including but not limited to a food stand, roadside stand, temporary booth, or any other temporary structure;

c. Door to door;

d. Through vending machines; or

e. At private parties.

156.6(2) A consumable hemp product may be sold at a stand at a farmers market, provided:

a. The farmers market is listed on the Iowa department of agriculture and land stewardship's farmers market directory;

b. The individual selling the consumable hemp product maintains a valid consumable hemp retailer registration at any location where consumable hemp is stored;

c. The consumable hemp establishment registration is posted in plain sight at the farmers market stand; and

d. All consumable hemp products sold are listed and maintained up to date with the department.

156.6(3) A consumable hemp product label and any associated marketing materials shall not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies unless the claim has been approved by the federal Food and Drug Administration.

156.6(4) A consumable hemp retailer cannot manufacture, process, package, repackage, relabel, mix, blend, or otherwise manipulate a consumable hemp product. This subrule does not apply to a food service establishment that utilizes a consumable hemp product from an approved hemp source as a food ingredient intended for immediate consumption by the consumer, provided that the food service establishment discloses all label information mandated by rule 641—156.4(204) to the consumer through the menu, menu board, placard, table tent, or other effective means.

156.6(5) A consumable hemp product that does not conform to this chapter is considered adulterated or misbranded and cannot enter commerce.

156.6(6) A consumable hemp retailer or manufacturer shall not sell or distribute consumable hemp products to person under 21 years of age, subject to verification. Proof of age may be established by a valid driver's license, identification card issued by Iowa or another state, or other form of government-issued identification and must include the photograph and date of birth of the person.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.7(204) Violations and enforcement.

156.7(1) Any consumable hemp product introduced into commerce by an individual or entity without a consumable hemp registration approved by the department in accordance with rule 641—156.2(204) is subject to immediate embargo.

156.7(2) A consumable hemp product that is adulterated or misbranded when introduced into commerce is subject to immediate embargo.

156.7(3) A consumable hemp product that the department reasonably believes may be injurious to public health or that has entered commerce and is not in conformance with this chapter is subject to immediate embargo.

156.7(4) The embargo of a consumable hemp product is effective until such a time as the violation is remedied or the product is disposed of in a reasonable manner as determined by the department. If the violation cannot be remedied and disposal is necessary, the cost of disposal is the responsibility of the consumable hemp establishment. Disposal shall be observed by a person approved by the department. The embargo of a consumable hemp product may be appealed in accordance with rule 641—156.8(204).

156.7(5) A consumable hemp manufacturer will conduct a recall of a consumable hemp product lot that has been tested and found to be adulterated. The cost of a recall or disposal of the product is the responsibility of the consumable hemp manufacturer.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.8(204) Denial, suspension, or revocation of registration. The department may deny, suspend, or revoke a registration in any case where the department finds there has been repeated failure on the part of the consumable hemp establishment to comply with the provisions of this chapter, or for any of the following reasons:

156.8(1) Failure to register. An individual or entity that introduces a consumable hemp product into commerce without a consumable hemp registration approved by the department in accordance with rule

641—156.2(204) may be denied a consumable hemp registration for a period of up to 30 days for a first violation, up to one year for a second violation, and up to five years for a third or any subsequent violation.

156.8(2) Nonconforming consumable hemp product. A registered consumable hemp establishment that introduces a consumable hemp product into commerce that is not in conformance with Iowa Code chapter 204 or this chapter is subject to the immediate revocation of its registration.

156.8(3) Qualifying criminal offense.

a. The conviction of any individual with an ownership interest in a consumable hemp establishment constituting a felony, serious misdemeanor, or aggravated misdemeanor and resulting from an activity constituting a criminal offense in the consumable hemp establishment may result in the denial, suspension, or revocation of the registration.

b. A conviction for committing a criminal offense involving a controlled substance as described in Iowa Code section 204.7 may result in the denial, suspension, or revocation of the registration.

c. A certified copy of the final order or judgment of conviction or plea of guilty shall be conclusive evidence of the conviction of the registration holder.

d. A deferred judgment, until discharged, is considered a conviction for purposes of this rule.

156.8(4) False or misleading information. Providing false or misleading information to the department under this chapter, including by submitting a false registration, may result in the denial, suspension, or revocation of the registration.

156.8(5) Failure to comply. Failing to comply with an order issued by the department under this chapter may result in the denial, suspension, or revocation of the registration.

156.8(6) Successive violations. A third violation of any provision of this chapter in a five-year period will result in the denial, suspension, or revocation of the registration. The department will disapprove any registration of the consumable hemp establishment for a five-year period following the date of the last violation.

156.8(7) Materially false information supplied. An individual or entity that materially falsifies any information contained in a consumable hemp registration is ineligible for registration.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.9(204) Inspection and access to records. The department may enter a consumable hemp establishment at any reasonable hour to assess compliance with Iowa Code chapter 204 and these rules. The manager or person in charge of the consumable hemp establishment will afford free access to every part of the premises, including access to records related to consumable hemp products, and render all aid and assistance necessary to enable the regulatory authority to make a thorough and complete assessment.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.10(204) Public examination of records.

156.10(1) *Public information.* Generally, information collected by the department and contractors is considered public information. Records are stored in computer files and are not matched with any other data system. Information is available for public review and will be provided when requested from the department.

156.10(2) *Confidential information.*

a. The following are examples of confidential records:

(1) Trade secrets and proprietary information including items such as formulations, processes, policies and procedures, and customer lists;

(2) Health information related to foodborne illness complaints and outbreaks;

(3) The name or any identifying information of a person who files a complaint with the department; and

(4) Other state or federal agencies' records.

b. A party claiming that information submitted to the department contains trade secrets or proprietary information should clearly mark those portions of the submission as confidential/trade secret.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24]

641—156.11(204) Appeals. All decisions of the department may be contested by an adversely affected party in accordance with 441—Chapter 2506.

[**ARC 8178C**, IAB 8/7/24, effective 7/17/24; Editorial change: IAC Supplement 6/10/26]

These rules are intended to implement Iowa Code section 124.506 and Iowa Code chapter 204 as amended by 2024 Iowa Acts, House File 2605.

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[Editorial change: IAC Supplement 6/10/26]

CHAPTER 157
STANDARDS FOR SUBSTANCE ABUSE TREATMENT AND ASSESSMENT PROGRAMS AND THE OPERATING A MOTOR VEHICLE WHILE INTOXICATED (OWI) LAW
[Prior to 3/29/06, see 643—Ch 8]

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—157.1(125) Definitions. Unless otherwise indicated, the following definitions apply to the specific terms used in these rules:

"Assessment" means the ongoing process of identifying a diagnosis, ruling out other diagnoses, and determining the level of care needed by the client.

"Course for drinking drivers" means an approved course designed to inform the offender about drinking and driving and to encourage the offender to assess the offender's own drinking and driving behavior in order to select practical alternatives. Enrollment in the course is not limited to persons ordered to enroll, attend, and successfully complete the course required under Iowa Code sections 321J.1 and 321J.17. However, any person under the age of 18 who is required to attend the course for violation of Iowa Code section 321J.2 or 321J.17 must attend a course offered by a substance abuse treatment program licensed under Iowa Code chapter 125. Any instructional course for drinking drivers shall be approved by the department of education in consultation with the community colleges and substance abuse treatment programs licensed under Iowa Code chapter 125 and using the course of instruction detailed in rule 281—21.31(321J).

"Evaluation" means the process to evaluate the client's strengths, weaknesses, problems, and needs for the purpose of defining a course of treatment. This includes use of a standardized placement screening and any additional patient/client profile information, and recommendation to an appropriate level of care.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

"Licensed" means issuance of a license by the department, which validates the licensee's compliance with substance use disorder treatment program standards and authorizes the licensee to operate a substance use disorder treatment program in the state of Iowa.

"Posttreatment" means continuing care after primary treatment has been completed.

"Primary treatment" means substance use disorder treatment modality, including licensed program services under 641—Chapter 155.

"Program" means any individual, partnership, corporation, association, governmental subdivision or public or private organization.

"Qualifying program" means a program that has a contract with the state of Iowa or the state's contracted managed care entity to provide substance abuse treatment using a sliding fee scale.

"Satisfactory completion of the drinking drivers course" means receiving at the completion of the course a grade from the course instructor of "C" or "2.0" or better.

"Screening" means the process by which a client/patient is determined at risk and in need of further evaluation. The focus is on the minimum criteria necessary for appropriateness/eligibility.

"Treatment" means the broad range of planned and continuing inpatient, outpatient, and residential care services, including diagnostic evaluation, counseling, medical care, psychiatric care, psychological care, and social service care, that may be extended to concerned persons, concerned family members, or significant others, and that is geared toward influencing the behavior of such individuals to achieve a state of rehabilitation.

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

641—157.2(125) Screening, evaluation, treatment, and drinking drivers course. Persons who are charged with operating a motor vehicle while intoxicated (OWI) under Iowa Code section 321J.2 and whose driver's license or nonresident operating privileges are revoked under Iowa Code chapter 321J shall be assigned to undergo a substance abuse evaluation and, if recommended, treatment from a provider licensed by the department under Iowa Code chapter 125.

157.2(1) *Screening.* The initial screening shall consist of a generally accepted standardized substance abuse screening instrument. The program shall utilize a recognized diagnostic test or tool to determine

a substance use disorder as those terms are defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the American Psychiatric Association (published 2013, with all changes and updates approved by the American Psychiatric Association through September 2023 incorporated herein). In addition, programs shall collect information on blood alcohol content at time of arrest, history of other alcohol or drug-related arrests, history of alcohol/drug treatment, history of mental health problems and treatment, any OWI arrest that included personal injury or additional charge(s), and family history of substance abuse.

157.2(2) *Evaluation.* In accordance with the American Society of Addiction Medicine (ASAM) Criteria (as amended to December 31, 2023) and accepted standards of practice, the evaluation shall consist of evaluating a person's strengths, resources, preferences, limitations, problems and needs; determining the licensed program services needed by the patient; determining the patient's eligibility for program services; and identifying treatment plan priorities.

157.2(3) *Treatment.* Treatment shall consist of a broad range of planned and continuing inpatient, outpatient, and residential care services, including ongoing diagnostic evaluation, counseling, and medical care, psychiatric care, psychological care, and social service care geared toward influencing the behavior of such individuals to achieve a state of rehabilitation. Individuals will be placed in the appropriate level of care at a substance use disorder treatment program licensed by the department under Iowa Code chapter 125 in accordance with ASAM Criteria (as amended to December 31, 2023).

157.2(4) *Drinking drivers course.* Substance abuse treatment programs licensed by the department under Iowa Code chapter 125 may provide the drinking drivers course if the course curriculum is approved by the department of education under Iowa Code section 321J.22 and rule 281—21.31(321J).

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

641—157.3(125) Screening, evaluation, treatment, and drinking drivers course completion. The program shall report substance use disorder screening, assessment, evaluation and treatment completion to the department of transportation and to the district court in accordance with Iowa Code sections 125.37, 125.84 and 125.86; the federal confidentiality regulations, "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2, effective June 9, 1987; HIPAA (1996); and other relevant provisions of federal and state law. The program shall report satisfactory completion of the drinking drivers course to the department of education in accordance with Iowa Code section 321J.22 and rule 281—21.31(260C); the federal confidentiality regulations, "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2, effective June 9, 1987; HIPAA (1996); and other relevant provisions of federal and state law.

157.3(1) *Reporting form.* Programs shall report screening, evaluation, and treatment completion utilizing the form "Notice Iowa Code 321J—Confidential Medical Record." Iowa substance abuse evaluation and treatment providers licensed by the department under Iowa Code chapter 125 shall submit this form online to the department of transportation using the department of transportation's website.

157.3(2) *Primary treatment.* Upon completion of primary treatment, programs shall report to the department of transportation and the courts that treatment has been completed in accordance with Iowa Code section 321J.22; the federal confidentiality regulations, "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2, effective June 9, 1987; HIPAA (1996); and other relevant provisions of federal and state law.

157.3(3) *Posttreatment results.* If the court orders a posttreatment program, the program shall report progress and attendance to the person's probation officer or otherwise as ordered by the court in accordance with Iowa Code section 321J.22; the federal confidentiality regulations, "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2, effective June 9, 1987; HIPAA (1996); and other relevant provisions of federal and state law.

157.3(4) *Drinking drivers course.* Substance abuse treatment programs licensed by the department under Iowa Code chapter 125 may provide the drinking drivers course and shall report satisfactory completion of the drinking drivers course to the department of education in accordance with Iowa Code section 321J.22 and rule 281—21.31(260C).

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

641—157.4(125) Cost of evaluation and treatment.

157.4(1) *Screening and evaluation.* The program shall charge no more than $125 for the cost of screening and evaluation. The individual or the individual's insurance provider shall be responsible for the costs of the screening and evaluation.

157.4(2) *Treatment.* Qualifying programs shall consider a person admitted to the program pursuant to Iowa Code section 321J.3 who does not possess sufficient income or estate to make payment of the costs of the treatment in whole or in part to be a state patient and eligible for state-funded treatment as provided in Iowa Code section 125.44. Qualifying programs shall utilize a sliding fee schedule approved by the department to determine cost of treatment. There is no prohibition on any individual from paying in whole the cost of treatment.

157.4(3) *Reimbursement.* Programs shall be able to seek reimbursement of the cost of screening, evaluation and treatment from an individual's insurance company, firm or corporation bound to pay, or from Medicaid for an individual who is eligible or enrolled in Medicaid.

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

641—157.5(125) Timeliness. The program shall conduct and complete substance abuse evaluations and treatment at the program's earliest convenience.

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

641—157.6(125) Confidentiality. Programs will abide by the standards for patient records set forth in rule 641—155.21(125,135).

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

641—157.7(125) Records. Programs shall maintain records in accordance with 641—subrule 155.21(10).

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

641—157.8(125) Reciprocity. For a resident of a state other than Iowa or an Iowa resident obtaining evaluation or treatment outside the state, screening, evaluation or treatment services shall be provided by programs licensed or approved by that state's substance abuse authority. Programs shall submit the results of the screening, evaluation and treatment to the department for review and reporting purposes to the department of transportation.

[**ARC 9179C**, IAB 4/30/25, effective 7/1/25]

These rules are intended to implement Iowa Code section 125.13.

[Filed 1/23/98, Notice 11/19/97—published 2/11/98, effective 3/18/98]
[Filed 3/9/06, Notice 2/1/06—published 3/29/06, effective 5/3/06]
[Filed 7/13/07, Notice 4/11/07—published 8/1/07, effective 9/5/07]
[Filed ARC 8796B (Notice ARC 8629B, IAB 3/24/10), IAB 6/2/10, effective 7/7/10]
[Filed ARC 9179C (Notice ARC 8517C, IAB 12/11/24), IAB 4/30/25, effective 7/1/25]

CHAPTER 158
REGIONS FOR SUBSTANCE ABUSE PREVENTION AND TREATMENT
[Prior to 3/29/06, see 643—Ch 9]
Rescinded **ARC 9180C**, IAB 4/30/25, effective 7/1/25

CHAPTERS 159 to 161
Reserved

CHAPTER 162
LICENSURE STANDARDS FOR PROBLEM GAMBLING TREATMENT PROGRAMS
[Prior to 7/3/96, see Human Services Department, 441—Ch 162]
Rescinded IAB 6/2/10, effective 7/1/10

CHAPTERS 163 to 169
Reserved

CHAPTER 170
ORGANIZATION OF THE DEPARTMENT
[Prior to 7/29/87, Health Department[470] Ch 170]
Rescinded **ARC 7712C**, IAB 3/6/24, effective 7/1/24[1]

[1] The effective date of **ARC 7112C** was corrected to July 1, 2024, in the April 3, 2024, Iowa Administrative Bulletin.

CHAPTER 171
PETITIONS FOR RULE MAKING
[Prior to 7/29/87, Department of Health[470] Ch 171]
Rescinded **ARC 7712C**, IAB 3/6/24, effective 7/1/24[1]

[1] The effective date of **ARC 7112C** was corrected to July 1, 2024, in the April 3, 2024, Iowa Administrative Bulletin.

CHAPTER 172
DECLARATORY ORDERS
[Prior to 7/29/87, Health Department[470] Ch 172]
Rescinded **ARC 7712C**, IAB 3/6/24, effective 7/1/24[1]

[1] The effective date of **ARC 7112C** was corrected to July 1, 2024, in the April 3, 2024, Iowa Administrative Bulletin.

CHAPTER 173
CONTESTED CASES
[Prior to 7/29/87, Health Department[470] Ch 173]
Rescinded **ARC 7712C**, IAB 3/6/24, effective 7/1/24[1]

[1] The effective date of **ARC 7112C** was corrected to July 1, 2024, in the April 3, 2024, Iowa Administrative Bulletin.

CHAPTER 174
AGENCY PROCEDURE FOR RULE MAKING
Rescinded **ARC 7712C**, IAB 3/6/24, effective 7/1/24[1]

[1] The effective date of **ARC 7112C** was corrected to July 1, 2024, in the April 3, 2024, Iowa Administrative Bulletin.

CHAPTER 175
FAIR INFORMATION PRACTICES AND PUBLIC RECORDS
Rescinded **ARC 7712C**, IAB 3/6/24, effective 7/1/24[1]

[1] The effective date of **ARC 7112C** was corrected to July 1, 2024, in the April 3, 2024, Iowa Administrative Bulletin.

CHAPTER 176
CRITERIA FOR AWARDS OR GRANTS
Rescinded **ARC 8125C**, IAB 7/10/24, effective 8/14/24

CHAPTER 177
HEALTH DATA

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/3/29

641—177.1(76GA,ch1212) Definitions. For purposes of this chapter, the following definitions shall apply:

"Confidential record" means a record that is not available as a matter of right for examination and copying by members of the public under applicable provisions of law. Confidential records include records or information contained in records that the agency is prohibited by law from making available for examination by members of the public, and records or information contained in records that are specified as confidential by Iowa Code section 22.7, or other provision of law, but that may be disclosed upon order of a court, the lawful custodian of the record, or by another person duly authorized to release the record. Mere inclusion in a record of information declared confidential by an applicable provision of law does not necessarily make that entire record a confidential record. Included in the definition are those data collected by the department, pursuant to 1996 Iowa Acts, chapter 1212, for preparation and dissemination as compilations.

"Record" means the whole or a part of a "public record" as defined in Iowa Code section 22.1 that is owned by or in the physical possession of this agency.

[**ARC 8044C**, IAB 5/29/24, effective 7/3/24]

641—177.2(76GA,ch1212) Description of data to be submitted.

177.2(1) The department shall collect information from other state agencies for the purpose of public dissemination of health data.

177.2(2) Hospitals shall submit data to the contractor selected through the request for proposal process, which shall serve as an intermediary for the department. The information shall include inpatient, outpatient and ambulatory information.

177.2(3) The contractor selected through the request for proposal process shall collect, maintain, and disseminate hospital inpatient, outpatient, and ambulatory information pursuant to a memorandum of understanding with the department. The contractor selected through the request for proposal process shall submit data to the department pursuant to the memorandum of understanding.

[**ARC 8044C**, IAB 5/29/24, effective 7/3/24]

641—177.3(76GA,ch1212) Fees. Fees charged for data provided by the department shall not exceed administrative costs. Such charges may include copying, postage, supervisory, computer programming, time, and medium fees. The department will work to provide requestors with an estimate of the charges to be assessed for copies and labor prior to producing copies of records.

[**ARC 8044C**, IAB 5/29/24, effective 7/3/24]

641—177.4(76GA,ch1212) Patient confidentiality. The department shall protect patient confidentiality. Confidential records or parts of such records collected as a part of this process shall be kept confidential. All health data shall be collected, maintained, and disseminated only in accordance with Iowa and federal law.

[**ARC 8044C**, IAB 5/29/24, effective 7/3/24]

These rules are intended to implement 1996 Iowa Acts, chapter 1212, section 5, and Iowa Code section 135.166.

[Filed 5/16/97, Notice 2/26/97—published 6/4/97, effective 7/9/97]
[Filed 3/14/02, Notice 2/6/02—published 4/3/02, effective 5/8/02]
[Filed ARC 2654C (Notice ARC 2458C, IAB 3/16/16), IAB 8/3/16, effective 9/7/16]
[Filed ARC 8044C (Notice ARC 7370C, IAB 1/24/24), IAB 5/29/24, effective 7/3/24]

CHAPTER 178
WAIVERS OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE RULES
Transferred to 441—Chapter 6, IAC Supplement 6/28/23

CHAPTER 179
COLLECTION OF DELINQUENT DEBTS
Transferred to 441—Chapter 10, IAC Supplement 1/24/24

CHAPTER 180
HOSPITAL PROTOCOL FOR DONOR REQUESTS
Rescinded IAB 4/4/90, effective 5/9/90; see 641—51.4(5) to 641—51.4(11)

CHAPTERS 181 to 185
Reserved

CHAPTER 186
GOVERNMENTAL PUBLIC HEALTH ADVISORY COUNCIL
Rescinded **ARC 4703C**, IAB 10/9/19, effective 11/13/19

CHAPTERS 187 to 189
Reserved

CHAPTER 190
CONSENT FOR THE SALE OF GOODS AND SERVICES
Rescinded IAB 4/11/07, effective 5/16/07

CHAPTER 191
ADVISORY BODIES OF THE DEPARTMENT
Rescinded **ARC 8126C**, IAB 7/10/24, effective 8/14/24

CHAPTER 192
CHILD SUPPORT NONCOMPLIANCE

Chapter rescission date pursuant to Iowa Code section 17A.7: 4/1/31

641—192.1(252J) Definitions. For the purpose of this chapter, the following definitions apply:

"Applicant" means an individual who is seeking the issuance of a license.

"Certificate of noncompliance" means a document as defined in Iowa Code section 252J.1 that is provided by child support services certifying that the applicant or licensee has defaulted on an obligation owed to or collected by child support services.

"License" means the same as defined in Iowa Code section 252J.1.

"Licensing authority" means a board, commission, or any other entity of the department that has authority within this state to suspend or revoke a license or deny the renewal or issuance of a license authorizing a person to engage in a business, occupation, or profession.

[**ARC 0077D**, IAB 2/18/26, effective 4/1/26]

641—192.2(252J) Denial of issuance or renewal of a license or suspension or revocation of a license. The licensing authority will deny the issuance or renewal of a license or suspend or revoke a license upon the receipt of a certificate of noncompliance from child support services according to the procedures in Iowa Code chapter 252J. In addition to the procedures set forth in Iowa Code section 252J.3(7), the following apply:

192.2(1) The notice required by Iowa Code section 252J.8 will be served upon the applicant or licensee by restricted certified mail, return receipt requested, or personal service in accordance with Iowa Rule of Civil Procedure 1.305. Alternatively, the applicant or licensee may accept service personally or through authorized counsel.

192.2(2) The suspension, revocation, or denial will be effective no sooner than 30 days following provision of notice to the individual.

192.2(3) Applicants and licensees shall keep the licensing authority informed of all court actions, and all child support services actions taken under or in connection with Iowa Code chapter 252J, and shall provide the licensing authority copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 252J.9, all court orders entered in such actions, and withdrawals of certificates of noncompliance by child support services.

192.2(4) All licensing authority fees required for application, license renewal, or license reinstatement must be paid by applicants or licensees before a license will be issued, renewed, or reinstated after the licensing authority has denied the issuance or renewal of a license pursuant to Iowa Code chapter 252J.

192.2(5) In the event an applicant or licensee timely files a district court action following service of a licensing authority notice pursuant to Iowa Code sections 252J.8 and 252J.9, the licensing authority will continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the licensing authority to proceed. For purposes of determining the effective date of the denial of the issuance, renewal, suspension or revocation of a license, the licensing authority will count the number of days before the action was filed and the number of days after the action was disposed of by the court.

192.2(6) The licensing authority will notify the applicant or licensee in writing through regular first-class mail, or such other means as the licensing authority determines appropriate in the circumstances, within ten days of the effective date of the denial of the issuance or renewal of a license and will similarly notify the applicant or licensee if the license is issued or renewed following the licensing authority's receipt of a withdrawal of the certificate of noncompliance.

[**ARC 0077D**, IAB 2/18/26, effective 4/1/26]

641—192.3(17A,22,252J) Sharing of information. Notwithstanding any statutory confidentiality provision, the licensing authority may share information with child support services through manual or automated means for the sole purpose of identifying applicants or licensees subject to enforcement under Iowa Code chapter 252J or 598.

[**ARC 0077D**, IAB 2/18/26, effective 4/1/26]

These rules are intended to implement Iowa Code chapter 252J.

[Filed emergency 1/11/96 after Notice 12/6/95—published 1/31/96, effective 1/11/96]
[Filed ARC 8798B (Notice ARC 8631B, IAB 3/24/10), IAB 6/2/10, effective 7/7/10]
[Filed ARC 0077D (Notice ARC 9668C, IAB 11/12/25), IAB 2/18/26, effective 4/1/26]

CHAPTER 193
MODEL RULES FOR LICENSEE REVIEW COMMITTEE
Transferred to 481—Chapter 505, IAC Supplement 7/10/24

CHAPTER 194
NONPAYMENT OF STATE DEBT

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/14/29

641—194.1(272D) Definitions. For the purpose of this chapter, the following definitions shall apply.

"Applicant" means an individual who is seeking the issuance of a license.

"Centralized collection unit" means the centralized collection unit of the Iowa department of revenue.

"Certificate of noncompliance" means the same as defined in Iowa Code section 272D.1.

"Denial notice" means a licensing authority notification denying an application for the issuance or renewal of a license as required by Iowa Code chapter 272D.

"License" means the same as defined in Iowa Code section 272D.1.

"Licensing authority" means a board, commission, or any other entity of the department that has authority within this state to suspend or revoke a license or deny the renewal or issuance of a license authorizing a person to engage in a business, occupation, or profession.

"Revocation or suspension notice" means a licensing authority notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by Iowa Code chapter 272D.

"Withdrawal certificate" means the same as defined in Iowa Code section 272D.1.

[**ARC 8127C**, IAB 7/10/24, effective 8/14/24]

641—194.2(272D) Denial of issuance or renewal of a license or suspension or revocation of a license. The licensing authority shall deny the issuance or renewal of a license or suspend or revoke a license upon the receipt of a certificate of noncompliance from the centralized collection unit per the procedure set forth in Iowa Code chapter 272D. This rule shall apply in addition to the procedures set forth in Iowa Code chapter 272D.

194.2(1) *Service of denial, suspension or revocation notice.* Notice will be served upon the applicant or licensee by certified mail, return receipt requested; by personal service; or through authorized counsel.

194.2(2) *Licensees and applicants responsible to inform licensing authority.* Licensees and applicants shall keep the licensing authority informed of all court actions and all centralized collection unit actions taken under or in connection with Iowa Code chapter 272D. Licensees and applicants shall also provide the licensing authority copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code chapter 272D, all court orders entered in such actions, and any withdrawals of certificates issued by the centralized collection unit.

194.2(3) *Reinstatement following license denial, suspension or revocation.* All licensing authority fees required for application, license renewal, or license reinstatement must be paid by applicants or licensees before a license will be issued, renewed, or reinstated after the licensing authority has denied the issuance or renewal of a license or suspended or revoked a license pursuant to Iowa Code chapter 272D.

194.2(4) *Effect of filing in district court.* In the event an applicant or a licensee files a timely district court action following service of a denial notice by a licensing authority or service of a revocation or suspension notice, the licensing authority will continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the licensing authority to proceed. For purposes of determining the effective date of the denial of the issuance or renewal of a license or of the suspension or revocation of a license, the licensing authority will count the number of days before the action was filed and the number of days after the action was disposed of by the court.

194.2(5) *Final notification.* The licensing authority will notify the applicant or licensee in writing through regular first-class mail, or by such other means as the licensing authority determines appropriate in the circumstances, and will similarly notify the applicant or licensee if the license is issued or renewed following the licensing authority's receipt of a withdrawal certificate.

[**ARC 8127C**, IAB 7/10/24, effective 8/14/24]

641—194.3(272D) Sharing of information. The department may share applicant or licensee information with the centralized collection unit pursuant to Iowa Code chapter 272D.

[**ARC 8127C**, IAB 7/10/24, effective 8/14/24]

These rules are intended to implement Iowa Code chapter 272D.

[Filed ARC 7671B (Notice ARC 7540B, IAB 1/28/09), IAB 4/8/09, effective 5/13/09]

[Filed ARC 8127C (Notice ARC 7361C, IAB 1/24/24), IAB 7/10/24, effective 8/14/24]

CHAPTER 195
STUDENT LOAN DEFAULT/NONCOMPLIANCE WITH AGREEMENT FOR PAYMENT OF OBLIGATION

Rescinded **ARC 4907C**, IAB 2/12/20, effective 3/18/20

CHAPTER 196
EMERGENCY MEDICAL SERVICES—MILITARY SERVICE, VETERAN RECIPROCITY, AND SPOUSES OF ACTIVE DUTY SERVICE MEMBERS

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/14/29

641—196.1(272C) Definitions.

"License" means the same as defined in Iowa Code section 272D.1.

"Licensing authority" means the same as defined in Iowa Code section 272D.1.

"Military service" means honorably serving on federal active duty, state active duty, or national guard duty, as defined in Iowa Code section 29A.1; in the military services of other states, as provided in 10 U.S.C. Section 101(c) (2021); or in the organized reserves of the United States, as provided in 10 U.S.C. Section 10101 (2006).

"Military service applicant" means an individual requesting credit toward licensure for military education, training, or service obtained or completed in military service.

"Spouse" means a spouse of an active duty member of the military forces of the United States.

"Veteran" means the same as defined in Iowa Code section 35.1.

[**ARC 8128C**, IAB 7/10/24, effective 8/14/24]

641—196.2(272C,147D) Military education, training, and service credit. A military service applicant may apply for credit for verified military education, training, or service toward any experience or educational requirement for licensure by submitting a military service application form to the licensing authority. No fee is required with submission of an application for military service credit.

196.2(1) The licensing authority shall grant credit requested in the application pursuant to the emergency medical services (EMS) personnel licensure interstate compact described in Iowa Code section 147D.1.

196.2(2) The licensing authority shall inform the military service applicant in writing of the credit, if any, given toward an experience or educational qualification for licensure or explain why no credit was granted. The applicant may request reconsideration upon submission of additional documentation or information.

196.2(3) A military service applicant who is aggrieved by the licensing authority's decision may appeal pursuant to the provisions of 441—Chapter 2506, except that no fees or costs shall be assessed against the military service applicant in connection with a contested case conducted pursuant to this subrule.

196.2(4) The licensing authority shall grant or deny the credit requested in the military service application prior to ruling on the application for licensure. The applicant shall not be required to submit any fees in connection with the licensure application unless the licensing authority grants the credit requested in the military service application. If the licensing authority does not grant the credit requested in the military service application, the applicant may withdraw the licensure application or request that the licensure application be placed in pending status for up to one year or as mutually agreed. The withdrawal of a licensure application shall not preclude subsequent applications supported by additional documentation or information.

[**ARC 8128C**, IAB 7/10/24, effective 8/14/24; Editorial change: IAC Supplement 6/10/26]

641—196.3(272C,147D) Veteran and active duty military spouse privilege to practice. A veteran or spouse with an unrestricted license in another EMS personnel licensure jurisdiction may practice in Iowa pursuant to the EMS personnel licensure interstate compact described in Iowa Code section 147D.1.

[**ARC 8128C**, IAB 7/10/24, effective 8/14/24]

These rules are intended to implement Iowa Code sections 272C.4 and 147D.1.

[Filed ARC 1749C (Notice ARC 1646C, IAB 10/1/14), IAB 12/10/14, effective 1/14/15]
[Filed ARC 5061C (Notice ARC 5000C, IAB 3/25/20), IAB 6/17/20, effective 7/22/20]
[Filed ARC 7032C (Notice ARC 6942C, IAB 3/8/23), IAB 5/31/23, effective 7/5/23]
[Filed ARC 8128C (Notice ARC 7337C, IAB 1/24/24), IAB 7/10/24, effective 8/14/24]

[Editorial change: IAC Supplement 6/10/26]

CHAPTERS 197 to 199
Reserved

CHAPTER 200
STANDARDS COMMITTEE PROCEDURES—CHANGES IN STANDARDS FOR THE STATE HEALTH PLAN
Rescinded IAB 5/30/90, effective 7/4/90

CHAPTER 201
ORGANIZED DELIVERY SYSTEMS
Rescinded **ARC 3398C**, IAB 10/11/17, effective 11/15/17

CHAPTER 202
CERTIFICATE OF NEED PROGRAM
[Prior to 7/29/87, Health Department[470] Ch 202]
Transferred to 481—Chapter 2202, IAC Supplement 9/4/24

CHAPTER 203
STANDARDS FOR CERTIFICATE OF NEED REVIEW
[Prior to 7/29/87, Health Department[470] Ch 203]
Transferred to 481—Chapter 2203, IAC Supplement 9/4/24

CHAPTER 204
UNIFORM REPORTING REQUIREMENTS
[Prior to 7/29/87, Health Department[470]Ch204]
Rescinded **ARC 1748C**, IAB 12/10/14, effective 1/14/15

CHAPTER 205
Reserved

CHAPTER 206
IOWA HEALTH INFORMATION NETWORK
Rescinded **ARC 3607C**, IAB 1/31/18, effective 3/7/18