**Regulatory Analysis**

Notice of Intended Action to be published: 641—Chapter 37
"General Provisions for Radiation and Radiation Protection Standards"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 136C
State or federal law(s) implemented by the rulemaking: Iowa Code chapter 136C and 10 CFR 20

*Public Hearing*

A public hearing at which persons may present their views orally or in writing will be held as follows:

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| November 4, 2025<br>10 a.m. | Microsoft Teams<br>Meeting ID: 256 572 060 444 0<br>Passcode: SG2Vc96j |

*Public Comment*

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Des Moines, Iowa 50319
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*Purpose and Summary*

This proposed chapter is one of eight chapters pertaining to radiologic health matters regulated by the Department. This proposed chapter and the seven others underwent a fulsome review as a part of the Red Tape Review process laid out in Executive Order 10. As a result of this review, restrictive terms were removed, areas that were duplicative were combined or eliminated, and editorial updates were made to reflect current policies and procedures. This proposed chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department. Unless otherwise exempted, the provisions of this proposed chapter apply to and provide regulatory guidance to all persons who receive, possess, use, transfer, own, or acquire any source of radiation.

*Analysis of Impact*

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

There are no costs associated with this proposed rulemaking.

- **Classes of persons that will benefit from the proposed rulemaking:**

All Iowans who depend on the use of radiological materials in all industries will benefit from clarified rules.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

The changes made in this proposed rulemaking are within the scope of Executive Order 10 and strengthen and clarify the regulations, but the changes do not diminish the chapter's effectiveness or add additional burdens. No changes have been made to the fees in this chapter.

- **Qualitative description of impact:**

Operators, clinical practitioners, patients, and anyone in an industry who handles or deals with radiological materials stands to benefit through the review and promulgation of this proposed chapter.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

The Department incurs personnel and other administrative costs in the enforcement of this proposed chapter.

- **Anticipated effect on State revenues:**

This rulemaking is not expected to have any impact on State revenues.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

Not applicable. The regulation of radiological materials is required by Iowa Code chapter 136B.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

Not applicable. The regulation of radiological materials is required by Iowa Code chapter 136B.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

Not applicable. The regulation of radiological materials is required by Iowa Code chapter 136B.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable. The regulation of radiological materials is required by Iowa Code chapter 136B.

*Small Business Impact*

**If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:**

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

**If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?**

This rulemaking is not expected to have an impact on small business.

*Text of Proposed Rulemaking*

ITEM 1. Rescind 641—Chapter 37 and adopt the following **new** chapter in lieu thereof:

CHAPTER 37
GENERAL PROVISIONS FOR RADIATION AND RADIATION PROTECTION STANDARDS

**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.

**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 are irradiated ($HE = \Sigma wTHT$).

*"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 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 assistants, nurse practitioners, radiologic technologists, and dental hygienists.

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

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

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

*"High radiation area"* means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual's receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 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 assistant as defined in Iowa Code section 148C.1(7) and is 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.
  - 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.
  - 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:
  - 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;
  - 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
  - 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 which 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.

**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.

**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.

**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 |
| | 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 |

| 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 $cm^{-2}$ $Sv^{-1}$) |
|---|---|---|---|
| 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.

**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.

**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.

**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—Chapters 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.* Except as provided by paragraph 37.8(8)*"b,"* each notice of registration will expire within 12 months of issuance or at the end of the last day of the month and year stated on the notice.

**37.8(8)** *Renewal of notice of registration.*

*a.* Application for renewal of registration shall be submitted in accordance with this chapter.

*b.* In any case in which a registrant has properly submitted an application for renewal of current registration within 90 days prior to the expiration of the existing registration, such existing registration will not expire until the application status has been finally determined by the department.

**37.8(9)** *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(10)** *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(11)** *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.

**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 the anniversary date thereafter, as long as the registrant owns the radiation machine, remit the applicable fee to the department in adherence with the fee schedule below. All fees shall be paid annually by credit card or by check or money order made payable to the Iowa Department of Health and Human Services.

*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) Application shall be submitted through the online licensing portal on an application furnished by the department. The application shall:

1. Contain complete and accurate information as required by the department;
2. Include an annual nonrefundable fee of $200.

*b. Mammography medical physicist.*

(1) Each person engaged in providing health physics services for mammography in Iowa who meets the requirements of 641—paragraph 41.3(1)*"c"* shall apply for Iowa approval with the department prior to providing such services.

(2) Application shall be submitted through the online licensing portal on an application furnished by the department. The application shall:

1. Contain complete and accurate information as required by the department;
2. Include an annual nonrefundable fee of $100.

*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) Application shall be submitted through the online licensing portal on an application furnished by the department. 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.

*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) Application shall be submitted through the online licensing portal on an application furnished by the department. The application shall:

1. Contain complete and accurate information as required by the department;
2. Include the annual nonrefundable fee of $200.

**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 |
| (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 late charge will be assessed per month for late payments.

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

*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.

**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 subrule 37.10(2) 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 641—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.

**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 641—subrule 41.2(27) 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.

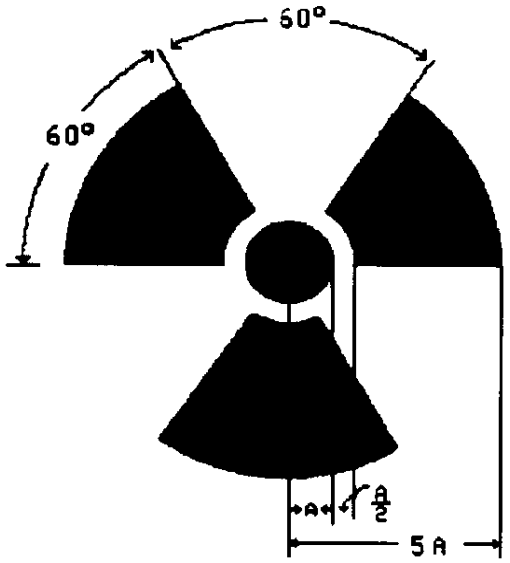
*e.* Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever portable gauges are not under the control and constant surveillance of the licensee.

**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.

**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.

**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 involves 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).

**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.

**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.

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.