

CHAPTER 38
GENERAL PROVISIONS FOR RADIATION MACHINES
AND RADIOACTIVE MATERIALS

641—38.1(136C) Purpose and scope.

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

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 2002.

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

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

“A₁” means the maximum activity of special form radioactive material permitted in a Type A package.

“A₂” means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix E of 641—Chapter 39, Table I, or may be derived in accordance with the procedure prescribed in Appendix E of 641—Chapter 39.

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

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

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

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

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

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

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

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

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

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

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

“Air kerma (K)” means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

“Annually” means at least once every 365 days.

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

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

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

“Barrier” (see “Protective barrier”).

“Beam axis” means the axis of rotation of the beam-limiting device.

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

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

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

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

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

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

“*By-product material*” means (1) any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “by-product material” within this definition.

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

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

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

“*CFR*” means Code of Federal Regulations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“*Extremity*” means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

“*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.

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

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

“*Gray (Gy)*” means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. (1 Gy=100 rad).

“*Half-value layer (HVL)*” means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

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

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

“*Healing arts screening*” means the testing of human beings using radiation for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an individual authorized under 641—subparagraph 41.1(3)“a”(7) or listed as an authorized user on an Iowa, U.S. Nuclear Regulatory Commission, or agreement state radioactive materials license.

“*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 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

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

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

“*Industrial radiography*” means a nondestructive testing method using ionizing radiation, such as gamma rays or X-rays, to make radiographic images.

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

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

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

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

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

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

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

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

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

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

“*Lens dose equivalent (LDE)*” applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

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

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

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

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

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

“*Light field*” means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

“*Limits.*” See “Dose limits.”

“*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.

“*mA*” means milliamperere.

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

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

“*Mammography unit*” means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the supporting structures for these components.

“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.

“Misadministration” means the administration of:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

Involving the wrong patient or human research subject, or wrong radiopharmaceutical; or

When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration; or

When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

3. A gamma stereotactic radiosurgery radiation dose:

Involving the wrong patient or human research subject, or wrong treatment site; or

When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

4. Radiation doses received from teletherapy, linear accelerator therapy, deep X-ray machine therapy or superficial therapy; involving the wrong patient or human research subject, wrong mode of treatment or wrong treatment site;

When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

5. A brachytherapy radiation dose:

Involving the wrong patient or human research subject, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

Involving a sealed source that is leaking;

When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration; or when the administered dosage differs from the prescribed dosage; and

When the dose to the patient or human research subject exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

“*Monitoring*” means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, “radiation monitoring” and “radiation protection monitoring” are equivalent terms.

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

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

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

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

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

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

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

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

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

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

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

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

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

“*Prescribed dosage*” means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or
2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

“*Prescribed dose*” means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“*Radiation dose.*” See “Dose.”

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

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

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

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

“*Radiobioassay*.” See “*Bioassay*.”

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

“*Recordable event*” means the administration of:

1. A radiopharmaceutical or radiation without a written directive where a written directive is required;

2. A radiopharmaceutical or radiation dose where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

3. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

a. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

b. The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

4. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

5. A teletherapy, particle accelerator or X-ray radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

6. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

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

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

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

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

“*Reportable medical event*” means the administration of radioactive material for diagnostic medical use that results in the patient’s or human research subject’s receiving:

1. Greater or less than 20 percent of a prescribed dose;

2. A dose intended for another individual; or

3. A dose that was not prescribed by an authorized user.

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

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

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

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

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

“*Sealed source*” means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

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

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

“*Shallow dose equivalent*” (*H_s*), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

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

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

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

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

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

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

“*Source material*” means:

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

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

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

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

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

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

3. It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

“*Special nuclear material*” means:

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

2. Any material artificially enriched by any of the foregoing but does not include source material.

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

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

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

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

“*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, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

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

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

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

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

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

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

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

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

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

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

“*Type A quantity*” means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 , for normal form radioactive material.

“*Type B quantity*” means a quantity of radioactive material greater than a Type A quantity.

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

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

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

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

“*Waste*” means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (1) not classified as high-level radioactive waste, spent nuclear fuel, or by-product material as defined in Section 11e(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (2) classified as low-level radioactive waste consistent with existing law and in accordance with (1) by the U.S. Nuclear Regulatory Commission.

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

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

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

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

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

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

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

“*Written directive*” means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or by an individual qualified by training and experience to conduct particle accelerator therapy or radiation for X-ray therapy, except as specified in paragraph “6” of this definition, containing the following information:

1. For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;
2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

4. For teletherapy, particle accelerator or X-ray: the total dose, dose per fraction, treatment site, and overall treatment period;

5. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

6. For all other brachytherapy:

a. Prior to implantation: the radioisotope, number of sources, and source strengths; and

b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

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

“Year” means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

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

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

38.3(2) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these rules to the extent that such contractor or subcontractor under contract receives, possesses, uses, transfers or acquires sources of radiation:

a. Prime contractors performing work for the U.S. Department of Energy at U.S. government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

b. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

c. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

d. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:

(1) That the exemption of the prime contractor or subcontractor is authorized by law; and

(2) That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

641—38.4(136C) General regulatory requirements.

38.4(1) 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.

38.4(2) Inspections.

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

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

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

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

38.4(4) Units of exposure and dose.

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

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent ^a
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

^aAbsorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

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

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

	Neutron Energy (MeV)	Quality Factor ^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
	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

^aValue of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

^bMonoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

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

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

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

641—38.6(136C) Prohibited uses. A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health. A shoe-fitting fluoroscopic device shall not be used.

641—38.7(136C) Communications.

38.7(1) All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, 401 SW 7th Street, Suite D, Des Moines, Iowa 50309-4611.

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

641—38.8(136C) Fees.**38.8(1) Radiation machines.**

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

ANNUAL FEE SCHEDULE

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

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

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

(1) Mammography unit inspections fees:

- \$850 for the first unit and, if the facility has additional units at the address of the first unit, a fee of \$300 for each additional unit; or
- \$850 per portable unit for each site where the unit is off-loaded and used and where the processing and patient films are stored; or
- Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria; or
- \$400 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances.

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

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

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

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

d. Each person engaged in providing health physics services in mammography in Iowa, who meets the requirements of 641—paragraph 41.6(3)“c” and is deemed qualified by this agency, must submit a \$35 annual listing fee to this agency.

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

38.8(2) Radioactive material licensing, inspection and registration fee.

a. Licensing.

(1) Fees associated with licensing of the possession and use of radioactive materials in Iowa shall not exceed those specified in 10 CFR 170.31. The radioactive materials fee schedule is available through the agency.

(2) All required fees for new radioactive materials licenses, amendments to licenses, or renewal of licenses shall accompany the application for the requested action.

b. Inspections.

(1) After completion of an inspection, an inspection fee shall be assessed to a facility based on the fees for inspection, which shall not exceed those found in 10 CFR 170.32 entitled “Schedule of Fees for Health and Safety, and Safeguards Inspections for Materials Licenses.” The radioactive materials fee schedule is available through the agency.

(2) All required fees for inspections conducted by the agency shall be paid within 30 days after receipt of the agency notification following the inspection.

c. *Registration.* Each person having generally licensed radioactive materials shall annually register with the department and pay a nonrefundable annual fee of \$150.

38.8(3) Industrial radiography testing and certification.

a. A nonrefundable fee of \$125 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

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

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

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

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

a. Annual fee. Each individual must submit a \$45 initial fee for the first year and \$35 annually. These fees are nonrefundable.

b. Examination fee.

(1) Each individual making application to take an examination given by the agency as a general diagnostic radiographer, or general radiation therapist as defined in 641—Chapter 42 must pay a nonrefundable fee of \$25 each time the individual takes the examination required by 641—Chapter 42. Effective January 1, 2000, each individual must pay a nonrefundable fee of \$80 each time the individual takes the examination.

(2) Each individual making application to take an examination given by the agency as a limited diagnostic radiographer, limited nuclear medicine technologist, or limited radiation therapist as defined in 641—Chapter 42 must pay a nonrefundable fee of \$35 each time the individual takes the examination required by 641—Chapter 42. Effective January 1, 2001, each individual must pay a nonrefundable fee of \$85 each time the individual takes the examination.

(3) Each individual making application to take an examination given by the agency as a general nuclear medicine technologist as defined in 641—Chapter 42 must pay a nonrefundable fee of either \$80 or \$145, depending upon the testing facility chosen, effective January 1, 2000.

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

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

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

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

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

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

a. Radiation machines. Any out-of-state person who wishes to bring an X-ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of \$100 for each source of radiation pursuant to 38.8(7).

b. Radioactive materials. Out-of-state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90)). If a reciprocity fee is applicable, it shall be assessed at the rate for reciprocity specified in the radioactive materials fee schedule available through the agency for each 365-day reciprocity period. In addition, if the agency performs an inspection of the out-of-state person's activities while in Iowa, the appropriate inspection fee as specified in the radioactive materials fee schedule will be assessed.

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

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

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

38.8(11) Radioactive waste transport fee schedule, effective July 1, 2002.

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

(1) \$1750 per highway cask for each truck shipment of spent nuclear fuel, high-level radioactive waste or transuranic waste traversing the state or any portion thereof. Single cask truck shipments are subject to a surcharge of \$15 per mile for every mile over 250 miles traveled.

(2) \$1250 for the first cask and \$100 for each additional cask for each rail shipment of spent nuclear fuel, high-level radioactive waste or transuranic waste traversing the state or any portion thereof.

(3) \$50 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.

b. All fees must be received by the department prior to shipment. Fees must be in the form of a check or money order made payable to the Iowa Department of Public Health and sent to the Iowa Bureau of Radiological Health, 401 SW 7th Street, Suite D, Des Moines, Iowa 50309-4611. Other methods of fee payment may be considered by the department on a case-by-case basis upon request of the shipper. A request for an alternative method of payment must be made to the department prior to shipment.

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

641—38.9(136C) Administrative enforcement actions.

38.9(1) Scope.

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

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

38.9(2) Notice of violation.

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

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

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

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

- (1) Severity Levels I and II: Violations are of very significant regulatory concern involving actual or high potential impact on the public health and safety.
- (2) Severity Level III: Violations are cause for significant concern.
- (3) Severity Level IV: Violations are less serious but are of more than minor concern and that, if left uncorrected, could lead to a more serious health and safety concern.
- (4) Severity Level V: Violations are of minor safety or environmental concern.

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

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

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

38.9(3) Orders.

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

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

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

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

(4) Specify the issues for hearing; and

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

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

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

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the regulated entity to whom the order has been issued shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the agency, and shall be effective as provided in the order.

38.9(4) *Settlement and compromise.* At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty. The stipulation or compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the chief administrative law judge, according due weight to the position of the staff. The presiding officer, or if none has been designated, the chief administrative law judge, may order such adjudication of the issues as deemed to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.

38.9(5) *Demand for information.*

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

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

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

b. A regulated entity to whom the agency has issued a demand for information under this subrule must respond to the demand by filing a written answer under oath or affirmation. The regulated entity’s answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described above, or by setting forth its reasons why the demand should not have been issued and, if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer filed pursuant to 38.9(5)“*a*”(2), or if no answer is filed, the agency may institute a proceeding pursuant to 38.9(3) to take such action as may be proper.

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

38.9(6) Civil penalties.

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to 38.9(2). The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

c. If the person charged with violation fails to answer within the time specified in 38.9(6)“*b.*,” an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6)“*a.*”

d. If the person charged with violation files an answer to the notice of violation, the agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the agency will issue an order designating the time and place of hearing.

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

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

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

i. Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties imposed under Iowa Code section 136C.4 shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

38.9(7) Requests for action under this rule.

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

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

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

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

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

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

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

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

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

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

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

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

641—38.10(136C) Deliberate misconduct.

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

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

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

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

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

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

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

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

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