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 May 1, 2003.

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.

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package.

"A_2" 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 (composed wholly or partly of licensed material) exists in concentrations (1) in excess of the derived air concentrations (DACs) specified in Appendix A of 641—Chapter 40; or (2) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

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

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

"Annually" means at least once every 365 days.

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

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

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

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

"Authorized medical physicist" means an individual who meets the requirements of 641—subrule 41.2(74) and 641—subrule 41.2(77) and is identified as an authorized medical physicist or teletherapy physicist on a specific medical license issued by this agency, the NRC, or an agreement state, a medical use permit issued by the NRC master material licensee, a permit issued by an NRC or agreement state broad scope medical use licensee, a permit issued by an NRC or agreement state broad scope medical use licensee, or a permit issued by an NRC master material license broad scope medical use permittee.

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

"Barrier" (see "Protective barrier").

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

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

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

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

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

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

"*Brachytherapy*" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, 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*" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

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

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

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

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

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

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

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

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

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

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

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

"Detector" (see "Radiation detector").

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

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

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

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

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

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

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

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

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

"Embryo/fetus" means the developing human organism from conception until the time of birth.

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

"Exposure" means being exposed to ionizing radiation or to radioactive material.

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

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

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

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

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

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

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

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

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

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

"Gray (Gy)" means the SI unit of absorbed dose, 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. The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

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

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

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

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

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

"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 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/cm^2).

"License" means a license issued by the agency in accordance with the rules adopted by the agency.

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

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

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

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

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

"Limits." See "Dose limits."

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

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

"mA" means milliampere.

"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. Radiation doses received from 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.

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

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

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

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

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

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

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator." See "Accelerator."

"Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

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

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

"Personnel monitoring equipment." See "Individual monitoring devices."

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

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

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

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

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

"Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

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

"Prescribed dose" means:

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

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

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been 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 decommissioning are not principal activities.

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

1. *"Primary protective barrier"* means the material, excluding filters, placed in the useful beam, 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 radiation or to radioactive material released by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation 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.

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

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

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

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

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

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

"Registration" means registration with the agency in accordance with the rules adopted by the agency.

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

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

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

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

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

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

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

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

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

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

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

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

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-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").

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

"Shallow dose equivalent" (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

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

"SI" means the abbreviation for the International System of Units.

"Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 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.

"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, 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.

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

"Total effective dose equivalent" (TEDE) means the sum of the 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."

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

"Tube" means an X-ray tube unless otherwise specified. See "X-ray tube."

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

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

"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).

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

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

"Waste" means those low-level radioactive wastes 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 radiopharmaceutial or by an individual qualified by training and experience to conduct particle accelerator therapy or radiation for X-ray therapy, as specified in 641—subrule 41.2(87).

"*X-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.