

Proposed Outline of Minnesota Rule

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4730.4002

§19.3 Definitions. (RAM)

-----A₁. "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, LSA and SCO material, permitted in a Type A package. These values are either listed in Appendix A of this part, Table A - 1, or may be derived in accordance with the procedure prescribed in Appendix A of this part.

----- Act. "Act" means the Atomic Energy Act of 1954, (68 Stat. 919) including any amendments thereto.

-----Activity. "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and becquerel (Bq).

-----Accelerator-produced material. "Accelerator-produced material" means material made radioactive by a particle accelerator.

-----Agreement state. "Agreement state" means any State with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended.

-----Airborne radioactive material. "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

----- Airborne radioactivity area. "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations.

(1) In excess of the derived air concentrations (DACs) specified in appendix B, to

~~§§20.1001-20.2401 of~~

(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.

-----ALARA as low as reasonably achievable. "ALARA (as low as reasonably achievable)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken,

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic

considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

-----Alert. "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

-----Annually. "Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

-----Area of use. "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

-----Associated equipment. "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

-----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 nuclear pharmacist. "Authorized nuclear pharmacist" means a pharmacist who is:

- (1) Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
- (2) Identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or,
- (3) Identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.

-----Authorized user. "Authorized user" means a physician, dentist, or podiatrist who is:

(1) Board certified by at least one of the boards listed in Paragraph (a) of §§35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;

(2) Identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(3) Identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.

-----Bioassay (radiobioassay). "Bioassay (radiobioassay)" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

Subp. 22a. Boring. "Boring" has the meaning given in Minnesota Statutes, section 1031.005

-----Brachytherapy source. "Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

-----Byproduct material. "Byproduct material" means:

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

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

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

-----Certifying Entity. "Certifying entity" means an independent certifying organization meeting the requirements in appendix A of this part or an Agreement State meeting the requirements in appendix A, Parts II and III of this part.

-----Chelating agent. "Chelating agent" means amine polycarboxylic acids (EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g. citric acid, carbonic acid, and glucinic acid).

-----Class. "Class (or lung class or inhalation class)" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days.

-----Committed dose equivalent ($H_{T,50}$). "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 ($H_{E,50}$). "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 these organs or tissues. ($H_{E,50} = \sum W_T H_{T,50}$).

-----Commencement of construction. "Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

-----Constraint (dose constraint). "Constraint (dose constraint)" means a value above which specified licensee actions are required.

-----Control (drive) cable. "Control (drive) cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

-----Control drive mechanism. "Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.

-----Control tube. "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

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

-----Curie. "Curie" See units. means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

-----Decommission. "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.

-----Dedicated check source. "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

-----Depleted uranium. "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.

-----Derived air concentration (DAC). "Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of appendix B to §§20.1001 - 20.2401

-----Derived air concentration-hour (DAC-hour). "Derived air concentration-hour (DAC-hour)" is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

-----Diagnostic clinical procedures manual. "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.

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.

-----Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

-----Effective kilogram. "Effective kilogram" means (1) for the source material uranium in which the uranium isotope uranium - 235 is greater than 0.005 (0.5 weight percent) of the total uranium present: 10,000 kilograms, and (2) for any other source material: 20,000 kilograms.

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

-----Exclusive use. "Exclusive use" means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

-----Exposure head. "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

-----Field station. "Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched to temporary jobsites.

-----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, not equipped with elastomeric sealing surfaces and adjustable straps.

Subp. 73a. Fishpole radiography. "Fishpole radiography" means industrial radiography performed with a sealed source that is not fastened to or contained in a radiographic exposure device.

-----Fissile material. "Fissile material" means plutonium-238, plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Certain exclusions from fissile material controls are provided in §71.53.

-----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.

-----Fresh water aquifer. "Fresh water aquifer" means

-----Guide tube (Projection sheath). "Guide tube (Projection sheath)" means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

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

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

-----Independent certifying organization. "Independent certifying organization" means an independent organization that meets all of the criteria of ~~Appendix A~~ to this part.

-----Injection tool. "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

-----Internal dose. "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

-----Irradiator. "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

-----Irradiator operator. "Irradiator operator" means an individual who has successfully completed the training and testing described in §36.51 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

-----Irretrievable well logging source. "Irretrievable well logging source" means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

-----Land disposal facility. "Land disposal facility" means the land, building and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this chapter, a "geologic repository" as defined in part ~~60~~ is not considered a "land disposal facility."

-----License. "License" means a license issued under the regulations in parts ~~30 through 36, 39,~~

~~40, 60, 61, 70, or 72 of this chapter, including~~ licenses to operate a production or utilization facility pursuant to part ~~50~~ of this chapter. ----?-----Licensee means the holder of such a license.

-----Licensed material. "Licensed material" means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the commissioner.

-----Logging assistant. "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by ~~SS 39.67~~

-----Logging supervisor. "Logging supervisor" means an individual who uses licensed material or provides personal supervision in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Commissioner's regulations and the conditions of the license.

-----Logging tool. "Logging tool" means a device used subsurface to perform well logging.

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

-----Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

-----Low Specific Activity. "Low Specific Activity (LSA)" material means radioactive material with limited specific activity that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(1) LSA - I.

- (i) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or
- (ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or
- (iii) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or
- (iv) Mill tailings, contaminated earth, concrete, rubble, other debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed $106 A_2/g$.

(2) LSA - II.

- (i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or
- (ii) Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.

(3) LSA - III. Solids (e.g., consolidated wastes, activated materials) in which:

- (i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and
- (ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed $0.1 A_2$; and
- (iii) The average specific activity of the solid does not exceed $2 \times 10^{-3} A_2/g$.

-----Low toxicity alpha emitters. "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

-----Management. "Management" means the chief executive officer or that person's delegate

-----Maximum normal operating pressure. "Maximum normal operating pressure" means the maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in ~~§ 71.71(c)(1)~~, in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

-----Medical Institution. "Medical institution" means an organization in which several medical disciplines are practiced.

-----Medical use. "Medical use" means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

-----Medical use. "Medical use" means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in 10 CFR Part 35.

-----Misadministration. "Misadministration" means the administration of:

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

(i) Involving the wrong individual, or wrong radiopharmaceutical; or

(ii) 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:

(i) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

(ii) 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:

(i) Involving the wrong individual, or wrong treatment site; or

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

(4) A teletherapy radiation dose:

(i) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;

(ii) 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;

(iii) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

(iv) 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:

(i) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site

but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

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

(iv) 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:

(i) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

-----Mobile nuclear medicine service means the transportation and medical use of byproduct material.

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

-----Uranium -- natural, depleted, enriched

(1) Natural uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

Subp. 116. Neutron generator. "Neutron generator" means a type of accelerator in which the ion beam is used mainly for the production of neutrons. Neutron generation is also possible for

high energy photon producing equipment.

-----Offshore waters. "Offshore waters" means that land of area and water, beyond Agreement States' Submerged Lands Act jurisdiction, on or above the U.S. Outer Continental Shelf.

Subp. 121a. Passive NARM device. "Passive NARM device" means a fixed device containing NARM material that is installed permanently on or in another device, a building, or a part of a building to perform a specific task.

-----Natural thorium. "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

-----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.

-----Normal form radioactive material. "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material."

*-----Nuclear logging or logging.

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

(1) Fissile material package means a fissile material packaging together with its fissile material contents.

(2) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lb/in²) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in ~~§ 71.73~~ (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in ~~§ 71.13~~.

-----Panoramic dry-source-storage irradiator. "Panoramic dry-source-storage irradiator" means

an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

-----Panoramic irradiator means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

-----Panoramic wet-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

-----Personal supervision means guidance and instruction by a logging supervisor, who is physically present at a temporary jobsite, who is in personal contact with logging assistants, and who can give immediate assistance.

OR

Subp. 125a. Personal supervision. "Personal supervision" means guidance and instruction by an industrial radiographer or logging supervisor, who:

- A. is physically present at a temporary jobsite;
- B. is in personal contact with an industrial radiographer's assistant or logging assistant; and
- C. can give immediate assistance.

-----Pharmacist. "Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

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 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, 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 dose 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.

-----Principal activities. "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.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

-----Production facility. "Production facility" means:

(1) Any nuclear reactor designed or used primarily for the formation of plutonium or uranium - 233; or

(2) Any facility designed or used for the separation of the isotopes of plutonium, except laboratory scale facilities designed or issued for experimental or analytical purposes only; or,

(3) Any facility designed or used for the processing of irradiated materials containing special nuclear material, except (i) laboratory scale facilities designed or used for experimental or analytical purposes, (ii) facilities in which the only special nuclear materials contained in the irradiated material to be processed are uranium enriched in the isotope U - 235 and plutonium produced by the irradiation, if the material processed contains not more than 106 grams of plutonium per gram of U - 235 and has fission product activity not in excess of 0.25 millicuries of fission products per gram of U - 235, and (iii) facilities in which processing is conducted pursuant to a license issued under

parts 30 and 70 of this chapter, or equivalent regulations of an Agreement State, for the receipt, possession, use, and transfer of irradiated special nuclear material, which authorizes the processing of the irradiated material on a batch basis for the separation of selected fission products and limits the process batch to not more than 100 grams of uranium enriched in the isotope 235 and not more than 15 grams of any other special

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.

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

-----Rad (See §20.1004). "Rad" is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray)

* Subp. 152. Radioactivity. "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

Subp. 155. Radiographic exposure device. "Radiographic exposure device" (also called a camera, or a projector) means any instrument containing a sealed source, fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to an unshielded position for purposes of making a radiographic exposure.

-----Radioactive marker. "Radioactive marker" means licensed material used for depth determination or direction orientation. For purposes of this part, this term includes radioactive collar markers and radioactive iron nails.

Subp. 151. Radioactive material. "Radioactive material" means any solid, liquid, or gaseous substance which emits radiation spontaneously.

-----Radiation room. "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

-----Radiation safety officer. "Radiation safety officer" means an individual with responsibility for the overall radiation safety program at the facility.

-----Recordable event. "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 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:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) 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 radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of 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.

-----Rem (See §20.1004).

-----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" as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings.

-----Residual radioactivity. "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 10 CFR part 20.

-----Respiratory protective device. "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

-----Restricted area. "Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

-----S-tube. "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

-----Safety review. "Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

-----Sanitary sewerage. "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

-----Sealed source. "Sealed source" means any licensed or by product material that is encased in a capsule designed to prevent leakage or escape of the licensed material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

Self-contained breathing apparatus. "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. "Shallow-dose equivalent (H_s)," which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²) averaged over an area of 1 square centimeter.

Subp. 174a. Shielded position. "Shielded position" means the location within a radiographic exposure device or storage container that, by manufacturer's design, is the location for storage of the sealed source.

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-----Sievert (See §20.1004).

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

-----Source assembly. "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

-----Source changer. "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

-----Source holder. "Source holder" means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.

-----Source material. "Source material" means:

(1) Uranium or thorium or any combination of uranium and thorium 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.

-----Special form radioactive material. "Special form radioactive material" means radioactive material that 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 mm (0.2 in); and

(3) It satisfies the requirements of §71.75. A special form encapsulation designed in accordance with the requirements of §71.4 in effect on June 30, 1983, (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985, and a special form encapsulation designed in accordance with the requirements of §71.4 in effect on March 31, 1996, (see 10 CFR part 71, revised as of January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

-----Special nuclear material. "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 commissioner, pursuant to the provisions of section 51 of

the Act, 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.

-----Specific activity of a radionuclide. "Specific activity of a radionuclide" means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

Subp. 187. Stochastic effects. "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Subp. 187a. Storage area. "Storage area" means any location, facility, or vehicle which is used to store, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

Subp. 188. Storage container. "Storage container" means a container in which sealed sources are secured and stored, in accordance with the manufacturer's guidance when the manufacturer's guidance is available.

-----Subsurface tracer study. "Subsurface tracer study" means the release of unsealed license material or a substance labeled with licensed material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

-----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.

-----Surface casing for protecting fresh water aquifers. "Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

-----Surface Contaminated Object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

- (1) SCO - I: A solid object on which:
 - (i) The non-fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 4 Bq/cm² (10⁻⁴

microcurie/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm² (10⁻⁵ microcurie/cm²) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 4x10⁴ Bq/cm² (1.0 microcurie/cm²) for beta and gamma and low toxicity alpha emitters, or 4x10³ Bq/cm² (0.1 microcurie/cm²) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 40x10⁴ Bq/cm² (1 microcurie/cm²) for beta and gamma and low toxicity alpha emitters, or 40x10³ Bq/cm² (0.1 microcurie/cm²) for all other alpha emitters.

(2) SCO - II: A solid object on which the limits for SCO - I are exceeded and on which:

(i) The non-fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 400 Bq/cm² (10⁻² microcurie/cm²) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm² (10⁻³ microcurie/cm²) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 8x10⁵ Bq/cm² (20 microcuries/cm²) for beta and gamma and low toxicity alpha emitters, or 8x10⁴ Bq/cm² (2 microcuries/cm²) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 8x10⁵ Bq/cm² (20 microcuries/cm²) for beta and gamma and low toxicity alpha emitters, or 8x10⁴ Bq/cm² (2 microcuries/cm²) for all other alpha emitters

-----Teletherapy physicist means the individual identified as the teletherapy physicist on a Commission license.

Subp. 193a. Temporary jobsite. "Temporary jobsite" means a location where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.

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

-----Total Effective Dose Equivalent (TEDE). "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).

-----Transient shipment. "Transient shipment" means a shipment of nuclear material,

origination and terminating in foreign countries , on a vessel or aircraft that stops the a United States port.

Subp. 201a. Transport container. "Transport container" means a package that:

A. is designed to provide radiation safety and security when sealed sources are transported; and

B. meets all applicable requirements of the United States Department of Transportation and part 4730.1000.

-----Transport index. "Transport index" means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

(1) For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)); or

(2) For fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)), or, for criticality control purposes, the number obtained as described in §71.59, whichever is larger.

-----Type A quantity. "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, where A_1 and A_2 are given in Table A - 1 of this part, or may be determined by procedures described in Appendix A of this part.

-----Type B quantity. "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

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

-----Unrestricted area. "Unrestricted area" means an area, access to which is neither limited

nor controlled by the licensee.

-----Uranium sinker bar. "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

-----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.

-----Waste. "Waste, means those low-level radioactive wastes containing source, special nuclear or by product material that are acceptable for disposal in a land disposal facility. For the purposes of this definition low-level waste has the same meaning as in the Low-Level Waste Policy Act, that is, radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste.)

-----Weighting factor. "Weighting factor W_T ," for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent,

Organ Dose Weighting Factors

Organ or tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surface	0.03
Remainder	¹ 0.30
Whole Body	² 1.00

¹ 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

² For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T=1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

-----Well. "Well" means a drilled hole in which well logging may be performed. As used in this part, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater, or

geological exploration.

-----Well logging. "Well logging" means all operations involving the lowering and raising of measuring devices or tools which contain licensed material or are used to detect licensed materials in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

-----Whole body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

-----Working level. "Working level (WL)" is any combination of short-lived radon daughters (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) in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

-----Working level month. "Working level month (WLM)" means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year=approximately 170 hours per month).

-----Written directive. "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 radiation, 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: 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:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) 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).

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

4730.0100 DEFINITIONS. (X-RAY)

Subp. 7. Aluminum equivalent. "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

Subp. 15. Automatic exposure control (AEC). "Automatic exposure control" or "(AEC)" means a device that automatically controls one or more technique factors to obtain a required quantity of radiation at a preselected location.

Subp. 16. Beam axis. "Beam axis" means a line from the source through the centers of the x-ray fields.

Subp. 18. Beam-limiting device (BLD). "Beam-limiting device" or "(BLD)" means a device used to restrict the dimensions of the x-ray field.

Subp. 23. Bucky. "Bucky" means an apparatus under the x-ray table or in a vertical cassette holder that holds the grid and cassette during the radiographic exposure.

Subp. 25. C-arm. "C-arm" means an x-ray system in which the image receptor and the x-ray tube housing assembly are connected by a common mechanical support system to maintain a desired spatial relation.

Subp. 28. Cephalometric device. "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Subp. 28a. Certified cabinet x-ray system. "Certified cabinet x-ray system" means an x-ray system that has been certified according to Code of Federal Regulations, title 21, part 1010, section 1010.2, April 1, 1996, and as subsequently amended, as being manufactured and assembled pursuant to Code of Federal Regulations, title 21, part 1020, section 1020.40, April 1, 1996, and as subsequently amended.

Subp. 30. Certified components. "Certified components" means components of x-ray systems that are subject to the x-ray equipment performance standards adopted under Public Law Number 90-602, the Radiation Control for Health and Safety Act of 1968.

Subp. 32. Certified system. "Certified system" means an

x-ray system that has one or more certified components.

Subp. 40. Computed tomography (CT). "Computed tomography" or "(CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Subp. 41. [Repealed, 16 SR 485]

Subp. 44. MR 1991 [Renumbered as Subp. 155, 16 SR 485]

Subp. 46. CT conditions of operation. "CT conditions of operation" means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in subpart 196.

Subp. 47. MR 1991 [Renumbered as Subp. 163, 16 SR 485]

Subp. 47. CT dose index (CTDI). "CT dose index" or (CTDI)" means the integral from minus $7T$ to plus $7T$ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness (T) and the number of tomograms produced in a single scan (n), that is:

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where:

z = position along a line perpendicular to the tomographic plane;

$D(z)$ = dose at position z ;

T = nominal tomographic section thickness; and

n = number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around $z=0$ and that, for a multiple tomogram system, the increment of adjacent scans is nT .

Subp. 48. CT gantry. "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and supporting structures and frames that hold these components.

Subp. 49. CT number. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

Subp. 51. Dead-man switch. "Dead-man switch" means a switch so constructed that a circuit-closing contact can be maintained only by continuous pressure on the switch by the operator.

Subp. 52. MR 1991 [Renumbered as Subp. 178, 16 SR 485]

Subp. 52. Densitometer. "Densitometer" means an instrument that measures the optical density of a film by measuring the amount of light transmitted through the film.

Subp. 53. Diagnostic source assembly. "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

Subp. 54. Diagnostic-type protective tube housing. "Diagnostic-type protective tube housing" means an x-ray tube housing so constructed that the leakage radiation measured at a distance of one meter from the source cannot exceed 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

Subp. 55. Diagnostic radiographic imaging system. "Diagnostic radiographic imaging system" means an assemblage of components for the generation, transmission, and reception of an x-ray and the transformation, storage, and visual display of the resultant radiographic image.

Subp. 65. Elemental area. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

Subp. 71. Field Emission equipment. "Field emission equipment" means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Subp. 74. Fluoroscopic imaging assembly. "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Subp. 75. Focal spot. "Focal spot" means the area of the anode from which x-rays originate.

Subp. 77. General purpose radiographic x-ray system. "General purpose radiographic x-ray system" means a radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

Subp. 85. Image intensifier. "Image intensifier" means a device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher energy density or higher luminance.

Subp. 86. Image receptor. "Image receptor" means a device, such as a fluorescent screen or radiographic film, that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

Subp. 87. Image receptor support. "Image receptor support" means, for mammographic systems, the part of the system designed to support the image receptor during mammography.

Subp. 88a. Industrial cabinet baggage system. "Industrial cabinet baggage system" means an x-ray system with the x-ray tube installed in a shielded cabinet that is freestanding and is designed primarily for the inspection of carry-on baggage at airline, railroad, or bus terminals, courthouses, correctional facilities, and similar facilities. The baggage to be irradiated is contained in the shielded cabinet and the shielded cabinet is designed to exclude personnel from its interior during generation of x-rays.

Subp. 91. Inherent filtration. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Subp. 98. Kilovolt peak (kVp). "Kilovolt peak" or "(kVp)" means the maximum value in kilovolts of the potential difference of an x-ray generator. When only one-half of the wave is used, the value refers to the useful half of the cycle.

Subp. 99. Kilowatt second (kWs). "Kilowatt second" or "(kWs)" means the equivalent of 103 kV X mA X s.

Percent line-voltage regulation = $100 (V_n - V_l)/V_l$

where:

V_n = no-load line potential; and

V_l = load line potential.

Subp. 107. mA. "mA" means milliamperere.

Subp. 108. mAs. "mAs" means milliamperere-second.

Subp. 117. Nominal tomographic section thickness.

"Nominal tomographic section thickness" means the full width at half-maximum at the center of the cross-sectional volume over which x-ray transmission data are collected.

Subp. 121. Optical density or O.D. "Optical density" or "O.D." means the logarithm of the incident light intensity minus the logarithm of the transmitted light intensity.

Subp. 123. Peak tube potential. "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

Subp. 128. Phototimer. "Phototimer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation that reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit that controls the duration of time the tube is activated. (See automatic exposure control.)

Subp. 137a. Pulsed mode. "Pulsed mode" means operation of an x-ray system so that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of less than one-half second duration.

Subp. 138. Quality assurance program. "Quality assurance program" means the program and procedures contained in parts 4730.1655 to 4730.1695.

Subp. 158. Reference plane. "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

Subp. 166. Scan increment. "Scan increment" means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of the displacement.

Subp. 167. Scan sequence. "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Subp. 173. Sensitometer. "Sensitometer" means an instrument designed to produce a series of exposures with known ratios to each other.

Subp. 183. Spot film. "Spot film" means a radiograph that is made during a fluoroscopic examination.

Subp. 184. Spot-film device. "Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier to make a radiograph.

Subp. 186. Stepless adjustment. "Stepless adjustment" means a method of adjusting collimator blades continuously rather than in fixed increments.

Subp. 192. Technique factors. "Technique factors" means the conditions of operation, specified as follows:

A. for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

B. for CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of milliamperage, x-ray pulse width, and the number of x-ray pulses in mAs;

C. for CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of milliamperage and exposure time in mAs and the scan time when the scan time and exposure time are equivalent;

D. for phototimed or automatic exposure controlled equipment, all necessary indicators including anatomical, if applicable, that must be activated before exposure; and

E. for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of milliamperage and exposure time in mAs.

*Subp.197

Subp. 198. Tomogram. "Tomogram" means an x-ray image of a thin section of the body.

Subp. 199. Tomographic plane. "Tomographic plane" means the geometric plane that is identified as corresponding to the output tomogram.

Subp. 200. Tomographic section. "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

Subp. 202. Tube housing assembly. "Tube housing assembly" means the tube housing with tube installed.

Subp. 204. Type 1100 aluminum alloy. "Type 1100 aluminum alloy" means an alloy of aluminum that has a nominal chemical composition of 99 percent minimum aluminum and 0.12 percent copper.

Subp. 212. Visible area. "Visible area" means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Subp. 214. X-ray control. "X-ray control" means a device that controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes components such as timers, phototimers or automatic exposure controls, automatic brightness stabilizers, and similar devices that control the technique factors of an x-ray exposure.

Subp. 215. X-ray equipment. "X-ray equipment" means an x-ray system, subsystem, or component. Types of x-ray equipment are listed in items A to D.

A. "Mobile x-ray equipment" means x-ray equipment

mounted in a self-contained transport vehicle.

B. "Portable industrial x-ray equipment" means industrial x-ray equipment designed to be brought to a temporary jobsite to perform temporary industrial radiography.

C. "Portable x-ray equipment" means x-ray equipment designed to be brought to a patient.

D. "Stationary x-ray equipment" means x-ray equipment installed in a fixed location within a facility.

Subp. 216. X-ray field. "X-ray field" means the area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

Subp. 217. X-ray generator. "X-ray generator" means a type of electron accelerator in which the electron beam is used mainly for the production of x-rays.

Subp. 218. X-ray high-voltage generator. "X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current filament transformers for the x-ray tube, high-voltage switches, electrical protective devices, and other appropriate elements.

Subp. 219. X-ray subsystem. "X-ray subsystem" means a combination of two or more components of an x-ray system.

Subp. 220. X-ray system. "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

Subp. 221. X-ray tube or tube. "X-ray tube" or "tube" means an electron tube designed to be used primarily for the production of x-rays.

4730.0100 DEFINITIONS. (General)

Subpart 1. Scope. For purposes of this chapter, the terms in this part have the meanings given them.

Subp. 2. Absorbed dose. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

* Subp. 4. Accelerator. "Accelerator" means a device that accelerates charged subatomic particles or nuclei to energies useful for research and therapy, medical and industrial applications

Subp. 7b. Annual limit on intake or ALI. "Annual limit on intake" or "ALI" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year.

A. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of five rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue.

B. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Code of Federal Regulations, title 10, part 20, Appendix B, table 1, columns 1 and 2, January 1, 1997, and as subsequently amended.

* Subp. 5a. Active NARM device. "Active NARM device" means a portable device containing NARM material that is usually hand carried by an individual to perform a specific mobile task.

* Subp. 6. Added filtration. "Added filtration" means filtration that is in addition to the inherent filtration.

Subp. 6a. Adult. "Adult" means an individual 18 or more years of age.

Subp. 7a. Analytical radiation producing equipment. "Analytical radiation producing equipment" means radiation producing equipment used for research, teaching, development, and quality control including x-ray diffractometers, fluorescence analyzers, spectroscopy analyzers, thickness measurement gauges, and electron microscopes.

-----Annual Limit on Intake (ALI). "Annual limit on intake (ALI)" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year.

(A) ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue.

(B) ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 of appendix B to §§20.1001 - 20.2401.

----- ALARA (acronym for "As Low as Reasonably Achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(A) Consistent with the purpose for which the licensed or registered activity is undertaken,

(B) taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(C) in relation to utilization of nuclear energy in the public interest.

Subp. 8. Applicator. "Applicator" means an added device that determines the extent of the treatment field at a given distance from the virtual source.

Subp. 9. Appropriate limit. "Appropriate limit" or "appropriate limits" means the maximum permissible dose or doses of radiation that may be administered to the whole body or a given part of a human being.

* Assembler vs vendor

Subp. 13. Attenuation. "Attenuation" means the reduction of exposure rate upon passage of radiation through matter.

Subp. 14. Attenuation block. "Attenuation block" means a block or stack, having dimensions of 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

-----Background radiation. "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, 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 or registrant. Background radiation does not include radiation from source, byproduct, or special nuclear materials regulated by the Commissioner.

Subp. 19. Beam monitoring system. "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

Subp. 20 Beam scattering filter. "Beam scattering filter" means a filter or foil used to scatter a beam of electrons.

----- Subp. 22. Becquerel (Bq). "Becquerel" or "(Bq)" means a unit of measurement of radioactivity. See units. One becquerel is equal to one disintegration per second. One curie is equal to 3.7×10^{10} becquerels. Multiples included in these regulations are kilobecquerel (kBq), megabecquerel (MBq), gigabecquerel (GBq), terabecquerel (TBq), and petabecquerel (PBq). The conventional system equivalent is the curie.

*-----Cabinet x-ray system. "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed cabinet) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

Subp. 26. Calibration. "Calibration" means the determination of:

(A). the response or reading of an instrument relative to a series of known radiation values over the range of the instrument;

(B). the strength of a source of radiation relative to a standard; or

(C). the radiation dose or exposure rate at a designated distance from a radiation source under specified conditions of measurement.

Subp. 33. Changeable filter. "Changeable filter" means a filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

* Subp. 34 Clinical Range... re-work

----- Subp. 35. Coefficient of variation or C. "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations.

-----Subp. 36 Cold flow. "Cold flow" means the viscous flow solid at ordinary temperatures; or, the distortion of a solid under sustained pressure especially with an accompanying inability to return to its original dimensions when pressure is removed.

Subp. 37. Collimation. "Collimation" means the restriction of the useful beam to an appropriate area.

Subp. 38 Collimator. "Collimator" means

A. a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure; or

B. a mechanism connected to the x-ray tube housing that controls the dimensions of the primary radiation beam. Types of collimators are cones, diaphragms, and variable-aperture beam-limiting devices.

-----Collective Dose "Collective dose" is 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.

Subp. 39. Commissioner. "Commissioner" means the commissioner of the Minnesota Department of Health.

* Subp. 43. Control panel. "Control panel" means the part of the control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

* Subp. 44. Controlled area. "controlled area" means (NEC) an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. Also an area in which the exposure of persons to radiation is under the supervision of a radiation safety officer. (This implies that a controlled area is one that requires control of access,

occupancy, and working conditions for radiation protection purposes.)

Subp. 50. Curie (Ci). "Curie" or "(Ci)" means a unit of radioactivity. See units. One curie (Ci) is the quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations per second (dps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) equals 0.001 curie = 3.7×10^7 dps. One microcurie (μ Ci) equals 0.000001 curie = 3.7×10^4 dps. The SI equivalent is the becquerel.

Subp. 45. Coulomb per kilogram (C/kg). "Coulomb per kilogram" or "(C/kg)" means the unit of exposure. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram. Submultiples of this unit are the millicoulomb per kilogram (mC/kg) and the microcoulomb per kilogram (μ C/kg).

-----Declared pregnant woman means a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

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

----- Subp. 56. Diagnostic radiographic system. "Diagnostic radiographic system" means an x-ray system designed for irradiation of any part of the human or animal body for diagnosis or visualization.

Subp. 57. Dose or radiation dose. "Dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent.

Subp. 58. Dose commitment. "Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of the estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

-----Dose equivalent (H_T). "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 rem and sievert (Sv).

❖-----Dose limits. "Dose limits" See "limits"

Subp. 60. Dose monitoring system. "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation that can be related to the absorbed dose at a given location within a defined geometry.

Subp. 61. Dose monitor unit. "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose has been calculated.

Subp. 62 Dose profile "Dose profile" means the dose as a function of position along a particular plane.

-----Effective dose equivalent (H_E). "Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated. ($H_E = \sum w_T H_T$) Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

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

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

* Subp. 66. Entrance exposure rate. "Entrance exposure rate" means the exposure (free in air) per unit of time at the point where the center of the useful beam enters the patient.

Subp. 67. ESE. "ESE" means the entrance skin exposure that is measured free in air.

Subp. 68. Exposure. "Exposure" means being exposed to ionizing radiation or to radioactive material. An individual receives a dose of radiation but the individual is exposed to the radiation that delivered the dose.

Subp. 69. Exposure rate. "Exposure rate" means the exposure per unit of time, such as roentgen per minute, milliroentgen per hour, sievert per minute, or millisievert per hour.

-----External dose means that portion of the dose equivalent received from radiation sources

outside the body.

----- Extremity. "Extremity" means hand, elbow, arm below the elbow, foot, knee or leg below the knee.

-----Eye Dose. (See Lense dose (LDE))

Subp. 70. Facility. "Facility" means the location at which one or more sources of radiation are installed or located within one building, vehicle, or under one roof, and are under the same administrative control.

Subp. 72. Field flattening filter. "Field flattening filter" means a permanent filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

Subp. 73. Filter or filtration. "Filter" or "filtration" means material placed in the useful beam to absorb preferentially selected radiations.

Subp. 76. Gantry. "Gantry" means the part of the system supporting and allowing possible movements of the radiation head.

Subp. 78. Gonad shield. "Gonad shield" means a protective barrier for the testes or ovaries.

Subp. 79. Gray (Gy). "Gray" or "(Gy)" is the SI unit of absorbed dose. See units.

Subp. 80. Half-value layer (HVL). "Half-value layer" or "(HVL)" means the thickness of a specified material that attenuates the beam of radiation to such an extent that the exposure rate is reduced to one-half of its original value. The contribution of all scattered radiation, other than any that might be present initially in the beam concerned, is considered excluded

Subp. 81. Healing arts. "Healing arts" means health professions for diagnostic or healing treatment of human and animal maladies that are regulated under Minnesota Statutes, chapter 147, 153, or 156; or section 148.01, 148.106, or 150A.05, subdivision 1, clause (4), for the lawful practice of medicine, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

Subp. 82. Healing arts screening or screening. "Healing arts screening" or "screening" means the testing of individuals using radiation to detect or evaluate health conditions when the tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe the tests for the purpose of diagnosis or treatment.

Subp. 83. High radiation area. "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 receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Subp. 88. Individual. "Individual" means any human being.

-----Individual monitoring. "Individual monitoring" means:

A. The assessment of dose equivalent by the use of devices designed to be worn by an individual;

B. The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed. i.e., DAC-hours; or

C. The assessment of dose equivalent by the use of survey data.

-----Individual monitoring device. "Individual monitoring device" means a device designed to be worn by a single individual for the assessment of dose equivalent such as a film badge, a thermoluminescence dosimeter (TLD), a pocket ionization chamber or a personal ("lapel") air sampling devices. Monitoring devices must be NVLAP approved when appropriate. See NVLAP.

Subp. 88b. Industrial cabinet radiography. "Industrial cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the unrestricted limitations in part 4730.0380.

----- Industrial radiographer. "Industrial radiographer" means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Commissioners regulations and the

conditions of the license.

----- Industrial radiographer's assistant. "Industrial radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instrument in industrial radiography.

Subp. 90. Industrial radiography. "Industrial radiography" means a nondestructive testing method using ionizing radiation to produce images for detecting flaws in objects without destroying them and for other quality control purposes.

Subp. 90. Industrial radiography. "Industrial radiography" means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

Subp. 92. Inspection. "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 commissioner.

Subp. 93. Interlock. "Interlock" means a device which automatically causes a reduction of the exposure rate upon entry by personnel into a high radiation area. Alternatively, an interlock may prevent entry into a high radiation area, or a device arranged or connected so the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

Subp. 94. Ionizing radiation. "Ionizing radiation" means gamma rays, x-rays, alpha particles, beta particles, high speed electrons, neutrons, protons, and other nuclear particles, capable of producing ions directly or indirectly, by interaction with matter.

Subp. 95. Irradiation. "Irradiation" means the exposure of matter to ionizing radiation.

Subp. 96. Isocenter. "Isocenter" means a fixed point in space through which pass the central axes of radiation beams for all possible beam orientations and field sizes.

Subp. 97. Iso-line. "Iso-line" means a line, usually irregular, along which the exposure rates are the same at any

point.

Subp. 100. Lead equivalence or lead equivalent. "Lead equivalence" or "lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Subp. 101. Leakage radiation. "Leakage radiation" means all radiation coming from the source or tube housing except the useful beam. Leakage radiation includes the portion of the direct radiation not absorbed by the protective source or tube housing as well as the scattered radiation produced within the housing.

Subp. 102. Leakage technique factors. "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly that are used in measuring leakage radiation, as defined in items A to D.

A. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated kVp and the maximum-rated number of exposures in an hour for operation at the maximum-rated kVp with the quantity of charge per exposure being ten millicoulombs, for example, ten milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.

B. For diagnostic source assemblies intended for field emission equipment for pulsed operation, the maximum-rated kVp and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated kVp.

C. For all other diagnostic or x-ray tube therapeutic source assemblies, the maximum-rated kVp and the maximum-rated continuous milliamperage for the maximum-rated kVp.

* D. Leakage with RAM

-----Lense dose equivalent (LDE). "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). (This replaces "eye dose")

Subp. 103. Licensed practitioner of the healing arts. "Licensed practitioner of the healing arts" means health professionals for diagnostic or healing treatment of human and

animal maladies, which are licensed under Minnesota Statutes, chapter 147, 153, or 156; or section 148.01, 148.106, or 150A.05, subdivision 1, clause (4), for the lawful practice of medicine, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

Subp. 104. Light field. "Light field" means the 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 (dose limits). "Limits (dose limits)" mean the permissible upper bounds of radiation doses. This does not include patients receiving radiation for diagnostic or therapeutic purposes under supervision of licensed practitioners of the healing arts.

Subp. 105. Line-voltage regulation. "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Subp. 106. Linear attenuation coefficient or μ . "Linear attenuation coefficient" or " μ " means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material. The linear attenuation coefficient is the photon fraction attenuated per centimeter for small thicknesses of the attenuator.

Subp. 109. Maximum line current. "Maximum line current" means the root-mean-square current in the supply line of an x-ray system or accelerator operating at its maximum rating.

Subp. 112. Maximum permissible dose or dose equivalent. (See "limits")

Subp. 113. Maximum permissible neutron radiation. "Maximum permissible neutron radiation" means the amount of neutron radiation in rems that is equivalent to the maximum permissible dose. Neutron flux dose equivalents are given in **Table**

-----Member of the public. "Member of the public" means any individual except when that individual is receiving an occupational dose.

-----Minor. "Minor" means an individual less than 18 years of age.

*-----Moving Web. "Moving Web" means a conveyor or other device that is a mechanical feeding system versus a hand fed system.

*-----NVLAP:

Subp. 114. NCRP. "NCRP" means the National Council on Radiation Protection and Measurements. Specific NCRP reports are incorporated by reference in this chapter. The reports may be viewed at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, are available through the Minitex interlibrary loan system, and are not subject to frequent change.

Subp. 115. NARM. "NARM" means a naturally occurring or accelerator produced radioactive material. It does not include by-product, source, or special nuclear material.

Subp. 118. Nonstochastic effect. "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

Subp. 119a. Nuclear logging or logging. "Nuclear logging" or "logging" means testing with a radioactive material performed in a well, boring, or drilled hole for geologic or hydrologic identification, environmental investigation, exploration for minerals, gas, or oil, or other testing purposes.

Subp. 120. Occupational dose. "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 registered, licensed and unlicensed sources of radiation, whether in the possession of the 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 radioactive materials and released in accordance with §35.75 from voluntary participation in medical research programs, or as a member of the public.

Subp. 120a. Open-beam configuration. "Open-beam configuration" means a radiation emitting system in which an individual could accidentally place some part of the body in the primary beam or secondary scattered beam path during operation.

-----Particle accelerator. "Particle accelerator" means a system capable of accelerating electrons, protons, 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 one MeV.

or

*-----Particle accelerator. "Accelerator means a device that accelerates charged subatomic particle or nuclei to energies useful for research and therapy.

Subp. 122. Patient. "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

Subp. 124. Permanent radiographic installation. "Permanent radiographic installation" means a shielded installation or structure that is not moved and is designed or intended for radiography, and in which radiography is regularly performed.

Subp. 125. Person. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, and any legal successor, representative, agent or agency of the foregoing, but not federal government agencies.

Person means: (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing.

OR?

Persons. "Persons" means (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and

section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842); any State or any political subdivision of or any political entity within a State, any foreign government or nation, or any political subdivision of any such government or nation, or other entity; and (2) Any legal successor, representative, agent, or agency of the foregoing.

The Department facilities and activities identified in section 202 are:

(1) Demonstration Liquid Metal Fast Breeder reactors when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(2) Other demonstration nuclear reactors, except those in existence on January 19, 1975, when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(3) Facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from licensed activities.

(4) Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive waste generated by the Department, which are not used for, or are part of, research and development activities.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Subp. 127. Phantom. "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.

Subp. 128a. Physician assistant or registered physician assistant. "Physician assistant" or "registered physician assistant" means a person registered according to Minnesota Statutes, chapter 147A.

Subp. 129. Picocurie. "Picocurie" means a micromicrocurie See units.

or that quantity of radioactive material which decays at the rate of 2.2 disintegrations per minute.

-----Planned special exposure. "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

-----Portal film or portal imaging. "Port film" or "portal imaging" means a diagnostic film or electronic image taken with a therapeutic x-ray system to verify proper setup of the treatment field.

Subp. 132a. Primary beam. "Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the x-ray tube or other radioactive source located in the radiation source housing.

Subp. 133. Primary dose monitoring system. "Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and will terminate irradiation when a preselected number of dose monitor units have been acquired.

Subp. 134. Primary protective barrier. "Primary protective barrier" means the material, excluding filters, placed in the useful beam for protection purposes to reduce the radiation exposure.

-----Product conveyor system. "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Subp. 135. Protective apron. "Protective apron" means an apron made of radiation absorbing materials, used to reduce radiation exposure.

Subp. 136. Protective barrier or barrier. "Protective barrier" or "barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. Types of protective barriers are primary protective barriers and secondary protective barriers.

Subp. 137. Protective glove. "Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure.

*-----Public dose. "Public dose" means

A. the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with ~~ss 35.75~~ or from voluntary participation in medical research programs.

B. x-ray definition?

Subp. 138. Quality assurance program. "Quality assurance program" means the program and procedures contained in parts 4730.1655 to 4730.1695.

Subp. 139. Quality factor. "Quality factor" means a factor used for radiation protection purposes that accounts for differences in biological effectiveness between different radiations. The quality factors are: one for gamma rays, x-rays, beta particles, and electrons; five for thermal neutrons; and 20 for neutrons other than thermal, protons, alpha particles, and multiple-charged particles of unknown energy.

~~of~~

*-----Quality Factor (Q) means the modifying factor (~~listed in tables 1004(b).1 and 1004(b).2 of §20.1004~~) that is used to derive dose equivalent from absorbed dose.

*-----Quarter means a period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks). A quarterly test must be performed approximately 13 weeks apart, four times per year.

Subp. 140. Rad. "Rad" means the special unit of absorbed dose. See units. One rad equals one one-hundredth of a joule per kilogram of any material. One millirad (mrad) equals 0.001 rad. The SI equivalent is the gray.

Subp. 141. Radiation. "Radiation" (ionizing radiation) means alpha particles, beta particles, gamma x-rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions.

Subp. 142. Radiation area. "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Subp. 143. Radiation detector or detector. "Radiation detector" or "detector" means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Subp. 144. Radiation hazard. "Radiation hazard" means a condition under which persons might receive radiation in excess of the maximum permissible dose.

Subp. 147. Radiation protection. "Radiation protection" means the use of shielding, protective clothing, protective equipment, and other means to eliminate or reduce exposure to ionizing radiation.

Subp. 148. Radiation safety. "Radiation safety" means a condition assumed to exist when following a policy of minimization the doses of radiation are eliminated or reduced to the lowest practicable amount and are less than those shown under the definitions of maximum permissible concentrations, maximum permissible doses, and maximum permissible neutron radiation.

* Subp. 149. Radiation safety officer. "Radiation safety officer" means an individual who has the knowledge and training to apply appropriate radiation protection regulations, and who has been designated by the facility in compliance with part

4730.0400 item B.

Subp. 150. Radiation therapy simulation system. "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Subp. 153. Radiograph. "Radiograph" means an image that is created directly or indirectly by radiation resulting in a permanent record or image.

Subp. 154. Radiography. "Radiography" means the process of making an image on a radiosensitive surface, such as a photographic film, by radiation other than visible light, passing through an object or by photographing a fluoroscopic image.

Subp. 156. Rating. "Rating" means the operating limits as

specified by the component manufacturer.

Subp. 157a. Reference man. "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

* Subp. 159. Registrant. "Registrant" means a person having possession of any source of radiation except those specifically exempted under part 4730.0400 or 4730.0700, who has complied with part 4730.0400, item B. rework

Subp. 160. Registration. "Registration" means registration with the commissioner according to parts 4730.0400 to 4730.0700.

* Subp. 161. Rem. "Rem" means a special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem=0.01 sievert)

* equivalence. One millirem (mrem) equals 0.001 rem. The SI equivalent is the sievert. For the purpose of this chapter, any of the following is considered to be equal to one rem:

A. an exposure of one roentgen of x or gamma radiation;

B. an absorbed dose of one rad due to x, gamma, or beta radiation;

C. an absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye; or

D. an absorbed dose of 0.1 rad due to neutrons or high energy protons.

Note: If it is more convenient to measure the neutron flux or equivalent than to determine the neutron absorbed dose in rads, one rem of neutron radiation may, for purposes of this chapter, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body, or, if there exists sufficient information to estimate with reasonable accuracy the

approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the neutron flux dose equivalence table:

Neutron Flux Dose Equivalence

Neutron energy (MeV) Number of neutrons per square centimeter for a dose equivalent of 1 rem (10 millisieverts) Average flux density to deliver 100 millirems (one millisievert) in 40 hours (neutrons/cm² per second)

Thermal	970 x 10 ⁶	670
0.0001	720 x 10 ⁶	500
0.005	820 x 10 ⁶	570
0.02	400 x 10 ⁶	280
0.1	120 x 10 ⁶	80
0.5	43 x 10 ⁶	30
1.0	26 x 10 ⁶	18
2.5	29 x 10 ⁶	20
5.0	26 x 10 ⁶	18
7.5	24 x 10 ⁶	17
10.0	24 x 10 ⁶	17
10 to 30	14 x 10 ⁶	10

Subp. 162. Response time. "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

Subp. 163. Restricted area. "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 radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Subp. 164. Roentgen (R). "Roentgen (R)" means a special unit of exposure equal to 2.58×10^{-4} coulomb per kilogram of air. One milliroentgen (mR) equals 0.001 roentgen.

* Subp. 165. Scan. "Scan" means the complete process of collecting x-ray transmission data for the production of a

tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

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Subp. 168. Scan time. "Scan time" means the time between the beginning and end of x-ray transmission data accumulation for a single scan.

Subp. 169. Scattered radiation. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction and may have also been modified by a decrease in energy.

Subp. 170. Secondary dose monitoring system. "Secondary dose monitoring system" means a system that will terminate irradiation if the primary system fails.

Subp. 171. Secondary protective barrier. "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation to the required degree.

Subp. 172. Secondary radiation. "Secondary radiation" means radiation emitted by an irradiated material such as bone or tissue and all inanimate objects.

Subp. 176. SI equivalent. "SI equivalent" means units that conform to the international system of units.

Subp. 175. Shutter. "Shutter" means a device attached to the tube housing assembly that can totally intercept the useful beam and has a lead equivalency not less than that of the tube housing assembly.

Subp. 177. Sievert (Sv). "Sievert" or "(Sv)" means the unit of dose equivalent that is equal to one joule per kilogram. One rem is equal to 0.01 sievert or ten millisievert (mSv). Submultiples included in this chapter are the millisievert (mSv) and the microsievert (μ Sv).

Subp. 178. Source. "Source" means a discrete amount of radioactive material or the target (focal spot) of the x-ray tube.

Subp. 179. Source of radiation. "Source of radiation"

means a radioactive material, device, or equipment which emits, or is capable of producing, radiation.

Subp. 180. Source-to-image (receptor) distance (SID). "Source-to-image (receptor) distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.

Subp. 181. Source-to-skin distance (SSD). "Source-to-skin distance" or "SSD" means the distance between the source and the skin of the patient.

Subp. 182. Spot check. "Spot check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

Subp. 185. Stationary beam therapy. "Stationary beam therapy" means a method of adjusting collimator blades continuously rather than in fixed increments.

Subp. 189. Stray radiation. "Stray radiation" means the sum of leakage radiation and scattered radiation.

Subp. 190. Survey. "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

* Subp. 190. Survey or radiation safety survey. "Survey" or "radiation safety survey" means an evaluation of the adequacy of

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radiation protection and assessment of the situation incident to the production, use, release, disposal, or presence of sources of ionizing radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present in and around the facility.

Subp. 190. Survey or radiation safety survey. "Survey" or "radiation safety survey" means an evaluation of the adequacy of radiation protection and assessment of the situation incident to the production, use, release, disposal, or presence of sources

of ionizing radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present in and around the facility.

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

Subp. 191. Target. "Target" means the part of a radiation head that by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

Subp. 201. Traceable to a standard. "Traceable to a standard" means a comparison, either directly or indirectly, to a standard maintained by the National Institute of Standards and Technology (NIST) and that all comparisons have been documented.

Subp. 203. Tube rating chart. "Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

Subp. 205. Unit of exposure. "Unit of exposure" means the roentgen in the conventional system of measurement or the coulomb per kilogram in the SI system of measurement.

Subp. 206. Unit of radioactivity. "Unit of radioactivity" means the curie under the conventional system of measurement or the becquerel in the SI system of measurement.

Subp. 207. Units of radiation dose. "Units of radiation dose" means the rad (unit of absorbed dose) and the rem (radiation to body tissues in terms of its estimated biological effect relative to a dose of one rad of x-ray). Under the SI measurement system the equivalent is the gray and the sievert.

Subp. 208. Unrestricted area. "Unrestricted area" means an area, the access to which is neither limited nor controlled by the licensee or registrant for the purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

Subp. 209. Useful beam. "Useful beam" means radiation that passes through the window, aperture, cone, or other collimating device of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

Subp. 210. Variable-aperture beam-limiting device. "Variable-aperture beam-limiting device" means a beam-limiting device that has a capacity for stepless adjustment of the radiation field size at a given SID.

Subp. 210a. Very high radiation area. "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 receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates. (Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

Subp. 212 Visible area.. "Visible area" means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

~~Week means 7 consecutive days starting on Sunday.~~

Subp. 213. Wedge filter. "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

* Subp. 213b. Worker. "Worker" means an individual who engages in activities with sources of ionizing radiation that require registration or license by the commissioner and that are controlled by a registrant or licensee. This does not include ???

*-----Well

*-----X-ray machine operator

**NOTICES, INSTRUCTIONS AND REPORTS
TO RADIOACTIVE MATERIAL WORKERS; INSPECTIONS 4/4/00**

10 CFR 19.:

4730.0900 GENERAL

1 Subpart 1. **Purpose.** The rules in this part establish requirements for notices, instructions, and reports by licensees to individuals participating in licensed activities and options available to these individuals in connection with commissioner inspections of licensees to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, title II of the Energy Reorganization Act of 1974, Minnesota Chapter 4730, and orders, and licenses thereunder regarding radiological working conditions. The rules in this part also establish the rights and responsibilities of the commissioner and individuals during interviews compelled by subpoena as part of agency inspections or investigations pursuant to section 161c of the Atomic Energy Act of 1954, as amended, on any matter within the commissioner's jurisdiction.

2 Subp. 2. **Scope.** The rules in this part apply to all persons who receive, possess, use, or transfer material licensed by the commissioner pursuant to the rules in Chapter 4730, NOT including persons licensed to operate a production or utilization facility pursuant to 10 CFR 50, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to 10 CFR 72, or in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan. The rules regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the commissioner other than those involving commissioner employees or commissioner contractors.

D **4730.0901 DISPLAYING OF NOTICES TO WORKERS.**

11 Subpart 1. **Types.** Each licensee must display current copies of the following documents:

- C
- A. The rules under 4730.0300, 4730.0900
 - B. The license, license conditions, or documents incorporated into a license by reference, and amendments thereto;
 - C. The operating procedures applicable to licensed activities;
 - D. Any notice of violation involving radiological working conditions, proposed imposition of administrative penalty order, or order issued pursuant to 4730.0109 of this chapter, and any response from the licensee.

Subp. 2. **Alternative.** If displaying of a document specified in Subp. 1, paragraph A, B or C is not practicable, the licensee may display a notice which describes the document and states where it may be examined.

Subp. 3. **MDH "Form 3"**. Each licensee and each applicant for a specific license must prominently display MDH "Form 3," "Notice to Employees," dated August 2002. Later versions of MDH "Form 3" that supersede this version must replace the previously displayed version within 30 days of receiving the revised Form 3 from the commissioner.

Subp. 4. **Location**. Documents, notices, or forms displayed pursuant to 4730.0901 must:

A. appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies,

B. be conspicuous, and

C. be replaced if defaced or altered.

Subp. 5. **Timing**. Documents displayed pursuant to 4730.0107 must be displayed within 2 working days after receipt; the licensee's response, if any, must be displayed within 2 working days after dispatch by the licensee. Such documents must remain displayed for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

4730.0902 INSTRUCTION TO WORKERS.

Subpart 1. **Applicability**. In determining those individuals subject to the requirements of this part, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

Subp. 2. **Requirements**. All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) must be:

A. Kept informed of the storage, transfer, or use of radiation and/or radioactive material;

B. Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

C. Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Chapter 4730 and licenses for the protection of personnel from exposure to radiation and/or radioactive material;

D. Instructed of their responsibility to report promptly to the licensee any

condition which may lead to or cause a violation of Chapter 4730 and licenses or unnecessary exposure to radiation and/or radioactive material;

E. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and

F. Advised as to the radiation exposure reports which workers may request pursuant to 4730.0903.

4730.0903 NOTIFICATIONS AND REPORTS TO INDIVIDUALS.

Subpart 1. **Data reports.** Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, must be reported to the individual as specified in this part.

A. The information reported must include data and results obtained pursuant to Chapter 4730, orders or license conditions, as shown in records maintained by the licensee.

B. Each notification and report to the individual must:

(1) be in writing;

(2) include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number;

(3) include the individual's exposure information;

(4) and contain the following statement:

This report is furnished to you under the provisions of the Minnesota Department of Health Radiation Rules Chapter 4730.0903. You should keep this report for further reference.

Subp. 2. **Frequency.** Each licensee must advise each worker quarterly of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of Chapter 4730.0175.

Subp. 3. **Worker request.** At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee must furnish to the worker a report of the worker's exposure to radiation and/or to radioactive material:

A. As shown in records maintained by the licensee pursuant to 4730.0175 for each

year the worker was required to be monitored under the provisions of 4730.0315

B. This report must be furnished within 30 days from the time the request is made or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later.

C. This report must cover the period of time that the worker's activities involved exposure to radiation from radioactive material licensed by the Commissioner and must include the dates and locations of licensed activities in which the worker participated during this period.

Subp. 4. **Individual report.** When a licensee is required pursuant to 4730.0184, 4730.0185, 4730.0186, and 4730.0187 of this chapter to report to the commissioner any exposure of an individual to radiation or radioactive material the licensee must also provide the individual a report on his or her exposure data included therein. This report must be transmitted at a time not later than the transmittal to the commissioner.

Subp 5. **Terminating worker.** At the request of a worker who is terminating employment with the licensee that involved exposure to radiation or radioactive materials, during the current calendar quarter or the current year, each licensee must provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee during the current quarter and year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

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4730.0904 PRESENCE OF REPRESENTATIVES OF LICENSEES AND WORKERS DURING INSPECTIONS.

C

Subpart 1. **Private consultations.** During an inspection, the commissioner may consult privately with workers as specified in 4730.0905. The licensee or licensee's representative may accompany the commissioner during other phases of an inspection.

Subp. 3. **Representation.** If, at the time of inspection, an individual has been authorized by the workers to represent them during commissioner inspections, the licensee must notify the commissioner of such authorization and must give the workers' representative an opportunity to accompany the commissioner during the inspection of physical working conditions.

Subp. 4. **Representative qualifications.** Each workers' representative must be routinely engaged in licensed activities under control of the licensee and must have received instructions as specified in 4730.0902.

Subp. 5. **Interference.** Different representatives of licensees and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a

time may accompany the commissioner.

Subp. 6 **Consultants.** With the approval of the licensee and the workers' representative an individual who is not routinely engaged in licensed activities under control of the license, for example, a consultant to the licensee or to the workers' representative, must be afforded the opportunity to accompany commissioner inspectors during the inspection of physical working conditions.

Subp. 7. **Classified and private data** Notwithstanding the other provisions of this section, commissioner inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area must be an individual previously authorized by the licensee to enter that area.

15

4730.0905 CONSULTATION WITH WORKERS DURING INSPECTIONS.

C

Subpart 1. **Private consultation.** The commissioner may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Chapter 4730 and licenses to the extent the commissioner deems necessary for the conduct of an effective and thorough inspection.

Subp. 2. **Past or present conditions.** During the course of an inspection any worker may bring privately to the attention of the commissioner, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of Chapter 4730, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing must comply with the requirements of 4730.0906. The provisions of this subpart must not be interpreted as authorization to disregard instructions pursuant to 4730.0902.

16

4730.0906 REQUESTS BY WORKERS FOR INSPECTIONS.

C

Subpart 1. **Notice to the commissioner.** Any worker or representative of workers who believes that a violation of Chapter 4730, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the commissioner.

Subp. 2. **Content.** Any such notice must be in writing, must set forth the specific grounds for the notice, and must be signed by the worker or representative of workers.

Subp. 3. **Copies.** A copy must be provided the licensee by the commissioner no later than

at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein must not appear in such copy or on any record published, released or made available by the commissioner, except for good cause shown.

Subp. 4. **Cause for inspection.** If, upon receipt of such notice, the commissioner determines that the complaint meets the requirements set forth in Subpart 1, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, the commissioner must cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this part need not be limited to matters referred to in the complaint.

17

4730.0907 INSPECTIONS NOT WARRANTED; INFORMAL REVIEW PROCEDURE.

C

Subpart 1. **Reasonable grounds.** If the commissioner determines, with respect to a complaint under 4730.0906 that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the commissioner must notify the complainant in writing of such determination.

A. The complainant may obtain review of such determination by submitting a written statement of position to the Commissioner of Health, 121 E. 7th Place, St. Paul, MN 55101, who will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant.

B. The licensee may submit an opposing written statement of position to the commissioner, who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the commissioner or designee may hold an informal conference in which the complainant and the licensee may orally present their views.

C. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant.

Subp. 2. **Inspection not warranted.** If the commissioner determines that an inspection is not warranted because the requirements of 4730.0906 have not been met, the commissioner must notify the complainant in writing of such determination. Such determination must be without prejudice to the filing of a new complaint meeting the requirements of 4730.0906.

18

4730.0908 SEQUESTRATION OF WITNESSES AND EXCLUSION OF COUNSEL IN INTERVIEWS CONDUCTED UNDER SUBPOENA.

D

Subpart 1. **Exception to sequestration.** All witnesses compelled by subpoena to submit to agency interviews must be sequestered unless the official conducting the interviews permits otherwise.

Subp. 2. **Counsel advice.** Any witness compelled by subpoena to appear at an interview during a commissioner inquiry may be accompanied, represented, and advised by counsel of his or her choice. However, when the commissioner conducting the inquiry determines, after consultation with the Office of the Attorney General that the commissioner has concrete evidence that the presence of an attorney representing multiple interests would obstruct and impede the investigation or inspection, the commissioner may prohibit that counsel from being present during the interview.

Subp. 3. **Decision to exclude.** The interviewing official is to provide a witness whose counsel has been excluded under Subpart 2 and the witness's counsel a written statement of the reasons supporting the decision to exclude.

A. This statement, which must be provided no later than five working days after exclusion, must explain the basis for the counsel's exclusion.

B. This statement must also advise the witness of the witness' right to appeal the exclusion decision and obtain an automatic stay of the effectiveness of the subpoena by filing a motion to quash the subpoena with the commissioner within five days of receipt of this written statement.

Subp. 4. **Appeal.** Within five days after receipt of the written notification required in Subpart 3, a witness whose counsel has been excluded may appeal the exclusion decision by filing a motion to quash the subpoena with the commissioner. The filing of the motion to quash will stay the effectiveness of the subpoena pending the commissioner's decision on the motion.

Subp. 5. **How to proceed.** If a witness' counsel is excluded under Subpart 3, the interview may, at the witness' request, either proceed without counsel or be delayed for a reasonable period of time to permit the retention of new counsel. The interview may also be rescheduled to a subsequent date established by the commissioner, although the interview must not be rescheduled to a date that precedes the expiration of the time provided under Subpart 4 for appeal of the exclusion of counsel, unless the witness consents to an earlier date.

**RADIATION SAFETY REQUIREMENTS
FOR NUCLEAR LOGGING 4/4/00**

10 CFR 39.:

4730.1100 PURPOSE AND SCOPE.

1 Subpart 1. **Requirements.** This part prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in nuclear logging in a single well or boring. This part also prescribes radiation safety requirements for persons using licensed materials in these operations. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of 4730.0200, 4730.0300, 4730.0900, and 4730.1500 apply to applicants and licensees subject to this part.

D Subp. 2. **Exceptions.** The requirements set out in this part do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to nuclear logging but not lowered into wells or borings.

39.13

4730.1100.5 SPECIFIC LICENSES FOR NUCLEAR LOGGING.

D/H&S

The commissioner will approve an application for a specific license for the use of licensed material in nuclear logging if the applicant meets the following requirements:

Subpart 1. **Requirements.** The applicant must satisfy the general requirements specified in 4730.0200, as appropriate, and any special requirements contained in this part.

Subp. 2. **Training.** The applicant must develop a program for training logging supervisors and logging assistants and submit to the commissioner a description of this program that specifies the --

A. Initial training;

B. On-the-job training;

C. Annual safety reviews provided by the licensee;

D. Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with Chapter 4730 and licensing requirements and the applicant's operating and emergency procedures; and

E. Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

Subp. 3. **Operating and emergency procedures.** The applicant must submit to the commissioner written operating and emergency procedures as described in 4730.1123 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

Subp. 4. **Performance inspections.** The applicant must establish and submit to the commissioner its program for annual inspections of the job performance of each logging supervisor to ensure that Chapter 4730, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for 3 years after each annual internal inspection.

Subp. 5. **Safety organization.** The applicant must submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in nuclear logging, including specified delegations of authority and responsibility.

Subp. 6. **Leak testing.** If an applicant wants to perform leak testing of sealed sources, the applicant must identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant must establish procedures to be followed and submit a description of these procedures to the commissioner. The description must include the

- A. Instruments to be used;
- B. Methods of performing the analysis; and
- C. Pertinent experience of the person who will analyze the wipe samples.

D
39.15

4730.1100.7 AGREEMENT WITH WELL OR BORING OWNER OR OPERATOR.

Subpart 1. **Written requirements.** A licensee may perform nuclear logging with a sealed source only after the licensee has a written agreement with the employing well or boring owner or operator. This written agreement must identify who will meet the following requirements:

- A. If a sealed source becomes lodged in the well or boring, a reasonable effort will be made to recover it.
- B. A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.
- C. The radiation monitoring required in 4730.1129 A. will be performed.
- D. If the environment, any equipment, or personnel are contaminated with

licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

E. If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

(1) Each irretrievable nuclear logging source must be immobilized and sealed in place with a cement plug.

(2) A mechanical device to prevent inadvertent intrusion on the source must be set at some point in the well or boring above the cement plug, unless the cement plug and source are not accessible to any subsequent drilling operations; and

(3) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well or boring, unless the mounting of the plaque is not practical. The size of the plaque must be at least 7 inches (17 cm) square and 1/8-inch (3 mm) thick. The plaque must contain --

- (a) The word "CAUTION";
- (b) The radiation symbol (the color requirement in 4730.0322 A need not be met);
- (c) The date the source was abandoned;
- (d) The name of the well or boring owner or well or boring operator, as appropriate;
- (e) The well or boring name and well or boring identification number(s) or other designation;
- (f) An identification of the sealed source(s) by radionuclide and quantity;
- (g) The depth of the source and depth to the top of the plug; and
- (h) An appropriate warning, such as, "DO NOT RE-ENTER THIS WELL OR BORING."

Subp. 2. Copy maintenance. The licensee must retain a copy of the written agreement for 3 years after the completion of the nuclear logging operation.

Subp. 3. Case-by-case approval. A licensee may apply, pursuant to 4730.120, for

commissioner approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable nuclear logging source in a manner not otherwise authorized in Subpart 1, E of this part.

Subp. 4. **Agreement not required.** A written agreement between the licensee and the well or boring owner or operator is not required if the licensee and the well or boring owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee must still otherwise meet the requirements in Subpart 1

4730.1101 LABELS, SECURITY, AND TRANSPORTATION PRECAUTIONS.

Subpart 1. **Labels.** The licensee must not:

A. Use a source, source holder, or logging tool that contains licensed material unless the smallest component that is transported as a separate piece of equipment with the licensed material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in 4730.0322, without the conventional color requirements, and the wording "DANGER (or CAUTION) RADIOACTIVE MATERIAL."

B. Use a container to store licensed material unless the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in 4730.0322 of this chapter and the wording "CAUTION (or DANGER), RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

C. Transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 4730.1500.

Subp. 2. **Security precautions during storage and transportation.** The licensee must:

A. Store each source containing licensed material in a storage container or transportation package.

(1) The container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel.

(2) The licensee must store licensed material in a manner which will minimize danger from explosion or fire.

B. Transport the package containing licensed material in a locked and physically secure condition in the transporting vehicle to prevent:

(1) accidental loss,

(2) tampering, or

(3) unauthorized removal of the licensed material from the vehicle.

33

4730.1103 RADIATION DETECTION INSTRUMENTS.

C

Subpart 1. **Instrument capabilities.** The licensee must keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by chapter 4730. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.1 mrem (0.001 mSv) per hour through at least 50 mrem (0.5 mSv) per hour.

D/H&S

Subp. 2. **Instrument sensitivity.** The licensee must have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.

C

Subp. 3. **Calibration specifics.** The licensee must have each radiation survey instrument required under Subpart 1 calibrated:

(1) At intervals not to exceed 6 months and after instrument servicing;

(2) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(3) So that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

D

Subp. 4. **Records and retention.** The licensee must retain records of calibrations required by 4730.1103 for a period of 4 years after the date of calibration for inspection by the commissioner.

35

4730.1105 LEAK TESTING OF SEALED SOURCES.

C

Testing and recordkeeping requirements are those in 4730.0155.

4730.1107 PHYSICAL INVENTORY.

D/H&S

A. Each licensee must conduct a semi-annual physical inventory to account for all licensed material received and possessed under the license.

(1) The licensee must retain records of the inventory for 4 years from the date of

the inventory for inspection by the commissioner.

(2) The inventory must indicate the quantity and kind of licensed material, the location of the licensed material, the date of the inventory, and the name of the individual conducting the inventory.

(3) Physical inventory records may be combined with leak test records.

39
C
4730.1109 RECORDS OF MATERIAL USE.

A. Each licensee must maintain records for each use of licensed material showing:

(1) The make, model number, and a serial number or a description of each sealed source used;

(2) In the case of unsealed licensed material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well or boring and the disposition of any unused tracer materials;

(3) The identity of the logging supervisor who is responsible for the licensed material and the identity of logging assistants present; and

(4) The location and date of use of the licensed material.

B. The licensee must make the records required by A of this part available for inspection by the commissioner. The licensee must retain the records for 4 years from the date of the recorded event.

41
B
4730.1111 DESIGN AND PERFORMANCE CRITERIA FOR SEALED SOURCES.

A. A licensee may not use a sealed source in well logging unless the sealed source:

(1) Is doubly encapsulated;

(2) Contains licensed material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(3) The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(a) Temperature. The test source must be held at -40° C for 20 minutes, 600° C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds.

(b) Impact Test. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.

(c) Vibration test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.

(d) Puncture test. A 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

(e) Pressure test. The test source must be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals).

B. The requirements in A of this section do not apply to sealed sources that contain licensed material in gaseous form.

4730.1113 INSPECTION, MAINTENANCE, AND OPENING OF A SOURCE OR SOURCE HOLDER.

A. Each licensee must visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present.

(1) If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the date of check, name of inspector, equipment involved, defects found, and repairs made.

(2) These records must be retained for 4 years after the defect is found.

B. Each licensee must have a program for semiannual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible.

(1) If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations performed, any defects found, and any actions taken to correct the defects.

(2) These records must be retained for 4 years after the defect is found.

C. Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to 4730.1123 has been approved either by

the commissioner pursuant to chapter 4730 or by an agreement state.

D. If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the commissioner, an agreement state or the U.S. Nuclear Regulatory Commission to perform this operation.

E. The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the commissioner, an agreement state or the U.S. Nuclear Regulatory Commission.

45

4730.1115 SUBSURFACE TRACER STUDIES.

C

A. The licensee must require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment to protect against contamination. The licensee must take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

B. A licensee may not knowingly inject licensed material into fresh water aquifers unless specifically authorized to do so by the commissioner.

47

4730.1117 RADIOACTIVE MARKERS.

D

The licensee may use radioactive markers in wells or borings only if the individual markers contain quantities of licensed material not exceeding the quantities specified in 4730.3003, B of this chapter. The use of markers is subject only to the requirements of 4730.1107.

49

4730.1119 URANIUM SINKER BARS.

C

The licensee may use a uranium sinker bar in nuclear logging only if it is legibly impressed with the words "CAUTION -- RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

51

4730.1121 USE OF A SEALED SOURCE IN A WELL OR BORING WITHOUT A SURFACE CASING.

D

The licensee may use a sealed source in a well or boring without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well or boring. The procedure must be approved by the commissioner in accordance to chapter 4730, by an agreement state or the U.S. Nuclear Regulatory Commission.

SAFETY REQUIREMENTS FOR NUCLEAR LOGGING

61

4730.1121 TRAINING. 0142

B

A. The licensee may not permit an individual to act as a logging supervisor until that person:

- (1) Has completed training in the subjects outlined in E of this section;
- (2) Has received copies of, and instruction in:

(a) The Department of Health regulations contained in the applicable sections of 4730.0200, 4730.0900, and 4730.1100.

(b) The license under which the logging supervisor will perform nuclear logging; and

(c) The licensee's operating and emergency procedures required by 4730.1123.

(3) Has completed on-the-job training and demonstrated competence in the use of licensed materials, remote handling tools, and radiation survey instruments by a field evaluation; and

(4) Has demonstrated understanding of the requirements in A (1) and (2) of this section by successfully completing a written test.

B The licensee may not permit an individual to act as a logging assistant until that person:

(1) Has received instruction in applicable sections of 4730.0300 and 4730.0900;

(2) Has received copies of, and instruction in, the licensee's operating and emergency procedures required by 4730.1123;

(3) Has demonstrated understanding of the materials listed in B (1) and (2) of this section by successfully completing a written or oral test; and

(4) Has received instruction in the use of licensed materials, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

C. The licensee must provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

D. The licensee must maintain a record on each logging supervisor's and logging assistant's training and annual safety review.

(1) The training records must include copies of written tests and dates of oral tests given;

(2) The training records must be retained until 3 years following the termination of employment.

(3) Records of annual safety reviews must list the topics discussed and be retained for 3 years.

E. The licensee must include the following subjects in the training required in A(1) of this section:

(1) Fundamentals of radiation safety including :

(a) Characteristics of radiation;

(b) Units of radiation dose and quantity of radioactivity;

(c) Hazards of exposure to radiation;

(d) Levels of radiation from licensed material;

(e) Methods of controlling radiation dose (time, distance, and shielding);

and

(f) Radiation safety practices, including prevention of contamination, and methods of decontamination.

(2) Radiation detection instruments including:

(a) Use, operation, calibration, and limitations of radiation survey instruments;

(b) Survey techniques; and

(c) Use of personnel monitoring equipment;

(3) Equipment to be used including :

(a) Operation of equipment, including source handling equipment and

remote handling tools;

(b) Storage, control, and disposal of licensed material; and

(c) Maintenance of equipment.

(4) The requirements of pertinent chapter 4730 rules; and

(5) Case histories of accidents in nuclear logging.

4730.1123 OPERATING AND EMERGENCY PROCEDURES.

Each licensee must develop and follow written operating and emergency procedures that cover:

A. The handling and use of licensed materials including the use of sealed sources in wells or borings without surface casing for protecting fresh water aquifers, if appropriate;

B. The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

C. Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 4730.1127, A, 2, 3, 4.

D. Minimizing personnel exposure including exposures from inhalation and ingestion of licensed tracer materials;

E. Methods and occasions for locking and securing stored licensed materials;

F. Personnel monitoring and the use of personnel monitoring equipment;

G. Transportation of licensed materials to field stations or temporary jobsites, packaging of licensed materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;

H. Picking up, receiving, and opening packages containing licensed materials, in accordance with 4730.0327;

I. For the use of tracers, decontamination of the environment, equipment, and personnel;

J. Maintenance of records generated by logging personnel at temporary jobsites;

K. The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by 4730.1113;

L. Identifying and reporting to the U.S. Nuclear Regulatory Commission defects and noncompliance as required by 10 CFR 21;

M. Actions to be taken if a sealed source is lodged in a well or boring;

N. Notifying proper persons in the event of an accident; and

O. Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required by 4730.1103 Subp. 2.

65

4730.1125 PERSONNEL MONITORING.

C

A. The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of licensed radioactive materials, a NVLAP-accredited personnel dosimeter. Each NVLAP-accredited personnel dosimeter must be assigned to and worn by only one individual.

B. Dosimetry must be replaced at the frequency recommended by the processor. After replacement, each NVLAP-accredited personnel dosimeter must be promptly processed.

D

C. The licensee must provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

D. The licensee must retain records of NVLAP-accredited personnel dosimetry and bioassay results for 30 years, or the lifetime of the employee, whichever is shorter.

67

4730.1127 RADIATION SURVEYS.

C

A. The licensee must make radiation surveys, including but not limited to the surveys required under paragraphs (1) through (4) of this section, of each area where licensed materials are used and stored.

(1) Before transporting licensed materials, the licensee must make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the licensed materials.

(2) If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee must confirm that the logging tool is free of

contamination by energizing the logging tool detector or by using a survey meter.

(3) If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee must conduct a radiation survey, including a contamination survey, during and after the operation.

(4) The licensee must make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

B. The results of surveys required under paragraphs (1) through (4) of this section must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey, instrument used, and the location of the survey. The licensee must retain records of surveys for inspection by the Commissioner for 3 years after they are made.

69

4730.1129 RADIOACTIVE CONTAMINATION CONTROL.

C

A. If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee must initiate immediately the emergency procedures required by 4730.1123.

B. If contamination results from the use of licensed material in nuclear logging, the licensee must decontaminate all work areas, equipment, and unrestricted areas.

C. During efforts to recover a sealed source lodged in the well or boring, the licensee must continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well or boring, if any, to check for contamination resulting from damage to the sealed source.

71

4730.1131 SECURITY DURING USE.

C

A. Logging supervisor must be physically present at a temporary jobsite whenever licensed materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well or boring.

B. During nuclear logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor must maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in 4730.0117.

73

4730.1133 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS.

C

Each licensee must maintain the following documents and records at the field station:

- A. A copy of 4730.0300, 4730.0900, 4730.1100;
- B. The license authorizing the use of licensed material;
- C. Operating and emergency procedures required by 4730.1123
- D. The record of radiation survey instrument calibrations required by 4730.1103
- E. The record of leak test results required by 4730.1105
- F. Physical inventory records required by 4730.1107
- G. Utilization records required by 4730.1109
- H. Records of inspection and maintenance required by 4730.1113
- I. Training records required by 4730.1121, D
- J. Survey records required by 4730.1127.

75

4730.1135 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOBSITES.

C

Each licensee conducting operations at a temporary jobsite must maintain the following documents and records at the temporary jobsite until the nuclear logging operation is completed:

- A. Operating and emergency procedures required by 4730.1123
- B. Evidence of latest calibration of the radiation survey instruments in use at the site required by 4730.1121
- C. Latest survey records required by 4730.1127 A, 1, 2, and 4
- D. The shipping papers for the transportation of radioactive materials required by 4730.1500; and
- E. When operating under reciprocity pursuant to 4730.0216 of this chapter, a copy of the agreement state or U.S. Nuclear Regulatory Commission license authorizing use of licensed materials.

77

4730.1137 NOTIFICATION OF INCIDENTS AND LOST SOURCES; ABANDONMENT

PROCEDURES FOR IRRETRIEVABLE SOURCES.

C
A. The licensee must immediately notify the commissioner by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. The letter must designate the well or boring or other location, describe the magnitude and extent of the escape of licensed materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

D
B. The licensee must notify the commissioner of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by 4730.0183, 4730.0184, 4730.0185.

C
C. If a sealed source becomes lodged in a well or boring, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee must:

(1) Notify the commissioner by telephone of the circumstances that resulted in the inability to retrieve the source and obtain approval to implement abandonment procedures; and

(2) Advise the well or boring owner or operator, as appropriate, of the abandonment procedures under 4730.1137.

(3) Either ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request of the commissioner an extension of time if unable to complete the abandonment procedures.

D. The licensee must, within 30 days after a sealed source has been classified as irretrievable, make a report in writing to the commissioner. The licensee must send a copy of the report to each appropriate State or Federal agency that issued permits or otherwise approved of the drilling operation. The report must contain the following information:

(1) Date of occurrence;

(2) A description of the irretrievable nuclear logging source involved including the radionuclide and its quantity, chemical, and physical form;

(3) Surface location and identification of the well or boring;

(4) Results of efforts to immobilize and seal the source in place;

(5) A brief description of the attempted recovery effort;

- (6) Depth of the source;
- (7) Depth of the top of the cement plug;
- (8) Depth of the well or boring;
- (9) Any other information, such as a warning statement, contained on the permanent identification plaque; and
- (10) State and Federal agencies receiving copy of this report.

RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS 4/4/00

10 CFR 36.:

4730.1401 APPLICABILITY

36.1

Subpart 1. **Requirements.** This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of parts 4730.0200, 4730.0300, 4730.0900, 4730.1500 of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

D

Subp. 2. **Applications.** The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

C

Subp. 3. **Exceptions.** The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

36.13

4730.1413 SPECIFIC LICENSES FOR IRRADIATORS.

D/H&S

The commissioner will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(a) The applicant must satisfy the general requirements specified in 4730.0200 of this chapter and the requirements contained in this part.

(b) The application must describe the training provided to irradiator operators including --

- (1) Classroom training;
- (2) On-the-job or simulator training;
- (3) Safety reviews;
- (4) Means employed by the applicant to test each operator's understanding of

chapter 4730 and licensing requirements and the irradiator operating and emergency procedures; and

(5) Minimum training and experience of personnel who may provide training.

(c) The application must include an outline of the written operating and emergency procedures listed in 4730.1453 that describes the radiation safety aspects of the procedures.

(d) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(e) The application must include a description of the access control systems required by 4730.1423, the radiation monitors required by 4730.1429, the method of detecting leaking sources required by 4730.1459 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(f) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant must establish procedures for leak testing and submit a description of these procedures to the commissioner. The description must include the --

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant must describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the commissioner, an agreement state or the U.S. Nuclear Regulatory Commission to load or unload irradiator sources.

(h) The applicant must describe the inspection and maintenance checks, including the frequency of the checks required by 4730.1461.

36.15

4730.1415 START OF CONSTRUCTION.

D

The applicant may not begin construction of a new irradiator prior to the submission to the

commissioner of both an application for a license for the irradiator and the fee required by MN Statute. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of chapter 4730.

36.17

4730.1417 APPLICATIONS FOR EXEMPTIONS.

Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The commissioner will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

21

4730.1421 PERFORMANCE CRITERIA FOR SEALED IRRADIATOR SOURCES.

B

Sealed sources must:

- A. Have a certificate of registration issued under 10 CFR 32.210;
- B. Be doubly encapsulated;
- C. Use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;
- D. Be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
- E. In prototype testing of the sealed source, have been leak tested and found leak-free after each of the tests described in items (1) through (6) of this subpart.
 - (1) Temperature test. The test source must be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.
 - (2) Pressure test. The test source must be twice subjected for at least five minutes to an external pressure (absolute) of two million Newtons per square meter.
 - (3). Impact test. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(4) Vibration test. The test source must be subjected three times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(5) Puncture test. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(6) Bend test. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 Newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

4730.1423 ACCESS CONTROL FOR PANORAMIC IRRADIATORS.

23

Subpart 1. **Entrance.** Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position.

D/H&S

A. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open.

B. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position.

C. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources.

D. The doors and barriers must not prevent any individual in the radiation room from leaving.

Subp. 2. **Entry detection.** In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed.

A. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard.

B. The alarm must also alert at least one other individual who is onsite of the entry.

C. That individual must be trained on how to respond to the alarm and prepared to

promptly render or summon assistance.

Subp. 3. **Monitoring.** A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry.

A. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high.

B. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in Subpart 2.

C. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

Subp. 4. **Alarms.** Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

Subp. 5. **In the room controls.** Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

Subp. 6. **Source activation.** Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

Subp. 7. **Posting.** Each entrance to the radiation room of a panoramic irradiator must be posted as required by 4730.0323. Radiation postings for panoramic irradiators must comply with the posting requirements except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

Subp. 8. **Movable shielding.** If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

4730.1424 ACCESS CONTROL FOR UNDERWATER IRRADIATORS.

Subpart 1. **Posting.** Each entrance to the area within the personnel access barrier of an

underwater irradiator must be posted as required by 4730.0323.

Subp. 2. **Personnel barrier.** Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended.

A. Only operators and facility management may have access to keys to the personnel access barrier.

B. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

25

4730.1425 SHIELDING.

D/H&S

Subpart 1. **Panoramic irradiator.** The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 millirem (0.02 millisievert) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 millirem (0.02 millisievert) per hour must be locked, roped off, or posted.

Subp. 2. **Pool irradiator.** The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 2 millirem (0.02 millisievert) per hour when the sources are in the fully shielded position.

Subp. 3. **Dry-source-storage panoramic irradiator.** The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 2 millirem (0.02 millisievert) per hour and at 5 centimeters from the shield may not exceed 20 millirem (0.2 millisievert) per hour.

27

4730.1427 FIRE PROTECTION FOR PANORAMIC IRRADIATORS.

D/H&S

Subpart 1. **Detectors.** The radiation room at a panoramic irradiator must have heat and smoke detectors.

A. The detectors must activate an audible alarm.

B. The alarm must be capable of alerting a person who is prepared to summon assistance promptly.

C. The sources must automatically become fully shielded if a fire is detected.

Subp. 2. **Fire extinguishing.** The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of

personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

29

4730.1429 RADIATION MONITORS.

D/H&S

Subpart 1. **Radioactivity alarms for irradiators with automatic product conveyor systems.** Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit.

A. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance.

B. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

Subp. 2. **Pool monitor for underwater irradiators.** Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels.

A. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool.

B. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

4730.1431 CONTROL OF PANORAMIC IRRADIATOR SOURCE MOVEMENT.

31

Subpart 1. **Control mechanism.** The mechanism that moves the sources of a panoramic irradiator must require a key to actuate.

D/H&S

A. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position.

B. Only one key may be in use at any time, and only operators or facility management may possess it.

C. The key must be attached to a portable radiation survey meter by a chain or cable.

D. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position.

E. The door to the radiation room must require the same key as the source mechanism.

Subp. 2. **Position indicator.** The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

Subp. 3. **Source control.** The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

Subp. 4. **Marking.** Each control for a panoramic irradiator must be clearly marked as to its function.

33

4730.1433 IRRADIATOR POOLS.

D/H&S

Subpart 1. **Leakage control.** Irradiator pools must:

A. Have a watertight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

B. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

C. In either A or B, the licensee must have a method to safely store the sources during repairs of the pool.

Subp. 2. **Outlet height.** Irradiator pools must have no outlets greater than 0.5 meters below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

Subp. 3. **Pool water replenishment.** A means must be provided to replenish water losses from the pool.

Subp. 4. **Water level indicator.** A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

Subp. 5. **Water purity.** Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

Subp. 6. **Fall prevention barriers.** A physical barrier, such as a railing or cover, must be

used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

Subp. 7. **Dose rates in handling area.** If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools must not exceed 2 millirem (0.02 millisievert) per hour.

35

4730.1435 SOURCE RACK PROTECTION.

D

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

37

4730.1437 POWER FAILURES.

D/H&S

Subpart 1. **Duration.** If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

Subp. 2. **Door lock.** The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

Subp. 3. **Survey meter required.** During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

4730.1439 IRRADIATOR DESIGN REQUIREMENTS.

39

Irradiators whose construction or manufacture began after July 1, 1993, must meet the design requirements of this part.

D/H&S

Subpart 1. **Shielding.** For panoramic irradiators, the licensee must design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of 4730.1425. If the irradiator will use more than five million curies (2×10^{17} becquerels) of activity, the licensee must evaluate the effects of heating of the shielding walls by the irradiator sources.

Subp. 2. **Foundations.** For panoramic irradiators, the licensee must design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

Subp. 3. **Pool integrity.** For pool irradiators, the licensee must design the pool to assure

that:

- A. The pool is leak resistant;
- B. That the pool is strong enough to bear the weight of the pool water and shipping casks;
- C. That a dropped cask would not fall on sealed sources;
- D. That all outlets or pipes meet the requirements of 4730.1433, Subpart 2 and that metal components are metallurgically compatible with other components in the pool.

Subp. 4. **Water handling system.** For pool irradiators, the licensee must verify that the design of the water purification system is adequate to meet the requirements of 4730.1433, Subpart 5. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

Subp. 5. **Radiation monitors.** For all irradiators, the licensee must evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 4730.1429 Subpart 1. The licensee must verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person.

Subp. 6. **Pool radiation monitors.** For pool irradiators, if the licensee uses radiation monitors to detect contamination under 4730.1459, Subpart 2, the licensee must verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

Subp. 7. **Source rack for pool irradiators.** For pool irradiators, the licensee must verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source.

Subp. 8. **Source rack for panoramic irradiators.** For panoramic irradiators, the licensee must:

- A. Determine that source rack drops due to loss of power will not damage the source rack
- B. Determine that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources.
- C. Review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with

minimal risk to personnel.

Subp. 9 Access control for panoramic irradiators. For panoramic irradiators, the licensee must verify from the design and logic diagram that the access control system will meet the requirements of 4730.1423.

Subp. 10 Fire detection for panoramic irradiators. For panoramic irradiators, the licensee must verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage.

Subp. 11 Fire extinguishing. The licensee must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

Subp. 12 Source return for panoramic irradiators. For panoramic irradiators, the licensee must verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

Subp. 13 Panoramic irradiators in seismic areas. For panoramic irradiators to be built in seismic areas, the licensee must design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318 - 89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes.

Subp. 14 Wiring and electrical equipment for panoramic irradiators. For panoramic irradiators, the licensee must verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

41

4730.1441 CONSTRUCTION MONITORING AND ACCEPTANCE TESTING.

The requirements of this section must be met for irradiators whose construction or manufacture began after July 1, 1993. The requirements must be met prior to loading sources.

D/H&S

Subpart 1. Shielding for panoramic irradiators. For panoramic irradiators, the licensee must monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

Subp. 2. Foundations for panoramic irradiators. For panoramic irradiators, the licensee must monitor the construction of the foundations to verify that their construction meets design specifications.

Subp. 3. **Pool integrity for pool irradiators.** For pool irradiators, the licensee must verify that the pool meets design specifications and must test the integrity of the pool. The licensee must verify that outlets and pipes meet the requirements of 4730.1433, Subpart 2.

Subp. 4. **Water handling system for pool irradiators.** For pool irradiators, the licensee must verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

Subp. 5. **Radiation monitors for all irradiators.** For all irradiators, the licensee must verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 4730.1429, Subpart 1.

A. For pool irradiators, the licensee must verify the proper operation of the radiation monitors and the related alarm if used to meet 4730.1459, Subpart 2.

B. For underwater irradiators, the licensee must verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 4730.14.29, Subpart 2.

Subp. 6. Source rack testing.

A. For all irradiators with product conveyor systems, the licensee must observe and test the operation of the conveyor system to assure that the requirements in 4730.1435 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers

B. For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power.

Subp. 7. **Access control for panoramic irradiators.** For panoramic irradiators, the licensee must test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

Subp. 8. **Fire protection for panoramic irradiators.** For panoramic irradiators, the licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing system.

Subp. 9. **Source return for panoramic irradiators.** For panoramic irradiators, the licensee must demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

Subp. 10. **Access control computer systems for panoramic irradiators.** For panoramic irradiators that use a computer system to control the access control system, the licensee must:

A. verify that the access control system will operate properly if offsite power is lost and

B. verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

Subp. 11. **Wiring for panoramic irradiators.** For panoramic irradiators, the licensee must verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

[Move up to 01xx]

0143

4730.1451 TRAINING FOR IRRADIATOR OPERATORS.

51

D/H&S

Subpart 1. **Fundamentals.** Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

A. basics

(1) the differences between external radiation and radioactive contamination;

(2) units of radiation dose;

(3) chapter 4730 dose limits;

(4) risks of large radiation doses;

(5) how shielding and access controls prevent large doses;

(6) how an irradiator is designed to prevent contamination;

(7) the proper uses of survey meters and personnel dosimeters;

(8) other radiation safety features of an irradiator; and

(9) the basic function of the irradiator;

B. the requirements of 4730.0900 and 4730.1400 that are relevant to the licensee's irradiator;

C. the operation of the licensee's irradiator;

D. those operating and emergency procedures listed in 4730.1453 that the individual is responsible for performing; and

E. case histories of accidents or problems involving irradiators.

Subp. 2. Test. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

Subp. 3. Hands on training. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must:

A. have received on-the-job training or simulator training in the use of the irradiator as described in the license application, and

B. also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

Subp. 4 Safety reviews. The licensee must conduct safety reviews for irradiator operators at least annually. The licensee must give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

A. Changes in operating and emergency procedures since the last review;

B. Changes in regulations and license conditions since the last review;

C. Reports on recent accidents, mistakes, or problems that have occurred at irradiators;

D. Relevant results of inspections of operator safety performance;

E. Relevant results of the facility's inspection and maintenance checks; and

F. A drill to practice an emergency or abnormal event procedure.

Subp. 5. Safety performance. The licensee must:

A. evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are

followed, and

B. discuss the results of the evaluation with the operator and must instruct the operator on how to correct any mistakes or deficiencies observed.

Subp. 6. **Unescorted access.** Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, must be instructed and tested (written or oral):

A. in any precautions they should take to avoid radiation exposure,

B. any procedures or parts of procedures listed in 4730.1453 that they are expected to perform or comply with, and

C. their proper response to alarms required in this part.

Subp. 7. **Alarm response.** Individuals who must be prepared to respond to alarms required by 4730.1423, Subparts 2 and 9; 4730.1427, Subpart 1; 4730.1429, Subpart 1; 4730.1429, Subpart 2; and 4730.1459, Subpart 2 must be trained and tested (written or oral) on how to respond. Each individual must be retested at least once a year.

53

4730.1453 OPERATING AND EMERGENCY PROCEDURES.

D/H&S

Subp. 1. **Operating requirements.** The licensee must have and follow written operating procedures for:

A. Operation of the irradiator, including entering and leaving the radiation room;

B. Use of personnel dosimeters;

C. Surveying the shielding of panoramic irradiators;

D. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

E. Leak testing of sources;

F. Inspection and maintenance checks required by 4730.1461;

G. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

H. Inspection of movable shielding required by 4730.1423, Subpart 8, if applicable.

Subp. 2. **Emergency requirements.** The licensee must have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

- A. Sources stuck in the unshielded position;
- B. Personnel overexposures;
- C. A radiation alarm from the product exit portal monitor or pool monitor;
- D. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
- E. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
- F. A prolonged loss of electrical power;
- G. A fire alarm or explosion in the radiation room;
- H. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
- I. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
- J. The jamming of automatic conveyor systems.

Subp. 3. **Revision.** The licensee may revise operating and emergency procedures without commissioner approval only if all of the following conditions are met:

- A. The revisions do not reduce the safety of the facility,
- B. The revisions are consistent with the outline or summary of procedures submitted with the license application,
- C. The revisions have been reviewed and approved by the radiation safety officer, and
- D. The users or operators are instructed and tested on the revised procedures before they are put into use.

4730.1455 PERSONNEL MONITORING.

D

Subpart 1. **Operator.** Each irradiator operator must wear a dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator.

A. The dosimeter processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges (see 4730.314, C, 1&2).

B. Each dosimeter must be assigned to and worn by only one individual.

Subp. 2. **Others.** Other individuals (non-operators) who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter.

A. For groups of visitors, at least one of every 10 people who enter the radiation room are required to wear dosimeters.

B. If pocket dosimeters are used to meet the requirements of item A, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

4730.1457 RADIATION AND RADIOACTIVITY SURVEYS.

D/H&S

Subpart 1. **Panoramic irradiator.** The following surveys must be conducted:

A. a radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate.

B. radiation surveys of the shielding at intervals not to exceed three years.

C. radiation surveys before resuming operation after addition of new sources

D. radiation surveys after any modification to the radiation room shielding or structure that might increase dose rates.

Subpart 2. **Pool irradiator.** The following surveys must be conducted:

A. A radiation survey of the area above the pool of pool irradiators after the sources are loaded but before the facility starts to operate.

B. Radiation surveys of the shielding at intervals not to exceed three years.

C. Radiation surveys before resuming operation after addition of new sources

D. Radiation surveys after any modification to the radiation room shielding or structure that might increase dose rates.

E. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 4730.3001.
B.

F. Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.05 millirem (0.5 microsievert) per hour. The resins may be released only if the monitoring does not detect radiation levels above background radiation levels. The meter used must be capable of detecting radiation levels of 0.05 millirem (0.5 microsievert) per hour.

Subp. 3. **Excessive radiation levels.** If the radiation levels specified in 4730.1425 are exceeded, the facility must be modified to comply with the requirements in 4730.1425.

Subp. 4. **Radiation meters.** Portable radiation survey meters must be calibrated at least annually to an accuracy of +/-20 percent for the gamma energy of the sources in use.

A. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used.

B. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

59

4730.1459 DETECTION OF LEAKING SOURCES.

D/H&S

Subpart 1. **Dry source tests.** Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the commissioner, an agreement state or the U.S. Nuclear Regulatory Commission.

A. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested.

B. The test must be capable of detecting the presence of 0.005 microcurie (200 becquerels) of radioactive material and must be performed by a person approved by the commissioner, an agreement State or the U.S. Nuclear Regulatory Commission license to perform the test.

Subp. 2. **Pool tests.** For pool irradiators, sources may not be put into the pool unless the

licensee tests the sources for leaks or has a certificate from a transferor that leak tests have been done within the six months before the transfer.

A. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm.

B. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

C. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using:

(1) a radiation monitor on a pool-water circulating system or

(2) analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours.

Subp. 3. Source removal. If a leaking source is detected:

A. the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a commissioner, agreement state or U.S. Nuclear Regulatory Commission licensee that is authorized to perform these functions.

B. The licensee must promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination.

C. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been contaminated, the licensee must arrange to locate and survey that product for contamination.

D. If any personnel are found to be contaminated, decontamination must be performed promptly.

E. If contaminated equipment, facilities, or products are found, the licensee must arrange to have them decontaminated or disposed of by a commissioner, agreement state or U.S. Nuclear Regulatory Commission licensee that is authorized to perform these functions.

F. If a pool is contaminated, the licensee must arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, appendix B to 4730.3001.

G. For reporting requirements see 4730.0184.

61

4730.1461 INSPECTION AND MAINTENANCE.

D/H&S

Subpart 1. **Inspection and maintenance.** The licensee must perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

A. Operability of each aspect of the access control system required by 4730.1423.

B. Functioning of the source position indicator required by 4730.1431, Subp. 2.

C. Operability of the radiation monitor for radioactive contamination in pool water required by 4730.1459, Subp. 2, Item A., using a radiation check source, if applicable.

D. Operability of the over-pool radiation monitor at underwater irradiators as required by 4730.1429, Subp. 2

E. Operability of the product exit monitor required by 4730.1429, Subp. 1

F. Operability of the emergency source return control required by 4730.1431, Subp. 4

G. Leak-tightness of systems through which pool water circulates visual inspection.

H. Operability of the heat and smoke detectors and extinguisher system required by 4730.1427 (but without turning extinguishers on).

I. Operability of the means of pool water replenishment required by 4730.1433, Subp. 3

J. Operability of the indicators of high and low pool water levels required by 4730.1433, Subp. 4

K. Operability of the intrusion alarm required by 4730.1423, Subp. 9, if applicable.

L. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

M. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 4730.1435.

N. Amount of water added to the pool to determine if the pool is leaking.

O. Electrical wiring on required safety systems for radiation damage.

P. Pool water conductivity measurements and analysis as required by 4730.1463, subpart 2.

Subp. 2. **Malfunctions and findings.** Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

63

4730.1463 POOL WATER PURITY.

D/H&S

Subpart 1. **Purification system.** Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee must take prompt actions to lower the pool water conductivity and must take corrective actions to prevent future recurrences.

Subp. 2. **Frequency.** The licensee must measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter.

Subp. 3. **Calibration.** Conductivity meters must be calibrated at least annually.

65

4730.1465 ATTENDANCE DURING OPERATION.

D/H&S

Subpart 1. **Scheduling.** Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, must be present onsite:

A. Whenever the irradiator is operated using an automatic product conveyor system; and

B. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

Subp. 2. **Static panoramic irradiations.** At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in 4730.1451, Subp. 11 must be onsite.

Subp. 3. **Moved underwater product.** At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool.

A. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 4730.1451, Subp. 10 and 11.

B. Static irradiations may be performed without a person present at the facility.

67

4730.1467 ENTERING AND LEAVING THE PANORAMIC RADIATION ROOM.

D/H&S

Subpart 1. **Survey meter.** Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator must use a survey meter to determine that the source has returned to its fully shielded position. The operator must check the functioning of the survey meter with a radiation check source prior to entry.

Subp. 2. **Controls.** Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator must:

A. Visually inspect the entire radiation room to verify that no one else is in it; and

B. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

4730.1468 ENTERING AND LEAVING THE POOL AREA OF AN UNDERWATER IRRADIATOR

During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 4730.1429, Subp. 2 is operating with backup power.

69

4730.1469 IRRADIATION OF EXPLOSIVE OR FLAMMABLE MATERIALS.

D/H&S

Subpart 1. **Authorization.** Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the commissioner. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

Subp. 2. **Small quantities in panoramic irradiators.** Irradiation of more than small quantities of flammable material (flash point below 140° F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the commissioner. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

4730.1471 RECORDS AND RETENTION PERIODS.

D

The licensee must maintain the following records at the irradiator for the periods specified:

A. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the commissioner terminates the license for documents not superseded.

B. Records of each individual's training, tests, and safety reviews provided to meet the requirements of 4730.1451, subparts 1 to 4, until 3 years after the individual terminates work.

C. Records of the annual evaluations of the safety performance of irradiator operators required by 4730.1451 subpart 5 for 3 years after the evaluation.

D. A copy of the current operating and emergency procedures required by 4730.1453 until superseded or the commissioner terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 4730.1453 subpart 3, item C retained for 3 years from the date of the change.

E. NVLAP-accredited personnel dosimeter results required by 4730.1455 until the commissioner terminates the license.

F. Records of radiation surveys required by 4730.1457 for 3 years from the date of the survey.

G. Records of radiation survey meter calibrations required by 4730.1457 and pool water conductivity meter calibrations required by 4730.1463 subpart 2 until 3 years from the date of calibration.

H. Records of the results of leak tests required by 4730.1459 subpart 1 and the results of contamination checks required by 4730.1459 subpart 2 for 3 years from the date of each test.

I. Records of inspection and maintenance checks required by 4730.1461 for 3 years.

J. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

K. Records of the receipt, transfer and disposal, of all licensed sealed sources as required by 4730.0170 and 4730.0215.

L. Records on the design checks required by 4730.1439 and the construction control

checks as required by 4730.1441 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

M. Records related to decommissioning of the irradiator as required by 4730.0209, F.

36.83

4730.1473 REPORTS.

C

Subpart 1. **Reportable events.** In addition to the reporting requirements in other parts of chapter 4730, the licensee must report the following events if not reported under other parts of chapter 4730:

- (1) Source stuck in an unshielded position.
- (2) Any fire or explosion in a radiation room.
- (3) Damage to the source racks.
- (4) Failure of the cable or drive mechanism used to move the source racks.
- (5) Inoperability of the access control system.
- (6) Detection of radiation source by the product exit monitor.
- (7) Detection of radioactive contamination attributable to licensed radioactive material.
- (8) Structural damage to the pool liner or walls.
- (9) Abnormal water loss or leakage from the source storage pool.
- (10) Pool water conductivity exceeding 100 microsiemens per centimeter.

Subp. 2. **Requirements.** The report must include a telephone report within 24 hours as described in 4730.0184 H 1, and a written report within 30 days as described in 4730.0184 H 2.