RULE
CHAPTER 4731

GENERAL PROVISIONS 6/13/02

4731.0100 Definitions 7/1/02

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

Subp. 1. **A_1.** "A_1" means the maximum activity of special form radioactive material permitted in a Type A package. These values are either listed in 4731.3002, Appendix A of this rule, Table A - 1, or may be derived in accordance with the procedure prescribed in Appendix A of this rule.

Subp: 2. **A_2.** "A_2" 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 4731.3002, Appendix A of this rule, Table A - 1, or may be derived in accordance with the procedure prescribed in Appendix A of this rule.

Subp. 3. **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 an accelerator or cyclotron 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 useful for research, therapy, medical and industrial applications.

Subp. 5. **Accelerator-produced material.** "Accelerator-produced material" means material made radioactive by an accelerator or cyclotron.

Subp. 6. **Accident.** "Accident" means something that occurs unexpectedly or unintentionally.

Subp. 7. **Activity.** "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and becquerel (Bq).

Subp. 8. **Added filtration.** "Added filtration" means filtration that is in addition to the inherent filtration.

Subp. 9. **Adult.** "Adult" means an individual 18 or more years of age.

Subp. 10. **Agreement State.** "Agreement State" means any state with which the Nuclear Regulatory Commission or the Atomic Energy Commission has entered into an effective agreement under sub section 274b of the Atomic Energy Act of 1954, as amended. Non-agreement state means any other state.

Subp. 11. **Air-purifying respirator.** "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element

Subp. 12. **Airborne radioactive material.** "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Subp. 13. **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.

A. In excess of the derived air concentrations (DACs) specified in 4731.3001 B.

B. 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.

Subp. 14. **As low as reasonably achievable (ALARA).** "As low as reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Subp. 15. **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.

Subp. 16. **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. 17. **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 and thickness measurement gauges.

Subp. 18. **Annually**. "Annually" means once per year, at about the same time each year (plus or minus 1 month).

Subp. 19. **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. 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. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Column 1 of 4731.3001 B.)

Subp. 20. **Annual refresher safety training.** "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography or well logging using radioactive materials. For review information see 4731.0151, subpart 2 and 4731.0152, subpart 4.

Subp. 21. **Applicator.** "Applicator" means an added device that determines the extent of the treatment field at a given distance from the virtual source.

Subp. 22. **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.

Subp. 23. **Area of use.** "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

Subp. 24. **Assembler.** "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into a radiation producing system or subsystem. Assembler includes the owner of the system or the owner's employee or agent who assembles components into the system that is subsequently used to provide professional or commercial services.

Subp. 25. **Assigned protection factor (APF).** "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.

Subp. 26. **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 sealed 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.

Subp. 27. **Atmosphere-supplying respirator.** "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.

Subp. 28. **Attenuation.** "Attenuation" means the reduction of exposure rate upon passage of radiation through matter.

Subp. 29. **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. 30. **Authorized medical physicist.** "Authorized medical physicist" means a individual who:

A. meets the requirements in 4731.0152, subp. 1, D and subp. 7, A; or

B. is identified as an authorized medical physicist or teletherapy physicist on:

(1) a specific medical use license issued by the Commission or Agreement State;

(2) a medical use permit issued by the Commission master material licensee;

(3) a permit issued by the Commission or Agreement State broad scope medical use licensee; or

(4) a permit issued by the Commission master material license broad scope medical use permited.

Subp. 31. **Authorized nuclear pharmacist.** "Authorized nuclear pharmacist" means a pharmacist who:

A. meets the requirement in 4731.0152 subp. 1, D and subp. 7 B; or

B. is identified as an authorized nuclear pharmacist on:

(1) a specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(2) a permit issued by the Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(3) a permit issued by the Commission or Agreement State broad scope medical use licensee that authorizes medial use or the practice of nuclear pharmacy; or

(4) a permit issued by the Commission master material license broad scope medical use permited that authorizes medical use or the practice of nuclear pharmacy; or

C. is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacist; or

D. is designated as an authorized nuclear pharmacist in accordance with 4731.0311, subp. 9, item B (4).

Subp. 32. **Authorized user.** "Authorized user" means a licensed practitioner of the healing arts (definition in subp. 189) who:

A. meets the requirements in 4731.0152, subp.1,D and 4731.1200-4731.1299; or

B. is identified as an authorized user on:

(1) a Commission or Agreement State license that authorizes the medical use of radioactive material;

(2) a permit issued by a Commission master material licensee that is authorized to permit the medical use of radioactive material;

(3) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(4) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

Subp. 33. **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, radioactive, or special nuclear materials regulated by the commissioner.

Subp. 34. **Beam axis.** "Beam axis" means a line from the source through the centers of the radiation fields.

Subp. 35. **Beam-limiting device (BLD).** "Beam-limiting device" or "(BLD)" means a device used to restrict the dimensions of the radiation field.

Subp. 36. **Beam monitoring system.** "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

Subp. 37. **Beam scattering filter.** "Beam scattering filter" means a filter or foil used to scatter a beam of electrons.

Subp. 38. **Becquerel (Bq).** " Becquerel" or "(Bq)". One becquerel is equal to one disintegration per second. One curie is equal to 3.7×10^{10} becquerels. The conventional system equivalent is the curie.

Subp. 39. **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.40. **Boring** "Boring" has the meaning given in Minnesota Statutes, section 103I.005, subdivision 2.

Subp. 41. **Brachytherapy.** "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Subp 42. **Brachytherapy source**. "Brachytherapy source" means a radioactive sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Subp. 43. **Broad scope license.** "Broad scope license" is one kind of a specific license that permits the licensee to use radionuclides, in any chemical or physical form as long as the amount

does not exceed the quantity indicated in the broad scope license.

Subp. 44. **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. 45. **Byproduct material.** "Byproduct material" means:

A. 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; or

B. 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 solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within the definition.

Subp. 46. **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. 47. **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:

(1) all x-ray systems designed for the industrial uses; and

(2) 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. 48. **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.

D. a series of tests that are performed to substantiate that manufacturer's specifications for the equipment are being maintained by the registrant.

Subp. 49. **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.

Subp. 50. **Cephalometric device.** "Cephalometric device" means a device intended for the

radiographic visualization and measurement of the dimensions of the human head.

Subp. 51. **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. 52. **Certified system**. "Certified system" means an x-ray system that has one or more certified components.

Subp. 53. **Certifying entity**. "Certifying entity" means an independent certifying organization meeting the requirements in 4731.3001 E or an agreement state meeting the requirements in 4731.3001 E, subp II and III for the certifying of industrial radiographers.

Subp. 54. **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. 55. **Chelating agent**. "Chelating agent" means amine polycarboxylic acids (EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g. citric acid, carbolic acid, and glucinic acid.)

Subp. 56. **Class.** "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.

Subp. 57. **Client's address.** "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with 4731.1206, subp. 3.

Subp. 58. **Clinical Range**. "Clinical range" means the range of control console technique settings that a facility would use in its routine x-ray projections. Equipment performance tests are performed over the clinical ranges.

Subp. 59. **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. 60. **Cold flow**. "Cold flow" means the viscous flow of a 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. 61. **Collimation.** "Collimation" means the restriction of the useful beam to an appropriate area.

Subp. 62. **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

2. 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.

Subp. 63. **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. 64. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 65. **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.

Subp. 66. **Committed effective dose equivalent ($H_{E,50}$).** "Committed effective dose equivalent ($H_{E,50}$)" is the sum of the products of the weighting factors (W_t) applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues.
$H_{E,50} = \Sigma W_T H_{T,50}$

Subp. 67. **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:

A. changes desirable for the temporary use of the land for public recreational uses,

B. 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.

Subp. 68. **Computed tomography.** "Computed tomography"or "(CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Subp. 69. **Constraint (dose constraint).** "Constraint (dose constraint)" means a value above which specified licensee or registrant actions are required.

Subp. 70. **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.

Subp. 71. **Control drive mechanism.** "Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.

Subp. 72. **Control panel**. "Control panel" means the part of the control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Subp. 73. **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.

Subp. 74. **Controlled area.** "Controlled area" means an area,

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

B. 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. 75. **Coulomb per kilogram (C/kg)**. "Coulomb per kilogram" or "(C/kg)" means the unit of exposure and dose. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram..

Subp. 76. **Critical group**. "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Subp. 77. **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 technique factors found in **subp. 357 B**.

Subp. 78. **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:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

Where:
z= position along a line perpendicular to the tomographic plane;
D(z) = dose at position z;
T = nominal tomographic section thickness; 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 multiple tomogram system, the increment of adjacent scans is nT.

Subp. 79. **CT gantry**. "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and supporting structures and frames that hold these components.

Subp. 80. **CT number**. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

Subp. 81. **Curie (Ci).** "Curie (Ci)" One curie (Ci) is the quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations per second (dps). The SI equivalent is the becquerel.

Subp. 82. **Cyclotron.** See Accelerator, subp. 4.

Subp. 83. **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. 84. **Declared pregnant woman.** "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Subp. 85. **Decommission.** "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

A. release of the property for unrestricted use and termination of the license or registration; or

B. release of the property under restricted conditions and termination of the license or registration.

Subp. 86. **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.

Subp. 87. **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/cm2).

Subp. 88. **Demand respirator.** "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Subp. 89. **Densitometer.** "Densitometer" means an instrument that measures the optical density of a film by measuring the amount of light transmitted through the film.

Subp. 90. **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.

Subp. 91. **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 4731.3001 B.

Subp. 92. **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 radionuclilde) and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Subp. 93. **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 or registrant performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the registrant or authorized user and includes the radiopharmaceutical, dosage, and route of administration or area of interest.

Subp. 94. **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. 95. **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. 96. **Diagnostic source assembly.** "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

Subp. 97. **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. 98. **Disposal.** "Disposal' means the isolation of radioactive wastes from the accessible environment.

Subp. 99. **Disposable respirator.** "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).

Subp. 100. **Distinguishable from background**. "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.

Subp. 101. **Distribution.** "Distribution" means the act of distributing or the condition of being distributed.

Subp. 102. **Distributor.** "Distributor" means one who distributes, markets or sells merchandise, which includes a radiation source or radiation producing equipment, esp. a wholesaler.

Subp. 103. **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).

Subp. 104. **Dose limits (limits).** "Dose limits (limits)" mean the permissible upper bounds of radiation doses.

Subp. 105. **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. 106. **Dose monitor unit.** "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose has been calculated.

Subp. 107. **Dose profile.** "Dose profile" means the dose as a function of position along a particular plane.

Subp. 108. **Doubly encapsulated sealed source**. "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.

Subp. 109. **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. ($H_E = \Sigma\, w_T\, H_T$).

Subp. 110. **Effective kilogram**. "Effective kilogram" means :

A. 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

B. for any other source material: 20,000 kilograms.

Subp. 111. **Electron Volt (eV).** "Electron volt (eV)" means a unit of energy equivalent to the energy gained by an electron in passing through a potential difference of one volt. Larger multiple units of the electron volt are frequently used.

Subp. 112. **Elemental area.** "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

Subp. 113. **Embryo/fetus.** "Embryo/fetus" means the developing human organism from conception until the time of birth.

Subp. 114. **Emergency.** "Emergency" means an unexpected situation or sudden occurrence of a serious and urgent nature that demands immediate action.

Subp. 115. **Energy compensation source (ECS).** "Energy compensation source (ECS)" means a small sealed source, with an activity not exceeding 100 microcuries (3.7MBq),used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

Subp. 116. **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. 117. **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. 118. **Equipment performance tests.** "Equipment performance tests" means a series of specified tests that are performed following the minimum performance criteria as found in 4731.1300 - 4731.1321 to substantiate that the imaging systems are functioning as effectively as possible.

Subp. 119. **"Entrance skin exposure (ESE).** "Entrance skin exposure" or "(ESE)" means the entrance skin exposure that is measured free in air.

Subp. 120. **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 included them with the shipping paper information provided to the carrier by the consignor.

Subp. 121. **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. 122. **Exposure head**. "Exposure head" or "source stop" means a device that locates the gamma radiography sealed source in the selected working position.

Subp. 123. **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.

Subp. 124. **External dose.** "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

Subp. 125. **Extremity.** "Extremity" means hand, elbow, arm below the elbow, foot, knee or leg below the knee.

Subp. 126. **Eye Dose Equivalent.** See "Lens dose equivalent (LDE)" **Subp. 186**

Subp. 127. **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. 128. **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. 129. **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. 130. **Field station.** "Field station" means a facility where licensed or registered material may be stored or used and from which equipment is dispatched.

Subp. 131. **Filter or filtration.** "Filter" or "filtration" means material placed in the useful beam to absorb preferentially selected radiations.

Subp. 132. **Filtering facepiece (dusk mask)**. "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. 133. **Fishpole radiography**. "Fishpole radiography" means industrial radiography performed with sealed source that is not fastened to or contained in a radiographic exposure device.

Subp. 134. **Fissile material**. "Fissile material" means plutonium-238, plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Unirradiatied 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 4731.1501 - 4731.1518.

Subp. 135. **Fit factor**. "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 it concentration inside the respirator when worn.

Subp. 136. **Fit test.** "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Subp. 137. **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. 138. **Focal spot**. "Focal spot" means the area of the anode from which x-rays originate.

Subp. 139. **Fresh water aquifer**. "Fresh water aquifer," for the purpose of this chapter, means a geologic formation that is capable of yielding fresh water to a well or spring.

Subp. 140. **Gantry.** "Gantry" means the part of the system supporting and allowing possible movements of the radiation head.

Subp. 141. **General license**. "General license" means a license that permits the licensee to obtain and use source material such as uranium in less than stipulated quantities or to obtain other radionuclides in quantities no greater than the amount permitted in the license for commercial, industrial or research purposes, but not for external or internal exposure to human beings.

Subp. 142. **Geologic repository**. "Geologic Repository" means a system which is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes:

A. the geologic repository operations area, and

B. the portion of the geologic setting that provides isolation of the radioactive waste.

Subp. 143. **Gonad shield.** "Gonad shield" means a protective barrier for the testes or ovaries.

Subp. 144. **Gray (Gy).** . The "gray" is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram. It is also equal to 100 rads.

Subp. 145. **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.

Subp. 146. **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. 147. **Hands-on experience**. "Hands-on experience" means experience in all of those areas considered to be directly involved in the industrial radiography process.

Subp. 148. **Hazardous waste.** "Hazardous waste" means those wastes designated as hazardous by Environmental Protection Agency regulations in 40 Code of Federal Regulations part 261.

Subp. 149. **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. 150. **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. 151. **Helmet.** "Helmet" means a rigid respiratory inlet covering that also provided head protection against impact and penetration.

Subp. 152. **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. 153. **High dose-rate remote afterloader**. "High dose-rate remote afterloader" means a device that remotely delivers a dose rate in excess of 1200 Rads (12 gray) per hour at the point or surface where the dose is prescribed.

Subp. 154. **Hood.** "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Subp. 155. **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. 156. **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. 157. **Incident**. "Incident" means an occurrence or event that interrupts normal procedure or precipitates a crisis.

Subp. 158. **Independent certifying organization.** "Independent certifying organization" see certifying entity **subp. 53.**

Subp. 159. **Individual.** "Individual" means any human being.

Subp. 160. **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, **subp. 39)** or by determination of the time-weighted air concentrations to which an individual has been exposed. i.e., derived air concentration-hours (DAC-hours); or

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

Subp. 161. **Individual monitoring devices.** "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as a film badges, thermoluminescence dosimeters (TLD), pocket ionization chambers or personal ("lapel") air sampling devices. Monitoring devices must be approved by the National Voluntary Laboratory Accreditation Program (NVLAP), when appropriate. (See "NVLAP" **subp. 224.)**

Subp. 162. **Industrial radiographer.** "Industrial radiographer" means any individual who performs or who, in attendance at the site where radiation exposure devices, 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 commissioner's regulations, and the conditions of the license or registration.

Subp. 163. **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 instruments in industrial radiography.

Subp. 164. **Industrial radiographer's certification**. "Industrial radiographer's certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

Subp. 165. **Industrial radiography.** "Industrial radiography" means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

Subp. 166. **Inhalation class**. See Class **subp. 56.**

Subp. 167. **Inherent filtration**. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Subp. 168. **Injection tool.** "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

Subp. 169. **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. 170. **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. 171. **Internal dose**. "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

Subp. 172. **Ionizing radiation.** "Ionizing radiation" means radiation capable of producing ionization including energetic charged particles such as alpha and beta particles, nonpraticulate radiation such as x-rays , and neutrons.

Subp. 173. **Irradiation.** "Irradiation" means the exposure of matter to ionizing radiation.

Subp. 174. **Irradiator.** "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 500 rads (5 grays) 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.

Subp. 175. **Irradiator operator**. "Irradiator operator" means an individual who has successfully completed the training and testing described in 4731.0152, subpart 3 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Subp. 176. **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 or boring and for which all reasonable effort at recovery has been expended.

Subp. 177. **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. 178. **Iso-line.** "Iso-line" means a line, usually irregular, along which the exposure rates are the same at any point.

Subp. 179. **Kilo electron volts (KeV).** " Kilo electron volts (KeV)" is a thousand volts.

Subp. 180. **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. 181. **Kilowatt second (kWs).** "Kilowatt second" or "(kWs)" means the equivalent of 10^3 kV x mA x s.

Subp. 182. **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. A "geologic repository" **subp 142** is not considered a "land disposal facility."

Subp. 183. **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. 184. **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 shield or tube housing as well as the scattered radiation produced within the housing.

Subp.185. **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.

Subp. 186. **Lens 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/cm^2).

Subp. 187. **License.** "License" means a license issued under the regulations in **4731.0300 - 4731.0317.**

Subp. 188. **Licensed material.** "Licensed material" means source material, special nuclear material, or radioactive material received, possessed, used, transferred or disposed of under a general or specific licensed issued by the commissioner.

Subp. 189. **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. 190. **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.

Subp. 191. **Limits (dose limits).** See Dose limits, **subp.104.**

Subp. 192. **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:

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. 193. **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. 194. **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 **4731.0807.**

Subp. 195. **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 Chapter 4731 and the conditions of the license.

Subp. 196. **Logging tool.** "Logging tool" means a device used subsurface to perform well logging.

Subp. 197. **Loose-fitting facepiece.** "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

Subp. 198. **Lost or missing licensed material.** "Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped by has not reached its destination and whose location cannot be readily traced in the transportation system.

Subp. 199. **Lot tolerance percent defective.** "Lot tolerance percent defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

Subp. 200. **Low dose-rate remote afterloader.** "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 200 rads (2 gray) per hour at the point or surface where the dose is prescribed.

Subp. 201. **Low specific activity material (LSA).** "Low Specific Activity material (LSA)"l 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; found in **subp. 202, subp. 203 and subp. 204.**

Subp. 202. **Low specific activity material (LSA) group I.** "Low specific activity material (LSA) group I" means:

A. ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or

B. solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

C. radioactive material, other than fissile material, for which the A_2 value is unlimited; or

D. 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 10^{-6} A_2/g.

Subp. 203. **Low specific activity material (LSA) group II.** "Low specific activity material (LSA) group II means:

A. water with tritium concentration up to 20.0 Ci/liter (0.8 TBq/liter); or

B. 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.

Subp. 204. **Low specific activity material (LSA) group III.** "Low specific activity material (LSA) group III" means solids (e.g., consolidated wastes, activated materials) in which:

A. 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

B. 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

C. the average specific activity of the solid does not exceed 2 $x10^{-3}$ A_2/g.

Subp. 205. **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.

Subp. 206. **Lung class.** "Lung class" see Class, **subp 56.**

Subp. 207. **mA.** "mA" means milliampere.

Subp. 208. **mAs.** "mAs" means milliampere-second.

Subp. 209. **Management.** "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Subp. 210. **Manual brachytherapy.** "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Subp. 211. **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. 212. **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 **4731.1501 - 4731.1518, in** the absence of venting, external cooling by an ancillary system, or operational controls during transport.

Subp. 213. **Medical event.** "Medical event" means an event that meets the criteria in 4731.0162, subp. 4.

Subp. 214. **Medical institution.** "Medical institution" means an organization in which more than one medical discipline is practiced.

Subp. 215. **Medical use.** "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or

human research subjects under the supervision of an authorized user.

Subp. 216. **Medium dose-rate remote afterloader.** "Medium dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

Subp. 217. **Mega electron volts (MeV).** "Mega electron volts (MeV)" is million electron volts.

Subp. 218. **Member of the public.** "Member of the public" means any individual except when that individual is receiving an occupational dose.

Subp. 219. **Minor.** "Minor" means an individual less than 18 years of age.

Subp. 220. **Mobile medical service.** "Mobile medical service" means the transportation of radioactive materials and its medical use by the same licensee or registrant at the client's address or at temporary jobsites.

Subp. 221. **Monitoring (radiation monitoring, radiation protection 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.

Subp. 222. **Moving Web.** See "product conveyor system" **subp. 268.**

Subp. 223. **National Council on Radiation Protection and Measurements (NCRP).** "National council on radiation protection and measurements (NCRP)" means the 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. 224. **National Voluntary Laboratory Accreditation Program (NVLAP).** "National voluntary laboratory accrediation program (NVLAP)" is the laboratory accreditation program of the National Institute of Standards and Technology (NIST).

Subp. 225. **Natural thorium.** "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes, essentially 100 weight percent thorium-232.

Subp. 226. **Naturally occurring or accelerator produced radioactive material. (NARM).** "Naturally occurring or accelerator produced radioactive material (NARM)" does not include byproduct, source, or special nuclear material.

Subp. 227. **Negative pressure respirator (tight fitting).** "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.

Subp. 228. **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.

Subp. 229. **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. 230. **Non-ionizing.** "Non-ionizing" means radiation that does not cause the formation of ions.

Subp. 231. **Non-stochastic effect (deterministic effect).** "Non-stochastic effect (deterministic 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.

Subp. 232. **Normal form radioactive material.** "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material."

Subp. 233. **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 licensee, registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released in accordance with **4731.1204, subp. 2, from** voluntary participation in medical research programs, or as a member of the public.

Subp. 234. **Offshore waters.** "Offshore waters" means that area of land and water, beyond Agreement States' Submerged Lands Act jurisdiction, on or above the U.S. Outer Continental Shelf.

Subp. 235. **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.

Subp. 236. **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. 237. **Output.** "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy , remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Subp. 238. **Package.** "Package" means the packaging together with its radioactive contents as presented for transport.

A. Fissile material package means a fissile material packaging together with its fissile material contents.

B. 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 100 lb/in^2 (700 kPa) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 4731.1501 - 4731.1518 (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 Department of Transportation regulations in 49 Code of Federal Regulations Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 4731.1501 - 4731.1518.

Subp. 239. **Packaging.** "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

Subp. 240. **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.

Subp. 241. **Panoramic irradiator.** "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.

Subp. 242. **Panoramic wet-source-storage irradiator.** "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.

Subp. 243. **Particle accelerator.** See Accelerator, subp. 4.

Subp. 244. **Patient.** "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

Subp. 245. **Patient intervention.** "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Subp. 246. **Peak tube potential.** "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

Subp. 247. **Permanent radiographic installation.** "Permanent radiographic installation" means a shielded, enclosed room, cell, vault, or structure that is not moved and not located at a temporary jobsite, and is designed or intended for radiography where radiography is regularly performed.

Subp. 248. **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.

Subp. 249. **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.

Subp. 250. **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.

Subp. 251. **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. 252. **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. 29.

Subp. 253. **Physician assistant or registered physician assistant.** "Physician assistant" or "registered physician assistant" means a person registered according to Minnesota Statutes, chapter 147A.

Subp. 254. **Planned special exposure.** "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

Subp. 255. **Pool irradiator.** "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.

Subp. 256. **Portal film or portal imaging.** "Portal 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. 257. **Positive pressure respirator.** "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Subp. 258. **Powered air-purifying respirator (PAPR).** "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.

Subp. 259. **Practical Examination.** "Practical Examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

Subp. 260. **Preceptor.** "Preceptor" means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Subp. 261. **Prescribed dosage.** "Prescribed dosage" means the specific activity or range of activity of unsealed radioactive material as documented:

A. in a written directive; or

B. in accordance with the directions of the authorized user for procedures performed pursuant to 4731.1212, subp. 1 and subp.2.

Subp. 262. **Prescribed dose.** "Prescribed dose" means:

A. for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

B. for teletherapy, the total dose and dose per fraction as documented in the written directive;

C. for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

D. for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Subp. 263. **Pressure demand respirator.** "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.

Subp. 264. **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. 265. **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. 266. **Primary protective barrier.** "Primary protective barrier" means the material, excluding filters, placed in the useful beam for protection purposes to reduce the radiation exposure.

Subp. 267. **Principal activities.** "Principal activities," 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.

Subp. 268. **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. This does not include a hand fed system.

Subp. 269. **Protective apron.** "Protective apron" means an apron made of radiation absorbing materials, used to reduce radiation exposure.

Subp. 270. **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. 271. **Protective glove.** "Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure.

Subp. 272. **Public dose.** "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant. 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 4731.1204, or from voluntary participation in medical research programs.

Subp. 273. **Pulsed dose-rate remote afterloader.** "Pulsed dose-rate remote afterloader" means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but

A. is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

B. is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Subp. 274. **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. 275. **Quality assurance program.** "Quality assurance program" means the program and procedures to ensure compliance with in 4731.1300 - 4731.1321.

Subp. 276. **Quality factor.** "Quality factor" means the modifying factor listed in 4731.3002, Table 5 that is used to derive dose equivalent from absorbed dose.

Subp. 277. **Qualitative fit test (QLFT).** "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.

Subp. 278. **Quarter.** "Quarter" means a period of time equal to one-fourth of the year observed by the licensee or registrant (approximately 13 consecutive weeks). A quarterly test must be performed approximately 13 weeks apart, four times per year.

Subp. 279. **Quantitative fit test (QNFT).** "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Subp. 280. **Rad.** The "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 (0.01gray).

Subp. 281. **Radiation.** "Radiation" means the emission and propagation of waves or particles. Alpha particles, beta particles, gamma x-rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions.

Subp. 282. **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. 283. **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. 284. **Radiation hazard.** "Radiation hazard" means a condition under which persons might receive radiation in excess of the dose limits.

Subp. 285. **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. 286. **Radiation room.** "Radiation room" means a shielded room in which irradiations take place.

Subp. 287. **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. 288. **Radiation safety officer.** "Radiation safety officer" is an individual who has the training, knowledge, and authority to apply appropriate radiation protection regulations in accordance with 4731.0127; 4731.0128; and 4731.0129. In addition, for radioactive materials in the healing arts, an individual must :

A. meet the requirements in 4731.128, subp.7 and 4731.0152 subp 1,D; or

B. is identified as the Radiation Safety Officer on:

(1) a specific medical use license issued by the Commission or Agreement State; or

(2) a medical use permit issued by a Commission master material licensee.

Subp. 289. **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. 290. **Radioactive marker.** "Radioactive marker" means licensed material used for depth determination or direction orientation. This term includes radioactive collar markers and radioactive iron nails.

Subp. 291. **Radioactive material.** "Radioactive material" means any solid, liquid, or gaseous substance which emits radiation spontaneously.

Subp. 292. **Radioactive waste**. "Radioactive waste" means those low-level radioactive wastes containing source, special nuclear or radioactive material that are acceptable for disposal in a land disposal facility.

Subp. 293. **Radiograph.** "Radiograph" means an image that is created directly or indirectly by radiation resulting in a permanent record or image.

Subp. 294. **Radiographer.** See Industrial Radiographer, **subp. 162.**

Subp. 295. **Radiographer's assistant.** See Industrial Radiographer's Assistant, **subp. 163.**

Subp. 296. **Radiographer certification**. See Industrial Radiographer's Certification, **subp.164.**

Subp. 297. **Radiographic exposure device.** "Radiographic exposure device" (also called a camera, or a projector) means any instrument containing a sealed or x-ray source, fastened or contained therein, in which the sealed or x-ray source or shielding thereof may be moved, or otherwise changed, from a shielded to an unshielded position for purposes of making a radiographic exposure

Subp. 298. **Radiographic operations.** "Radiographic operations" means all activities associated with the presence of radiation sources in a radiographic exposure device including x-ray radiographic devices, during use of the device or transport, except when being transported by a common or contract transport, to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

Subp. 299. **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. 300. **Rating.** "Rating" means the operating limits as specified by the component manufacturer.

Subp. 301. **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. 302. **Reference plane.** "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

Subp. 303. **Registrant.** "Registrant" means a person having possession of any x-ray source of radiation or a generally license device except those specifically exempted under 4731.0103.

Subp. 304. **Registration.** "Registration" means registration with the commissioner according to 4731.0103.

Subp. 305. **Rem.** The "rem" is the 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).

Subp. 306. **Research and development.** "Research and development" means:

A. theoretical analysis, exploration, or experimentation; or

B. the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" does not include the internal or external administration of radioactive material, or the radiation therefrom, to human beings.

Subp. 307. **Residual radioactivity.** "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee or registrant's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee or registrant, 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 Chapter 4731.

Subp. 308. **Respiratory protective device.** "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

Subp. 309. **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. 310. **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. 311. **S-tube.** "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

Subp. 312. **Safety review.** See Annual refresher safety training, **subp. 20.**

Subp. 313. **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.

Subp. 314. **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. 315. **Scan sequence.** "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Subp. 316. **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. 317. **Sealed source.** "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Subp. 318. **Sealed source and device registry.** "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Subp. 319. **Secondary dose monitoring system.** "Secondary dose monitoring system" means a system that will terminate irradiation if the primary system fails.

Subp. 320. **Seismic area.** "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

Subp. 321. **Self-contained breathing apparatus (SCBA).** "Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Subp. 322. **Sensitometer.** "Sensitometer" means an instrument designed to produce a series of exposures with known ratios to each other.

Subp. 323. **Shallow-dose equivalent.** "Shallow-dose equivalent (H_S)," which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

Subp. 324. **Shielded position.** "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

Subp. 325. **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 source or tube housing assembly

Subp. 326. **SI equivalent.** "SI equivalent" means units that conform to the international system

of units.

Subp. 327. **Sievert**. "Sievert" is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv=0.01 rems). The quality factors for converting absorbed dose to dose equivalent are shown in **4731.3002, 5.**

Subp. 328. **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.

Subp. 329. **Source.** "Source" means a discrete amount of radioactive material or the target (focal spot) of the x-ray tube.

Subp. 330. **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.

Subp. 331. **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.

Subp. 332. **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.

Subp. 333. **Source material.** "Source material" means:

A. Uranium, thorium or any other material which is determined by the commission pursuant to the provision of section 61 of the Atomic Energy Act of 1954, as amended to be source material; or

B. ores that containing one or more of the foregoing materials, in such concentration as the commissioner may by regulation determine from time to time.

Subp. 334. **Source of radiation.** "Source of radiation" means radioactive material, device, or equipment which emits, or is capable of producing, radiation.

Subp. 335. **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. 336. **Source-to-skin distance (SSD).** "Source-to-skin distance" or "SSD" means the distance between the source and the skin of the patient.

Subp. 337. **Special form radioactive material.** "Special form radioactive material" means

radioactive material that satisfies the following conditions:

A. it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

B. the piece or capsule has at least one dimension not less than 0.2 in. (5 mm); and

C. it satisfies the requirements of **4731.1501 - 4731.1518.** A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983, (see 10 Code of Federal Regulations 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 10 CFR 71.4 in effect on March 31, 1996, (see 10 Code of Federal Regulations 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.

Subp. 338. **Special nuclear material.** "Special nuclear material" means:

A. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material the Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material. but does not include source material; or,

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

Subp. 339. **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. 340. **Specific license.** "Specific license" means a license that permits a licensee to obtain radionuclides in amounts no greater than the indicated limit and for the identified uses as listed on the license.

Subp. 341. **Spot check.** "Spot check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

Subp. 342. **Spot film.** "Spot film" means a radiograph that is made during a fluoroscopic examination.

Subp. 343. **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. 344. **Stationary beam therapy.** "Stationary beam therapy" means a method of adjusting collimator blades continuously rather than in fixed increments.

Subp. 345. **Stepless adjustment.** "Stepless adjustment" means a method of adjusting collimator blades continuously rather than in fixed increments.

Subp. 346. **Stereotactic radiosurgery.** "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

Subp. 347. **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. 348. **Storage area.** "Storage area" means any location, facility, or vehicle which is used to store, or to secure an industrial x-ray or 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. 349. **Storage container.** "Storage container" means a container in which sealed sources are secured and stored.

Subp. 350. **Structured educational program.** "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Subp. 351. **Subsurface tracer study.** "Subsurface tracer study" means the release of unsealed license material or a substance labeled with licensed material in a single well or boring for the purpose of tracing the movement or position of the material or substance in the well, boring, or adjacent formation.

Subp. 352. **Supplied-air respirator (SAR) or airline respirator.** "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.

Subp. 353. **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 or boring to isolate fresh water aquifers from the well or boring.

Subp. 354. **Surface Contaminated Object (SCO).** "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:

A. SCO - I: A solid object on which:

(1) the non-fixed contamination on the accessible surface averaged over 300 cm^2

(or the area of the surface if less than 300 cm^2) does not exceed 10^{-4} microcurie/cm^2 (4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-5} microcurie/cm^2 (0.4 Bq/cm^2) for all other alpha emitters;

(2) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1.0 microcurie/cm^2 ($4x10^4$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 ($4x10^3$ Bq/cm^2) for all other alpha emitters; and

(3) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1 microcurie/cm^2 ($40x10^4$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 ($40x10^3$ Bq/cm^2) for all other alpha emitters.

B. SCO - II: A solid object on which the limits for SCO - I are exceeded and on which:

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

(2) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcuries/cm^2 ($8x10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcuries/cm^2 ($8x10^4$ Bq/cm^2) for all other alpha emitters; and

(3) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcuries/cm^2 ($8x10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcuries/cm^2 ($8x10^4$ Bq/cm^2) for all other alpha emitters.

Subp. 355. **Survey or radiation safety survey.** "Survey or radiation safety 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 or radioactive material or other radiation sources and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Subp. 356. **Target.** "Target" means the part of a radiation producing system that by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

Subp. 357. **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. 358. **Teletherapy.** "Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Subp. 359. **Temporary jobsite.** "Temporary jobsite" means

A. A location where radiographic operations are conducted and where licensed or registered material may be stored other than those location(s) of use authorized on the license or registration; or

B. A location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Subp. 360. **Therapeutic dosage.** "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Subp. 361. **Therapeutic dose.** "Therapeutic dose" means a radiation dose delivered from source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Subp. 362. **Tight-fitting facepiece.** "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

Subp. 363. **Tomogram.** "Tomogram" means an x-ray image of a thin section of the body.

Subp. 364. **Tomographic plane.** "Tomographic plane" means the geometric plane that is identified as corresponding to the output tomogram.

Subp. 365. **Tomographic section.** "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram

Subp. 366. **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.

Subp. 367. **Traceable to a standard.** "Traceable to a standard" means a comparison directly to

a standard maintained by the National Institute of Standards and Technology (NIST) and that all comparisons have been documented.

Subp. 368. **Transient shipment.** "Transient shipment" means a shipment of nuclear material originating and terminating in foreign countries , on a vessel or aircraft which stops at a United States port.

Subp. 369. **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:

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

B. for fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour at 3.3 ft (one meter) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 3.3 ft. (one meter)), or, for criticality control purposes, the number obtained as described in 4731.1501 - 4731.1518 whichever is larger.

Subp. 370. **Treatment site.** "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Subp. 371. **Tritium neutron generator target source.** "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

Subp. 372. **Tube housing assembly.** "Tube housing assembly" means the tube housing with tube installed.

Subp. 373. **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. 374. **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 1 of **4731.3002** or may be determined by procedures described in **4731.3001(I).**

Subp. 375. **Type B quantity.** "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

Subp. 376. **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. 377. **Underwater irradiator.** "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.

Subp. 378. **Unit dosage.** "Unit dosage" means a dosage prepared for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed pursuant to 4731.0300 - 4731.0317 of this chapter or equivalent Agreement State requirements.

Subp. 379. **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.

Subp. 380. **Unrestricted area.** "Unrestricted area" means an area, the access to which is neither limited nor controlled by the licensee or registrant

Subp. 381. **Uranium–depleted.** "Uranium–depleted" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

Subp. 382. **Uranium–enriched.** "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

Subp. 383. **Uranium--natural.** " 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.

Subp. 384. **Uranium sinker bar.** "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

Subp. 385. **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. 386. **User seal check (fit check).** "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.

Subp. 387. **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.

Subp. 388. **Vendor** "Vendor" means one who sells or vends products which include radiation source, radiation producing equipment or accessories for these products.

Subp. 389. **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 generates. (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. 390. **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. 391. **Waste.** See radioactive waste **subp.292.**

Subp. 392. **Week.** "Week" means 7 consecutive days.

Subp. 393. **Wedge filter.** "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

Subp. 394. **Weighting factor W_t.** "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, the values of W_t are found in **4731.3002, 7.**

Subp. 395. **Well.** "Well" has the meaning given in Minnesota Statutes, section 103I.005.

Subp. 396. **Well logging or logging.** "Well logging or 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 or borings for the purpose of obtaining information about the well, boring or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

Subp. 397. **Whole body.** "Whole body" means for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Subp. 398. **Worker.** "Worker" means an individual who engaged in activities licensed or registered by the commissioner and controlled by a registrant or licensee. This does not include the licensee or registrant.

Subp. 399. **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.

Subp. 400. **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).

Subp. 401. **Written directive.** "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 4731.1200 - 4731.1299.

Subp. 402. **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. 403. **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. 404. **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. 405. **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. 406. **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. 407. **X-ray operator.** "X-ray operator" means an individual who has met the requirements in 4731.0150, subp.2 and 4731.1300 - 4731.1321.

Subp. 408. **X-ray subsystem.** "X-ray subsystem" means a combination of two or more components of an x-ray system.

Subp. 409. **X-ray system.** "X-ray system" means an assemblage of components for the controlled production of x-rays. At a minimum, it includes 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. 410. **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.

Subp. 411. **Year.** "Year" means the period of time beginning in January, a total of 12 months, used to determine compliance with the provisions of this chapter. For the licensee, they 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.

4731.0101 Purpose

Radiation can be instrumental in the improvement of health, welfare, and productivity of the public if properly used but may impair the health of the people and the industrial and agricultural potentials of the state if improperly used. The commissioner of health has the statutory authority and duty to adopt, alter, and enforce regulations, in order to prevent dangers to public health from radiation and preserve and protect the public's health, must ensure the control of radiation producing equipment including gauges and x-ray equipment, sources of radiation, the handling, storage, transportation, use, and disposal of radioactive isotopes and fissionable materials within this state, secure information concerning the nature and extent of the use of radiation producing equipment and radioactive materials within this state, and observe the effect upon human health.

Subpart 1. **Scope**. The scope of this chapter consists of regulation of radiation from x-ray, radioactive materials including source and special nuclear material not sufficient to form a critical mass, and other non-power plant radiation hazards. Except as otherwise specifically provided, this chapter applies to all persons who own, lease or use radiation producing equipment or who receive, possess, use, transfer, acquire or dispose of any radioactive material. Nothing in this chapter shall apply to any person to the extent that such person is subject to regulation by the United States Nuclear Regulatory Commission (NRC) or to sources in the possession of federal agencies.

Subp. 2. **Exemptions**. Requirements for the exemption of radioactive material, including Naturally Occurring or Accelerator Produced Radioactive Material (NARM) and source material, certain contracts with U.S. Department of Energy (DOE), certain carriers, unimportant or exempt quantities and concentrations, certain items containing radioactive material and some radiation producing equipment are located in an appendix in 4731.3001, D.

producing equipment are located in an appendix in 4731.3001, D.

Subp. 3. **Responsibilities**: Responsibilities of licensees or registrants shall include compliance with applicable parts of Minnesota Rules, Chapter 4731 consistent with each licensee or registrant's area of use. Each applicant, licensee or registrant shall notify the commissioner of any change in information related to the regulated activity which has an impact on public health and safety. Notification shall be provided to the commissioner within two working days of identifying the information. This requirement is not applicable to information which a person is already required to provide to the commissioner by other reporting requirements of this rule. Any information provided to the commissioner by an applicant for a license or registration shall be complete and accurate in all material submitted.

Except as otherwise specified in this chapter, all communications and reports concerning the regulations in this chapter should be addressed to or delivered in person to: Radiation Control unit, Minnesota Department of Health, St. Paul, Minnesota, 55108.

4731.0102 License Types For Radioactive Material. There are two types of radioactive material licenses, specific and general.

Subpart 1. **Specific license**. The commissioner issues a specific license to a named person who has filed an application for the license under the provisions of chapter 4731. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document.

A. The requirements of this part apply to a person who is an applicant for, or holder of a specific radioactive materials license issued pursuant to 4731.0101-4731.0195, 4731.0300 - 4731.0320, 4731.0500 - 4731.0520, 4731.0700 - 4731.0720, 4731.0800 - 4731.0820, 4731.1000 - 4731.1020, 4731.1200 - 4731.1220.

B. Those persons who hold a specific license from the U.S. NRC, an agreement state or licensing state and conduct activities under a reciprocal agreement with this State shall meet the requirements of 4731.0316, and pay the annual fee as specified in 4731.0104 subp. 1.

Subp 2. **General license.** A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the commissioner or the issuance of a licensing document to a particular person. The filing of a certificate with the commissioner by a general licensee may be required by the particular general license. Registration with the commissioner may be required by the particular general license.

4731.0103 Registration of X-ray Equipment and Generally Licensed Devices That Contain Radioactive Material.

Subpart 1. **Registration requirements of x-ray facilities**. The owner or person having possession of any source of radiation except those specifically exempted under this part or under 4731.0101, subp.2 shall:

A. Register all sources with the commissioner o f health within 30 days of its acquisition or its proposed temporary use in Minnesota, except demonstration units in place for 15 days or less, upon forms prescribed and provided for that purpose.

B. The registrant shall designate an individual who will be responsible for radiation protection form the source. The individual who is the radiation safety officer must meet the requirements in 4731.0127, 4731.0128 and 4731.0129, subp. 8.

C. No person in any advertisement shall refer to the fact that a source is registered with the commissioner of health, and no person shall state or imply that any activity under such registration has been approved by the commissioner of health

D. The registrant must notify the commissioner in writing:

(1) within 30 days of nay change in the ownership or disposition of registered sources; and

(2) 30 days prior to any temporary use of radiation sources in Minnesota, except demonstration units in place for 15 days or less. The notification must include locations at which the source is to be used, the estimated time period of use in the state, and the estimated date of completion.

E. The registrant shall be subject to all applicable requirements of this chapter.

Subp. 2. **Generally licensed devices**. The registrant or licensee that owns a generally licensed device must register or license the device in accordance with 4731.0304, subp. 2, C (13), (a).

Subp. 3. **Biennial renewal of registration for x-ray and generally licensed device facilities**

A. Each registration pursuant to this chapter shall be renewed biennially according to the staggered schedule specified in subp. 3, B so long as the activity requiring registration continues. If there has been no substantial change in the matters described in the last prior registration or renewal, the renewal of the registration shall so state. If there has been any accession of additional radiation sources or other substantial change in the matters described in the preceding registration or renewal, the renewal shall state the accession or other change and give the information relating to the accession or other change that would be required upon original registration.

B. Each registration pursuant to this chapter shall be renewed on or before the first day of the calendar quarter specified in subitems (1)-(8). The schedule is based on the registrant's business address within the state.

(1) January 1 of the odd-numbered years: Hennepin County dentists and all radiation sources in the University of Minnesota system, regardless of location.

(2) April 1 of the odd-numbered years: Hennepin County registrants other than those included in subitem (1).

(3) July 1 of the odd-numbered years: Ramsey County registrants.

(4) October 1 of the odd-numbered years: Anoka, Dakota, and Washington County registrants.

(5) January 1 of the even-numbered years: Aitkin, Benton, Carlton, Cass, Chisago, Cook, Crow Wing, Isanti, Itasca, Kanabec, Koochiching, Lake, Mille Lacs, Morrison, Pine, and St. Louis County registrants.

(6) April 1 of the even-numbered years: Becker, Beltrami, Big Stone, Chippewa, Clay, Clearwater, Douglas, Grant, Hubbard, Kittson, Lac Qui Parle, Lake of the Woods, Mahnomen, Marshall, Norman, Ottertail, Pennington, Polk, Pope, Red Lake, Roseau, Stearns, Stevens, Swift, Todd, Traverse, Wadena, and Wilkin County registrants, and registrants whose business addresses are outside the state.

(7) July 1 of the even-numbered years: Brown, Carver, Cottonwood, Faribault, Jackson, Kandiyohi, Lincoln, Lyon, Martin, McLeod, Meeker, Murray, Nicollet, Nobles, Pipestone, Redwood, Renville, Rock, Sherburne, Sibley, Watonwan, Wright, and Yellow Medicine County registrants.

(8) October 1 of the even-numbered years: Blue Earth, Dodge, Fillmore, Freeborn, Goodhue, Houston, Le Sueur, Mower, Olmsted, Rice, Scott, Steele, Wabasha, Waseca, and Winona County registrants.

C. Renewals affected by change of location. A registrant whose business address changes from one county to another must renew the registration with the county of relocation according to the schedule in subp. 3, B, and shall not accrue penalty fees for not renewing with the county of previous location.

4731.0104 Fee Schedules For Radioactive Material Licenses, X-ray and Generally Licensed Device Registration. Radioactive material, as used here, includes material in quantities not sufficient to form a critical mass licensed by the NRC and NARM registered by MDH.

Subpart 1. **Fees for radioactive material licenses and inspection.**

A. Application and renewal fee.

(1) when a license is required for radioactive material or source or special nuclear material by a rule adopted section under Minnesota statutes section 144.1202, subdivision 2, an application fee as listed in D, below must be paid upon initial application for a license.

(2) the licensee must renew the license 60 days before the expiration date of the license by paying a license renewal fee equal to the application fee listed in D, below. The expiration date of a license is set by the NRC before transfer of the licensing program under Minnesota statutes section 144.1202 and thereafter as specified by rule of the commissioner of health.

(3) each application for a specific license for which a fee is required shall be accompanied by a remittance in the full amount of the fee. No application will be processed prior to payment of the fee specified in D, below. The application fee is not refundable except in those cases where the commissioner has determined that a license is not required.

(4) the commissioner will consider any application abandoned if the commissioner does not receive a reply within 90 days with the additional information requested. In such cases, the applicant must submit a new application with the application fee as listed in D, below.

B. Annual fee. A licensee must pay an annual fee at least 60 days before the anniversary date of the issuance of the license. The annual fee is an amount equal to 80 percent of the application fee listed in D, below, rounded to the nearest whole dollar.

C. Fee categories. The categories incorporate the federal licensing categories.

(1) Fee categories in this part are equivalent to the licensing categories used by

the NRC under Code of Federal Regulations, title 10, parts 30 to 36, 39, 40, 70, 71, and 150, except as provided in C, (2), below.

(2) The category of "Academic, small" is the type of license required for the use of radioactive materials in a teaching institution. Radioactive materials are limited to ten radionuclides not to exceed a total activity of one curie.

D. Application fee. A licensee must pay an application fee as follows:

Radioactive material, including source and special nuclear material	Application fee	U.S. Nuclear Regulatory Commission licensing Category
Type A broadscope	$20,000	Medical institution Type A
Type B broadscope	$15,000	Research and development Type B
Type C broadscope	$10,000	Academic Type C
Medical use	$4,000	Medical, medical institution, medical private practice
Mobile nuclear medical laboratory	$4,000	Mobile medical laboratory
Medical special use sealed source	$6,000	Teletherapy, high dose rate afterloaders, stereotactic radiosurgery devices
In vitro testing	$2,300	In vitro testing laboratories
Measuring gauge, sealed sources	$2,000	Fixed gauges, portable gauge, analytical instruments, measuring systems - other
Gas chromatographs	$1,200	Gas chromatographs
Manufacturing and distribution	$14,700	Manufacturing and distribution - other
Distribution only	$8,800	Distribution of radioactive material for commercial use only
Other services	$1,500	Other services
Nuclear medicine pharmacy	$4,100	Nuclear pharmacy
Waste disposal	$9,400	Waste disposal service prepackage, waste disposal service processing/repackage
Waste storage only	$7,000	To receive and store radioactive material waste
Industrial radiography	$8,400	Industrial radiography fixed location , industrial radiography portable/ temporary sites
Irradiator - self shielded	$4,100	Irradiators self-shielded less

		than 10,000 curies
Irradiator - less than 10,000 curies	$7,500	Irradiators less than 10,000 curies
Irradiator - more than 10,000 curies	$11,500	Irradiators more than 10,000 curies
Research and development, no distribution	$4,100	Research and development
Radioactive material possession only	$1,000	Byproduct material possession only
Source material	$1,000	Source material shielding
Special nuclear material, less than 200 grams	$1,000	Special nuclear material plutonium-neutron sources less than 200 grams
Pacemaker manufacturing	$1,000	Pacemaker byproduct and/or special nuclear material - medical institution
General license distribution	$2,100	General license distribution
General license distribution, exempt	$1,500	General license distribution - certain exempt items
Academic, small	$1,000	Possession limit of ten radionuclides, not to exceed a total of one curie of activity
Veterinary	$2,000	Veterinary use
Well logging	$5,000	Well logging

E. Penalty for late payment. An annual fee or a license renewal fee submitted to the commissioner after the due date specified by rule must be accompanied by an additional amount equal to 25 percent of the fee due.

F. Inspections. The commissioner shall make periodic safety inspections of the radioactive material, including source and special nuclear material, of a licensee. The commissioner shall prescribe the frequency of the safety inspections by rule.

G. Recovery of reinspection cost. If the commissioner finds serious violations of Chapter 4731 during an inspection under F., above, the licensee must pay all costs associated with subsequent reinspection of the source. The costs shall be the actual costs incurred by the commissioner and include, but not limited to, labor, transportation, per diem, materials, legal fees, testing, and monitoring costs.

H. Reciprocity fee. A licensee submitting an application for reciprocal recognition of a materials license issued by another agreement state or the U.S. Nuclear Regulatory Commission for a period of 180 days or less during a calendar year must pay one-half of the application fee listed in D, above.

I. A licensee must pay a fee to amend a license as follows:

(1) to amend a license requiring no license review including, but not limited to, facility name change or removal of a previously authorized user, no fee.

(2) to amend a license requiring review including, but not limited to, addition of isotopes, procedure changes, new authorized users, or a new radiation safety officer, $200; and

(3) to amend a license requiring a review and a site visit including, but not limited to, facility move or addition of processes, $400.

J. Method of payment. Checks, drafts, or money orders for payment of fees must be payable to Treasurer, State of Minnesota; and sent to Radiation Control unit, Minnesota Department of Health, St. Paul, MN 55108.

Subp. 2. **Registration fees for x-ray facilities.**

A. Fee for initial or renewal registration.

(1) The initial or renewal biennial registration of every source of radiation required to be registered by 4731.0103, Subp 1, must be accompanied by fees as prescribed in this part and Minnesota Statutes, section 144.121, subdivision 1a.

(2) A facility with x-ray machines or other sources of radiation must biennially pay a registration fee consisting of a base facility fee of $132 and an additional fee for each x-ray machine or other source of radiation as follows:

(a) medical or veterinary equipment, $106;
(b) dental x-ray equipment, $66;
(c) accelerator, $132;
(d) radiation therapy equipment, $132;
(e) x-ray equipment not used on humans or animals, $106;
(f) devices with sources of radiation not used on humans or animals, $106; and
(g) sources of radium, $198.

B. Penalty fee for late registrations. Applications for initial or renewal registrations submitted to the commissioner of health after the time specified by 4731.0103 subp. 1A and 4731.0104 subp. 3 shall be accompanied by a penalty fee of $20 in accordance with Minnesota Statutes, section 144.121, subdivision 1a, in addition to the fee prescribed in subp. 2.

C. Fee for sources requiring registration during last 12 months of a biennial registration period. In accordance with Minnesota Statutes, section 144.121, subdivision 1a, the initial registration fee of x-ray machines or other sources of radiation required to be registered during the last 12 months of a biennial registration period shall be 50 percent of the applicable registration fee prescribed in subp. 2.

Subp 3. **Registration fee for generally licensed devices will consist of the base fee of $132.**

4731.0105 Data privacy. Any information gathered for collection, security and dissemination of records for either a registration or license is governed by the Data Privacy Act found in Minnesota Statute Chapter 13.02; 13,39; and 13.41.

4731.0106 Opportunities to Inspect and Conduct Tests All Facilities

Subpart 1. **Inspections**

A. Each licensee, registrant, owner, renter, or other person possessing a radiation source, including source material, special nuclear material, radiation producing equipment

including x-ray shall afford to the commissioner at all reasonable times opportunity to inspect the radiation source, radiation producing equipment, the radioactive material activities and the premises and facilities wherein the radioactive material or radiation producing equipment is used or stored. The inspection may include the following:

(1) consulting privately with employees as needed.

(2) if, at the time of inspection, an individual has been authorized by the workers to represent them during commissioner inspections, the licensee or registrant 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.

(3) the licensee, registrant or their representative may accompany the commissioner during other phases of an inspection

(4) with the approval of the licensee, registrant and the workers' representative an individual who is not routinely engaged in licensed or registered activities under control of the license or registration, for example, a consultant to the licensee, registrant or to the workers' representative, must be afforded the opportunity to accompany commissioner inspectors during the inspection of physical working conditions.

(5) 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.

(6) 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.

(7) with regard to any area containing proprietary information, the workers' representative for that area must be an individual previously authorized by the licensee or registrant to enter that area.

B. Each licensee or registrant shall make available to the commissioner for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this rule

C. The commissioner will perform inspections to assure the radiation sources, radiation producing equipment and radioactive materials are used only as specified in these regulations.

D. Inspections for radioactive materials may be announced or unannounced.

E. Routine x-ray inspections will continue to be announced.

Subp. 2. **Tests**. Each licensee or registrant shall perform and provide results to the commissioner of such tests as the commissioner deems appropriate or necessary for the administration of the regulations in this rule. The licensee or registrant must also permit the commissioner to perform such tests as are deemed necessary to determine compliance with this rule.

Subp. 3. **Allegations and complaints**.

A. 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 4731, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material,

radiation producing equipment under the licensee's or registrant's control. The provisions of this subpart must not be interpreted as authorization to disregard instructions pursuant to 4731.0151, subpart 1.

B. Any worker or representative of workers who believes that a violation of Chapter 4731, or license conditions exists or has occurred in license or registered 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.

C. 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.

D. A copy must be provided to the licensee or registrant 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.

E. If, upon receipt of such notice, the commissioner determines that the complaint meets the requirements set forth in items A through D, above, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, the commissioner may 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.

F. If the commissioner determines, with respect to a complaint under this subpart that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the commissioner may notify the complainant in writing of such determination.

(1) the complainant may obtain review of such determination by submitting a written statement of position to the commissioner of health, 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.

(2) the licensee or registrant 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 or registrant may orally present their views.

(3) 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.

G. If the commissioner determines that an inspection is not warranted because the requirements of items A through D 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 this subpart.

4731.0107 Variances. The commissioner may grant a variance to 4731.0100 to 4731.3004, except 4731.0102, 4731.0103 and 4731.0104 only according to the procedures and criteria specified in Minnesota Rules 4717.7000 to 4717.7050.

4731.0108 Violations, Enforcement and Penalties For All Facilities. Violations found by either routine inspection, complaint based inspection, incident/accident inspection or other inspection deemed necessary by the commissioner of health will be subject to complete compliance within 30 days from date of report or as otherwise instructed in writing. All violations are subject to a penalty under Minnesota Statutes, sections 144.989 to 144.993, "Health Enforcement Consolidations Act of 1993."

4731.0109. Deliberate Misconduct and Employee Protection.
Subpart 1. Any licensee, registrant, applicant for a license or a registration, employee of a licensee, registrant or applicant; or any contractor, including supplier or consultant, subcontractor, employee of a contractor or subcontractor of any licensee, registrant, or applicant for a license, who knowingly provides to any licensee, registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's, or applicant's activities in this chapter may not:

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

B. Submit to the commissioner, a licensee, registrant, an applicant, a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate and, in some respect material, to the commissioner.

C. For the purposes of 4731.0109, deliberate misconduct by a person means an intentional act or omission that the person knows

(1) would cause a licensee, registrant or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license or registration issued by the commissioner; or

(2) constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

Subp 2. **Employee protection and employment discrimination issues** are covered in Minnesota Statutes, sections 181.931-181.935.

4731.0110 Prohibitions
Subpart 1. **General provisions for all facilities.** No individual shall be exposed to the useful beam except for healing arts purposes and only if the exposure has been authorized by a licensed practitioner of the healing arts. Any exposure of an individual for the following other purposes is prohibited:

A. Exposure for training, instruction, demonstration, or research except when the research has been approved by an institutional review board and is conducted under federal regulations for the protection of human subjects in research found in 21 CFR 56, or 45CFR 46. Any other exposure of a human subject for the purpose of research may be made only with an approved variance as described in 4731.0107. Documentation of the research approval process must be on site and available to the commissioner upon request; and

B. Exposure for the purpose of healing arts screening except as authorized by 4731.1312.

Subp. 2. **Other prohibited radiation dose levels.** No worker shall be subjected to a radiation dose occupationally or for training that would exceed the doses specified in 4731.0124 and 4731.0125.

Subp. 3. **Prohibited radiation producing equipment and procedures.** The equipment specified in this subpart shall not be used nor the specified procedures performed:

A. Fluoroscopic devices for fitting shoes;

B. Photofluorographic equipment;

C. Dental fluoroscopic imaging assemblies;

D. Hand-held radiographic or fluoroscopic imaging devices, or hand-held therapy units, except for contact therapy units operated according to 4731.1320, subpart 17;

E. The use of fluoroscopy by x-ray machine operators for positioning a patient for radiographic imaging, except when done by a licensed practitioner of the healing arts, or except for radiation therapy simulators;

F. The use of fluoroscopy by a person other than a licensed practitioner of the healing arts when the licensed practitioner of the healing arts is not physically present in the room except during therapy simulations, maintenance activities, and training courses;

G. The use of direct exposure x-ray film (without intensifying screens) for all radiological imaging other than intraoral dental radiography, therapeutic portal imaging, industrial radiography, and radiographic absorptiometry using readipack film especially designed for radiographic absorptiometry;

H. Non-image intensified fluoroscopic x-ray equipment;

I. Dental intraoral radiography units operating at 50 kVp or less;

J. The use of mammographic imaging systems not specifically designed by the manufacturer for imaging of the breast;

K. Fishpole radiography; and

L. Demonstrations or training without the use of phantoms, when necessary, and without proper shielding for observers and x-ray machine operators as specified in subpart 1, item A, of this part and 4731.1300, subpart 6.

Subp. 4. **Unauthorized exposure of individual monitoring devices.** Exposure of individual monitoring devices to deceptively indicate a dose delivered to an individual is prohibited.

Subp. 5. **Possession of radium-226 by secondary or elementary schools.** The possession by secondary or elementary schools of radium-226 in excess of those quantities exempted in 4731.3003, Schedule B is prohibited.

4731.0111 Vendor and Manufacturers Responsibility.

Subpart 1. **General requirements for all vendors and manufacturers.** No person shall make, sell, lease, transfer, lend, or install x-ray or fluoroscopic imaging assembly equipment or the supplies used in connection with such equipment unless the supplies and equipment, when

properly placed in operation and properly used, meet the requirements of this chapter. Supplies and equipment include, but are not limited to, responsibility for delivery of cones or collimators, filters, accurate timers, and fluoroscopic shutters, where applicable.

Subp. 2. **Notification requirements**. Persons selling, leasing, or transferring of licensed or registrable sources of radiation shall notify the commissioner of health in writing within 30 days of such sale, lease, or transfer, and shall supply the name and address of the purchaser and such pertinent information as is requested by the commissioner of health.

Subp. 3. **Calibration reports at time of installation**. A vendor or manufacturer must perform calibrations on the radiation producing machine according to 4731.1304 through 4731.1311 when applicable, at the time of installation, and provide the facility with written numerical results of the calibration. If the result of the test is not a numerical answer, a pass or fail or yes or no answer is acceptable.

Subp. 4. **Individual monitoring devices**. A vendor or manufacturer must provide its employees with individual monitoring devices and reports for recording occupational exposure according to 4731.0124, and 4731.0171.

Subp. 5. **Phantom use**. For maintenance, demonstrations, and training, a vendor or manufacturer must use phantoms instead of humans.

4731.0112 Environmental and Health Protection Regulations. Nothing in these regulations relieves the licensee or registrant from complying with other applicable federal, state, or local regulations governing any other toxic, or hazardous properties of materials that may be disposed of under chapter 4731.

SAFETY PROVISIONS

4731.0120 Standards For Protection Against Radiation. The requirements in this part control the receipt, possession, use, disposal, and transfer of sources of radiation by any licensee or registrant so that the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in 4731.0124-.4731.0126 and 4731.0136. The limits in this part do not apply to doses from exposure to radiation from medical diagnosis or therapy, or to voluntary participation in medical research programs. However, nothing in 4731.0124-4731.0126, and 4731.0136 shall be construed to limit actions necessary to protect health and safety.

4731.0121 Implementation of License or Registration
Subpart 1. Any existing license condition or registration that is more restrictive than Chapter 4731 remains in force until there is an amendment or renewal of the license or registration.

Subp 2. If a license condition or registration exempts a licensee or registrant from a provision of

the chapter in effect on or before the effective date of this chapter, it also exempts the license or registrant from the corresponding provisions of this chapter.

Subp 3. If a license condition or registration cites provisions in effect prior to the effective date of this chapter which do not correspond to any provisions of this chapter, the license condition or registration remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition or provision.

Subp 4. To determine the occupational doses, a dose from x-rays or gamma rays up to ten million electron volts (MeV) may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

Subp. 5. **For licenses for medical use of radioactive materials:**

A. A licensee shall implement the provisions in 4731.1200-4731.1220 on or before October 24, 2002, with the exception of the requirements in 4731.0121, subp. 5, B, below.

B. A licensee shall implement the training requirements in 4731.0128, subp. 7, A, 4731.0151, subp. 7, A, (1), 4731.0152, subp. 7, B, (1), 4731.0152, subp. 1, D, 4731.1207, subparts 1, A, 2, A, , 3, A, 4, A, 5, A, 6, A, 12, A, 13, A, and 14, A, on or before { date- 2 years from publication of final rule}.

C. Prior to October 25, 2004, a licensee shall satisfy the training requirements of 4731.0128, subp. 7, Radiation Safety Officer, 4731.0152, subp. 7, A, an authorized medical physicist, 4731.0152, subp. 7, B, an authorized nuclear pharmacist, or an authorized user by complying with either:

(1) the appropriate training requirements in 4731.1207,

(2) the appropriate training requirements in 4731.0128, subp. 7, and 4731.0152, subp. 7.

D. If a license condition exempted a licensee from a provision of 4731.1200-4731.1220 on October 24, 2002, then the license condition continues to exempt the lice4nsee from the requirements in the corresponding provision in 4731.1200-4731.1220..

E. When a requirement in 4731.1200-4731.1220 differs from the requirement in an existing license condition, the requirement in 4731.1200-4731.1220 shall govern .

F. If a license condition exempted a licensee from a provision in 10 CFR 35 on { date – 6 months from publication of the final rule}, it will continue to exempt a licensee from the corresponding rule in 4731.1200-4731.1220.

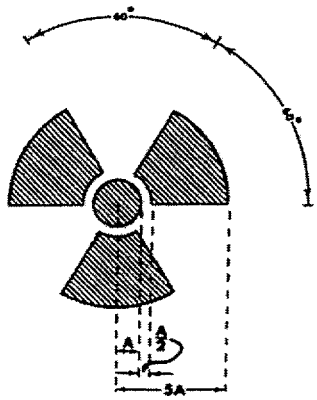
G. A licensee shall continue to comply with any license condition that requires the licensee to implement procedures required by by 4731.1214, subparts 5 A, 5 B, 5 C, and 6 D, until there is a license amendment or renewal that modifies the license condition.

4731.0122 Safety Posting Procedures For All Facilities

Subpart 1. **Caution signs.** The use of the specified radiation symbol for any purpose other than designating or referring to an area of detectable radiation is prohibited.

A. Standard radiation symbol. To be used in areas of detectable radiation unless

otherwise authorized by the commissioner, the symbol prescribed in this section shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-blade design:



RADIATION SYMBOL

(1) Cross-hatched area is to be magenta, or purple, or black, and
(2) The background is to be yellow.

B. Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of 4731.0122, A, above, licensees are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

C. In addition to the contents of signs and labels prescribed in this section, the licensee or registrant may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

Subp 2. **Posting requirements**

A. The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA or DANGER RADIATION AREA."

B. In high radiation areas, the licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" OR "DANGER, HIGH RADIATION AREA."

C. In very high radiation areas, the licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words " VERY HIGH RADIATION AREA."

D. In areas of airborne radioactivity, the licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

E. In areas or rooms in which licensed material is used or stored, the licensee shall post each area or room in which there is used or stored an amount of licensed material

exceeding 10 times the quantity of such material specified in 4731.3001, C, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Subp. 3. **Posting of notices to employees for facilities using radioactive materials**

A. Each licensee must post current copies of the following documents:

(1) the rules under 4731.0100-4731.0194,

(2) the license, license conditions, amendments or documents incorporated into a license by reference;

(3) the operating and emergency procedures applicable to licensed activities;

(4) any notice of violation involving radiological working conditions, or order issued pursuant to 4731.0108 of this chapter, and any response from the licensee.

B. If posting of a document specified in paragraph A, items 1-4 is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

C. Each licensee and each applicant for a specific license must prominently post the form found in 4731.3004, 5. A copy of any revision of the form must be posted within 30 days of receiving the revised form 4731.3004,5 from the commissioner.

D. Documents, notices, or forms posted pursuant to 4731.0122 must:

(1) appear in locations that 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;

(2) be conspicuous, and

(3) be replaced if defaced or altered.

E. Documents posted pursuant to 4731.0122 must be posted within 2 working days after receipt; the licensee's response, if any, must be posted within 2 working days after dispatch by the licensee. Such documents must remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

Subp 4. **Exceptions to posting requirements**

A. A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than 8 hours, if each of the following conditions is met:

(1) the materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in 4731.0124-4731.0126, and 4731.0136, and

(2) the area or room is subject to the licensee's control.

B. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 4731.0122, subp. 2 provided that the patient could be released from licensee control pursuant to 4731.1204, subp. 2, of this chapter.

C. Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 4731.0122, subp. 2 if:

(1) access to the room is controlled pursuant to 4731.1203, subp. 7; and

(2) personnel in attendance take necessary precautions to prevent the inadvertent

exposure of workers, other patients, and members of the public to radiation in excess if the limits established in 4731.0126

D. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level does not exceed 0.005 rem(0.05 mSv) per hour.

4731.0123. Precautionary Procedures For Radioactive Material Facilities. These are in addition to precautionary procedures that can be found in 4731.0123.

Subpart 1. **Use of individual respiratory protection equipment**

A. If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to 4731.0123, subp. 1:

(1) the licensee or registrant must use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(2) if the licensee or registrant wishes to use equipment:

(a) that has not been tested or certified by NIOSH/MSHA,

(b) has not had certification extended by NIOSH/MSHA, or

(c) for which there is no schedule for testing or certification, the licensee or registrant must submit an application to the commissioner for authorized use of that equipment, except as provided in this part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. The evidence must be demonstrated by licensee testing or demonstrated on the basis of reliable test information.

(3) the licensee or registrant must implement and maintain a respiratory protection program that includes:

(a) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;

(b) surveys and bioassays, as appropriate, to evaluate actual intakes;

(c) testing of respirators for operability immediately prior to each use;

(d) written procedures regarding selection, fitting, issuance, maintenance and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and record keeping; and

(e) determination by a physician prior to the initial fitting of respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.

(4) the licensee or registrant must issue a written policy statement on respirator usage covering:

(a) the use of process or other engineering controls, instead of respirators;

(b) the routine, nonroutine, and emergency use of respirators; and

(c) the periods of respirator use and relief from respirator use.

(5) the licensee or registrant must advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction,

physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(6) the licensee or registrant must use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

B. When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to 4731.0123, subp 2, provided that the following conditions, in addition to those in 4731.0123, subp. 1, are satisfied:

(1) the licensee or registrant selects respiratory protection equipment that provides a protection factor as found in 4731.3001, A greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in 4731.3001, B, Table 1, column 3. The following conditions apply:

(a) if the selection of a respiratory protection device with a protection factor greater than the multiple defined in B, (1), above, is inconsistent with the goal specified in 4731.0123, subp. 2 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA .

(b) the concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor.

(c) if the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used.

(2) the licensee or registrant must obtain authorization from the commissioner before assigning respiratory protection factors in excess of those specified in 4731.3001 A. The commissioner may authorize a licensee or registrant to use higher protection factors on receipt of an application that:

(a) describe the situation for which a need exists for higher protection factors, and

(b) demonstrate that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

C. The licensee or registrant must use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

D. The licensee or registrant must notify the commissioner, in writing, at least 30 days before the date that respiratory protection equipment is first used under the provisions of 4731.0123, subp 1.

E. The commissioner may impose restrictions in addition to those 4731.0123, subparts 1 and 2, and 4731.3001, A, to:

(1) ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials; and

(2) limit the extent to which a licensee may use respiratory protection equipment

instead of process or other engineering controls.

F. The licensee or registrant must obtain authorization from the commissioner before using assigned protection factors in excess of those specified in 4731.3001, A. The commissioner may authorize a licensee to use higher protection factors on receipt of an application that:

(1) describe the situation for which a need exists for higher protection factors; and

(2) demonstrate that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

Subp. 2. **Use of process or other engineering controls**

A. The licensee or registrant must use, to the extent practical, process or other engineering controls (e.g. containment or ventilation) to control the concentrations of radioactive material in air.

B. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant must, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(1) control of access;
(2) limitation of exposure times;
(3) use of respiratory protection equipment; or
(4) other controls.

C. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

Subp 3. **Labeling containers and radiation producing equipment**

A. The licensee or registrant must ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must provide sufficient information including the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

B. Each licensee or registrant must, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

C. Industrial x-ray, accelerators, and analytical radiation producing equipment must be labeled with a readily discernible sign or signs bearing the radiation symbol and the words: "CAUTION RADIATION - THIS EQUIPMENT PRODUCES IONIZING RADIATION WHEN ENERGIZED," or words having similar intent:

(1) near any switch;

(2) on the enclosure containing the x-ray tube that energizes an industrial or analytical x-ray tube, or

(3) on the radiation source housing.

Subp. 4 . **Exemptions to labeling requirements .** A licensee or registrant is not required to label:

A. Containers holding licensed material in quantities less than the quantities listed in 4731.3001, C; or

B. Containers holding licensed material in concentrations less than those specified in 4731.3001, B, Table 3; or

C. Containers attended to by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by 4731.0124-4731.0126 and 4731.0136; or

D. Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation; or

E. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record, for example containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record must be retained as long as the containers are in use for the purpose indicated on the record; or

F. Installed manufacturing or process equipment, such as piping or tanks.

Subp 5. **Procedures for receiving and opening packages**

A. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as determined in 4731.3001, I, and listed in 4731.3002, 1, must make arrangements to receive:

(1) the package when the carrier offers it for delivery; or

(2) notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

B . Each licensee must:

(1) monitor the external surfaces of packages for radioactive contamination that are labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations in 49CFR172.403 to 172.436.440, unless the package contains only radioactive material in the form of gas or in special form as defined in 4731.0100 and 4731.3001, I.

(2) monitor the external surfaces of packages for radiation levels that are labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. department of Transportation regulation in 49CFR172.403 and 172.436-172.440, unless the package contains quantities of radioactive material that are less than or equal to the A_1 and A_2 quantities as determined in 4731.3001, I, and listed in 4731.3002, 1; and

(3) monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such

as packages that are crushed, wet, or damaged.

C . The licensee must perform the monitoring required by 4731.0123, subp. 5, B, above, as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the license's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day it is received after working hours.

D . The licensee must immediately notify the final delivery carrier and the commissioner, by telephone, when:

(1) removable radioactive surface contamination exceeds the limits of 4731.1504, F ; or

(2) external radiation levels exceed the limits of 10 CFR 71.47.

E. Each licensee must:

(1) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

F. Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of 4731.0123, subp 5, B, above, but are not exempt from the survey requirement of 4731.0123, subp5, B, for measuring radiation levels that are required to ensure that the source is still properly lodged in its shield.

4731.0124 Dose Limit Requirements . All licensees and registrants must comply with the dose limits listed in this rule part.

Subp 1. **Occupational dose limits for adults**

A. The licensee or registrant must control the occupational dose to individual adults. Except for planned special exposures as specified in 4731.0124, subpart 1, E, to the following dose limits:

(1) an annual limit, which is the more limiting of:

(a) the total effective dose equivalent equal to 5 rem (0.05 Sv); or

(b) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye equal to 50 rem (0.5 Sv).

(2) the annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

(a) a lens dose equivalent of 15 rem (0.15 Sv), and

(b) a shallow dose equivalent of 50 rem (0.50 Sv) to the skin or to any extremity.

B. Doses received in excess of the annual limits, including doses received during accidents, emergencies and planned exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime as specified in 4731.0124, subp. 4, E, (1).

C. The assigned deep-dose equivalent must be for the part of the body receiving the

highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual personnel monitoring device was not in the region of highest potential exposure, or the results of individual personnel monitoring are unavailable.

D. The licensee or registrant must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by another person as in 4731.0125, subp 1, B, (f).

E. Derived air concentrations (DACs) and annual limit on intake (ALI) values in 4731.3001, B, may be used by the licensee to determine the individual's dose as required in 4731.0124, subp. 5 and to demonstrate compliance with the occupational dose limits.

F. In addition to the annual dose limits, the licensee must limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity as in footnote to 4731.3001, B.

Subp. 2. **Occupational dose limits for minors .** No licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to cause any individual under 18 years of age, within a restricted area, to receive an annual occupational radiation dose greater than 10 percent of the annual occupational radiation dose limit as specified for adult occupational workers as specified in 4731.0124, subp. 1. For specific individual personnel monitoring requirements, see 4731.0130, subp. 1 A, (5).

Subp. 3. **Occupational dose to an embryo/fetus of a declared pregnant woman.**

A. The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem(5mSv). Records will be kept in accordance with 4731.0171, C.

B. The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 4731.0124, subp.3, A, above.

C. The dose to an embryo/fetus shall be taken as the sum of:

(1) the deep-dose equivalent to the declared pregnant woman; and

(2) the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

D. If the dose to the embryo/fetus is found to have exceeded 0.5 rem(5mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee or registrant shall be deemed to be in compliance with 4731.0124, subp. 3, A, above, of this section if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

E. Specific individual personnel monitoring requirements can be found in 4731.0130, subp. 1, A (6).

Subp. 4. **Occupational dose for a planned special exposure.** A licensee or registrant may

authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 4731.0124, subp. 1 provided that each of the following conditions is satisfied.

A. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

B. The licensee or registrant and employer, if the employer is not the licensee, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

C. Before a planned special exposure, the licensee or registrant ensures that the individuals involved are:

(1) informed of the purpose of the planned exposure;

(2) informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) individuals, whenever possible, who are without procreative potential and have low lifetime effective dose equivalents.

D. Prior to permitting an individual to participate in as planned special exposure, the licensee or registrant ascertains prior doses as required by 4731.0125, subp. 1, B, during the lifetime of the individual for each individual involved.

E. Subject to 4731.0125, subp.1, B, the licensee or registrant does not authorize a planned special exposure that would cause an individual to receive a dose from all planned exposures in excess of the limits to exceed:

(1) the numerical values of any of the dose limits in 4731.0124, subp.1, A, in any year; and

(2) five times the annual dose limits in 4731.0124, subp. 1, A, during the individual's lifetime.

F. The licensee or registrant submits and maintains records and written reports of the conduct of planned special exposure in accordance with 4731.0172, subp. 1.

G. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under 4731.0124, subp.1, A, but is to be included in evaluations required by 4731.0124, subp. 4, D and E.

H. Doses resulting from planned special exposures are included in the lifetime record of dose for each individual worker but are separately identified.

4731.0125 Determination of Occupational Dose For All Licensees and Registrants.

Subpart 1. **Determination of prior occupational dose.**

A. For each individual who is likely to receive in a year, an occupational dose requiring monitoring as specified in 4731.0125, subp. 2 the licensee or registrant must:

(1) determine the occupational radiation dose received during the current year; and

(2) attempt to obtain the records of cumulative occupational radiation dose.

B. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant must determine:

(1) the internal and external doses from all previous planned special exposures; and

(2) all doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

(3) in complying with the requirements of 4731.0125, subp.1, A, of this section, a licensee or registrant may:

(a) accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

(b) accept, as the record of cumulative radiation dose, an up-to-date part 4731.3004, 2, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

(c) obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if electronic media, or letter and if authenticity of the transmitted report cannot be established..

(d) the licensee or registrant must record the exposure history of each individual, as required by 4731.0125, subp.1, A, of this section, on a form found in 4731.3004, 3, or other clear and legible record, including all of the information required by the form. This information must show:

((1)) each period in which the individual received occupational exposure to radiation or radioactive material; and

((2)) must be signed by the individual who received the exposure.

((3)) for each period , the licencee or registrant receives reports, they shall use the dose shown in the report in preparing the form 4731.3004, 2 or equivalent.

((4)) for any period in which the licensee or registrant does not obtain a report, the licensee or registrant must place a notation on the form, indicating the periods of time for which data are not available.

(e) licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed as specified in the rules in this part in effect before the effective date of this rule. Further, occupational exposure histories obtained and recorded on form found in 4731.3004, 3, or equivalent before the effective date of this rule might not have included effective dose equivalents, but can be used in the absence of specific information on the intake of radionuclides by the individual.

(f) if the licensee or registrant is unable to obtain a complete record of an

individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

((1)) in establishing administrative controls under 4731.0124, subp.1, D, for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual; was engaged in activities that could have resulted in occupational radiation exposure; and

((2)) that the individual is not available for planned special exposures.

(g) the licensee or registrant shall retain the records on 4731.3004, 2, or equivalent until the commissioner terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the form for 4 years or until the next inspection by the commissioner, after the record us made. This included records required under the U.S. NRC standards for protection against radiation in effect prior to Jan. 1, 1994.

Subp. 2. **Conditions requiring individual monitoring of occupational external and internal doses.** Each licensee or registrant shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 4731.0124-4731.0126. As a minimum:

A. Each licensee must monitor occupational exposure to radiation from licensed or unlicensed radiation sources under the control of the licensee and must supply and require the use of individual monitoring devices by:

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 4731.0124, subp. 1,

(2) minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent on excess of 0.15 rem(1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem(5 mSv);

(3) declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv). All of the occupational doses in 4137.0124, subp. 1, continue to be applicable as long as the embryo/fetus dose limit is not exceeded.; and

(4) individuals entering a high or very high radiation area.

B. Each licensee must monitor as required in 4731.0125, subp.4, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, column 1 and 2, of 4731.3001, 1.

(2) minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 rem(1 m Sv); and

(3) declared pregnant women likely to receive, during the entire pregancy, a committed effective dose equivalent in excess of 0.1 rem(1 mSv).

Subp 3. **Compliance with requirements for summation of occupational external and**

internal doses.

A. If the licensee or registrant is required to monitor personnel under both 4731.0125, subp. 2, A and B, the licensee or registrant must demonstrate compliance with the dose limits by summing external and internal doses.

B. If the licensee is required to monitor personnel only under 4731.0125, subp. 2, B, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in 4731.0125, subp.3, B, of this section and conditions in 4731.0125, subp. 3, C and D, of this section. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

C. If the only intake of radionuclides is by inhalation, the total effective dose equivalent (TEDE) limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following does not exceed unity. The licensee shall calculated the TEDE by:

(1) the sum of the fractions of the inhalation ALI for each radionuclide; or

(2) the total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(3) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is considered significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T, and the committed dose equivalent, $H_{T,50,}$ per unit intake is greater then 10 percent of the maximum weighted value of H_{50}, or $W_T H_{T,50,}$ per unit intake for any organ or tissue.

D. If the only intake of radionuclides is by oral ingestion, the licensee must account for this intake and include it in demonstrating compliance with the limits only if the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI.

E. If the only intake of radionuclides is through wounds or absorption through the skin, the licensee must evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

Subp 4. **Determination of occupational internal exposure.**

A. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under 4731.0125, subp.2, take suitable and timely measurements of:

(1) concentrations of radioactive materials in air in work areas; or

(2) quantities of radionuclides in the body; or

(3) quantities of radionuclides excreted from the body; or

(4) combination of these measurements.

B. Unless respiratory protective equipment is used, as provided in 4731.0123, subp. 1,

or the assessment of intake is based in bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

C. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may:

(1) use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

(2) upon prior approval of the commissioner, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material for example aerosol size distribution or density; and

(3) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide as listed in 4731.3001, B, to the committed effective dose equivalent.

D. If the licensee chooses to assess intakes of Class Y material using the measurements given in 4731.0125, subp. 4, A, (2) or (3), the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required in 4731.0162 or 4731.0163, in order to permit the licensee to make additional measurements basic to the assessments.

E. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC- hours must be either:

(1) the sum of the ratios of the concentration to the appropriate DAC value, for example D, W, Y, from 4731.3001, B, for each radionuclide in the mixture; or

(2) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

F. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

G. When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

(1) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 4731.0125, subp. 1, and in complying with the monitoring requirements in 4731.0125, subp. 3, B; and

(2) the concentration of any radionuclide disregarded is less than 10 percent of its DAC ; and

(3) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

H. When determining the committed effective dose equivalent, the following information can be considered:

(1) in order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 sievert) , for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) when the ALI and the associated DAC are determined by the nonstochastic

organ dose limit of 50 rems (0.5 sievert), the intake of radionuclide that would result in a committed effective dose equivalent dose equivalent of 5 rem (0.05 sievert), the stochastic ALI, as listed in parentheses in Table 1 of 4731.3001, B. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee must also demonstrate that the limit in 4731.0124, subp. 1, A, (1), (b), is met.

Subp. 5. **Determination of occupational external dose from airborne radioactive material.**

A. Licensees must, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud as in footnotes 1 and 2 for 4731.3001, B.

B. Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

4731.0126 Dose Limits For The Public

All licensees and registrants must comply with the dose limits for the public as listed in this rule.

Subpart 1. **Dose limits for individual members of the public.**

A. Each licensee and registrant shall conduct operations so that:

(1) the total effective dose equivalent (TEDE) to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, from any medical administration of individual has received, from exposure to individuals administered radioactive material and released in accordance with 4731.1204, subp.2, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 4731.0136, subp. 3, and

(2) the dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 4731.1204, subp.2, does not exceed 0.002 rem(0.02 millisievert) in any one hour.

B. If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

C. A licensee or registrant or an applicant for a license or registration may apply for prior authorization from the commissioner to operate up to an annual dose limit for an individual member of the public or 0.5rem (5 mSv) . The licensee or registrant or an applicant for a license or registration shall include the following information in this application:

(1) demonstration of the need for and the expected duration of operations in excess of the limit in 4731.0126, subp. 1, A, above;

(2) the licensee's or registrant's program to assess and control dose within the 0.5

rem (5mSv) annual limit; and

(3) the procedures to be followed to maintain the dose as low as is reasonably achievable (ALARA).

D. In addition to the requirements of 4731.0124- 4731.0126, a licensee or registrant subject to the provisions of U.S. Environmental Protection Agency (U.S. EPA) generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

E. The commissioner may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

Subp 2. **Compliance with dose limits for individual members of the public.** The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 4731.0126, subp. 1.

A. A licensee or registrant shall show compliance with the annual dose limit in 4731.0126, subp. 1 by:

(1) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit: or

(2) demonstrating that:

(a) for radioactive materials the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in 4731.3001, B, Table 2.

(b) if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

B. Upon approval from the commissioner, the licensee or registrant may adjust the effluent concentration values in 4731.3001, B, Table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents for example aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form.

4731.0127. Radiation Safety Officer Requirements For All Facilities. Each licensee or registrant shall:

A. Appoint an individual as radiations safety officer (RSO) who is responsible for and has the authority for the implementation of the radiation safety program.

B. Recognize that the RSO shall serve as a contact with the commissioner for events such as a loss, theft or damage of radioactive material or radiation producing equipment, including x-ray equipment and generally licensed devices.

C. Ensure that the RSO meets the training and experience requirements in 4731.0128, subp. 1 and additional requirements for their specific license or registration.

D. Ensure that radiation safety activities are performed using approved procedures and

regulatory requirements in the daily operation of the licensee's or registrant's radiation safety program through the RSO.

4731.0128 Radiation Safety Officer Training and Experience

Subpart 1. **General requirements for all facilities.**

A. The licensee or registrant shall ensure that the RSO :

(1) is qualified by training and possesses the knowledge and experience concerning all hazards and precautions in operating or using the sources for which the RSO is responsible;

(2) has the knowledge and experience to perform radiation safety surveys;

(3) has the knowledge and experience to provide instructions to individuals on hazards and safety practices;

(4) has the knowledge and experience to obtain documentation on safety and equipment performance required in this chapter.

B. When, in the opinion of the commissioner of health, the individual designated to be responsible for radiation safety does not have qualifications sufficient to ensure safe operation or use of the source, the commissioner of health may require the licensee or registrant to designate another individual who meets the requirements of this item.

Subp. 2. **Industrial radiography facilities using radioactive material**. In addition to subp.1 of this part, the industrial radiography facility RSO training requirements are:

A. Completion of the training requirements of 4731.0152, subp. 1 and 2;

B. 2000 clock-card hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

C. Formal training in the establishment and maintenance of a radiation protection program.

D. The commissioner will consider alternatives when the RSO has appropriate training and/or experience in the field of radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

Subp. 3. **Industrial irradiator facilities.** In addition to subp.1 of this part, the irradiator facility RSO training requirements are:

A. Training on the transfer of radioactive materials;

B. Training on the transport of radioactive materials including the packaging types;

C. Training on effects of large doses of radiation to humans; and

D. At least three months, full-time equivalent, of experience at the applicant's irradiator or at another irradiator of a similar type. The three months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

Subp. 4. **Well logging facilities**. In addition to subp.1 of this part, the well logging facilities RSO training requirements are:

A. Training on handling and transfer of radioactive materials;

B. Training on leak testing radioactive sources;

C. Monitoring of the environment in case of an accident; and

D. On-the-job training:

(1) 160 hours for a mineral logging licensee or a licensee using sealed sources with activities less than 500 millicuries

(2) 3 months or 520 hours for gas or oil well logging operations using sealed sources with activities greater than 500 millicuries.

Subp. 5. **Accelerator and cyclotron (PET) facilities**. In addition to subp. 1 of this part, the accelerator and cyclotron facility RSO training requirements are:

A. Training in proper room ventilation and stack monitoring;

B. Training on handling and transport of radioactive materials including packaging types; and

C. Training on monitoring the surrounding environment.

Subp 6. **Sealed and unsealed sources in industrial and research facilities**. In addition to subp.1 of this part, the sealed and unsealed industrial and research facilities RSO training requirements are:

A. Training on the handling and transfer of radioactive sources;

B. Training on leak testing of the radioactive sources;

C. Training on decontamination procedures, both area and personnel;

D. Training on stack or vent monitoring; and

E. Training on environmental monitoring.

Subp. 7. **Healing arts facilities that use radioactive materials**, except as provided in 4731.0152, subp 8, the licensee shall require an individual fulfilling the responsibilities of Radiation Safety Officer as provided in 4731.1201, subp. 1 to be an individual who:

A. Is certified by a speciality board whose certification process includes all of te requirements in 4731.0152, subp.7.B, below, and whose certification has been recognized by the commissioner, NRC or an agreement state; or

B. Has completed a structured educational program consisting of:

(1) 200 hours of didactic training in the following areas:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radioactivity;

(d) radiation biology;

(e) radiation dosimetry; and

(2) one year of full time radiation safety experience under the supervision of the individual identified as the RSO on a commissioner's,. NRC or agreement state license or permit issued by the commissioner master material licensee that authorizes similar type(s) of use of radioactive material involving the following:

(a) shipping, receiving, and performing related radiation surveys;

(b) using and performing checks for proper operation of instruments used to measure radionuclides;

(c) securing and controlling radioactive material;

(d) using administrative controls to avoid mistakes in the administration of radioactive material;

(e) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(f) using emergency procedures to control radioactive material; and

(g) disposing of radioactive material; and

(3). has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 4731.0128, subp 7, B, (1) and (2), above, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

C. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use by radioactive material for which the individual has RSO responsibilities.

Subp. 8. **Healing arts facilities using x-ray** shall follow the training and experience requirements found in subp. 1.

4731. 0129. Radiation Safety Officer Duties

Subpart 1. **General requirements for all facilities**, shall include but are not limited to the following:

A. The radiation safety officer shall promptly investigate, implement corrective actions and provide a written report to management, as necessary regarding:

(1) overexposures;

(2) losses;

(3) thefts;

(4) other deviations from approved radiation safety practice.

(5) accidents;

(6) spills;

(7) unauthorized receipts for radioactive materials

(8) medical events

B. The radiation safety officer shall establish and implement written policies and procedures of the licensee or registrant to ensure that:

(1) radiation sources and radiation producing equipment are used only by individuals who are authorized by the licensee or registrant in accordance with Chapter 4731;

(2) personnel who work in or frequent areas where radiation sources and or radiation producing equipment are used or stored are properly trained;

(3) all individuals wear individual monitoring devices as required in 4731.0125, subp. 2.

(4) radiation sources and radiation producing equipment are used safely;

(5) radiation safety surveys, equipment performance evaluations and quality control tests are performed at the required frequency, repairs completed on equipment and x-ray processors, are documented and any corrective actions needed are taken;

(6) appropriate emergency actions are taken if control of a radiation source or radiation producing equipment is lost;

(7) radiation sources and radiation producing equipment are transferred or disposed of properly;

(8) an inventory record of radiation sources and radiation producing equipment is kept;

(9) checks and calibration of radiation safety survey instruments and other safety equipment are performed at required frequency

(11) authorize the purchase of radioactive material or radiation producing equipment;

(12) radioactive materials and radiation producing equipment are stored properly and secured against unauthorized access or removal

(13) sealed sources are leak tested at the required times and as prescribed by the manufacturer or by the license;

(14) radioactive material packages are received and opened properly;

(15) individual monitoring devices are calibrated appropriately; and

(16) copies of all records and reports required by the commissioner, a copy of each licensing request and license including amendments, registration and the written policies and procedures required by these regulations are kept.

C. The RSO must review at least quarterly the occupational radiation exposure records of all personnel working with radiation.

D. The RSO must ensure that all personnel read and understand the licensee's or registrant's emergency, operating and radiation safety procedures.

E. The RSO must establish and oversee all operating, emergency, and ALARA procedures as required by 4731.0120-4731.0136 of this chapter, and reviewing them regularly to ensure that the procedures in use conform to current rule and to the license conditions or registration.

F. Ensure that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

G. Implement the "as low as reasonably achievable" requirement of 4731.0131, subp. 1, B, and notwithstanding the requirements of 4731.0126, subp. 1, a constraint of air emissions of radioactive material to the environment, excluding radon-222 and its daughters, must be established by licensees other than those subject to 10 CFR 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement, exceeds this dose constraint, the licensee shall report the exceedance as provided in 4731.0163 and promptly take appropriate corrective action to ensure against recurrence.

Subp 2. **Industrial radiography facilities that use radioactive materials.** In addition to subp. 1, RSO duties for industrial radiography are as follows:

A. Oversee and approve all phases of the training program for radiographic personnel;

B. Ensure that appropriate and effective radiation protection practices are taught;

C. Ensure that:

(1) required radiation surveys and leak tests are performed and documented in accordance with the regulations,

(2) all corrective measures made when levels of radiation exceed established limits are included in the documentation; and

D. Ensure that:

(1) individual monitoring devices are calibrated and used properly by occupationally exposed personnel,

(2) records are kept of the monitoring results, and

(3) timely notifications are made as required by 4731.0163.

Subp. 3. **Industrial irradiator facilities.** In addition to subp.1, RSO duties are:

A. Review and approve revisions to the operating and emergency procedures;

B. Review additional personnel monitoring and environmental monitoring needs; and

C. Check security measures

Subp. 4. **Well logging facilities.** In addition to subp. 1, RSO duties are:

A. Check containment of sources;

B. Review transport of sources;

C. Decontaminate following an accident;

D. Calculate exposure to the public following an accident;

E. Act in an advisory capacity to the licensee's management and logging personnel; and

F. Ensure proper handling and transfer of radionuclides.

Subp. 5. **Accelerator and cyclotron (PET) facilities**. In addition to subp.1, RSO duties are:

A. Ensure that proper vent monitoring is done, if applicable;

B. Ensure proper handling and transfer of radionuclides;

C. Ensure that proper laboratory and quality control procedures are used; and

D. Authorize the bypassing of interlocks and safety controls when required.

Subp. 6. **Sealed and unsealed sources in industrial and research facilities**. In addition to subp.1, RSO duties are:

A. Approve and sign leak test records;

B. Approve and sign inventory records

C. Tracking of the institutional review board approvals for research under 21 CFR, 56 or title 45, part 46.

Subp. 7. **Healing arts facilities using radioactive material.** Additional requirements for the RSO in facilities using radioactive materials are found in 4731.1200- 4731.1299.

4731.0130 Individual Monitoring Requirements

Subpart 1. **General requirements for all facilities**

Each licensee or registrant must monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the dose limit requirements in 4731.0124- 4731.0126.

A . Each licensee or registrant must supply their personnel specified in subitems 1 to 6, below, with NVLAP-accredited individual monitoring devices and require the personnel to wear the monitoring device.

(1) each individual who enters a radiation area or restricted area under such circumstances that the individual receives, or is likely to receive, a dose in any calendar quarter from sources external to the body, over 10 percent of the limit in 4731.0124, subp.1.

(2) each individual who enters a high radiation area or very high radiation area.

(3) all veterinarians and their staff who are being occupationally exposed during a radiation procedure must be provided a personal monitoring dosimeter according to Minnesota Statutes, section 144.121, subdivision 4.

(4) all individuals using industrial radiation sources.

(5) minors likely to receive in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremeties in excess of 0.5 rem(5 mSv);

(6) each declared pregnant woman likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1mSv). The licensee or registrant must provide the pregnant individual with an individual monitoring device to be worn at the level of the abdomen and under any lead shield worn. The dose to the embryo/fetus must comply with 4731.0124, subp 3;

B. Each licensee must monitor, as required in 4731.0125, subp. 4, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in 4731.3001, b, Table 1, columns 1 and 2;

(2) minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem(1 mSv); and

(3) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem(1 mSv).

C. Each NVLAP-accredited individual monitoring device must be:

(1) assigned to and worn by only one employee;

(2) replaced at the frequency recommended by the processor; and

(3) promptly processed after replacement.

D. When protective clothing is worn and individual monitoring devices are required, at least one such device shall be worn, according to subitems 1 and 2.

(1) when a protective apron is worn, the individual monitoring device shall be worn at the collar outside of the protective apron.

(2) when more than one individual monitoring device is used, the record must identify the location of the monitor on the body and must state whether it was worn outside or under the protective clothing. The effective dose equivalent shall be recorded in the reports required by 4731.0171.

D. The control monitoring device which accompanies personnel monitoring dosimeters during shipment must be obtained and kept in an area of natural background radiation at the

facility between shipments.

E. All individual monitoring devices, except for direct and indirect read pocket ionization chambers and those dosimeters used to measure the dose to the extremities, that require processing to determine the radiation dose and that are used by licensees or registrants comply with 4731.0124, subp. 1, with other applicable provisions of 4731.0124-4731.0126, or with conditions specified in a license or registration, must be processed and evaluated by an individual monitoring device processor:

(1) holding current individual monitoring devices accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP); and

(2) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(3) the licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

Subp 2. **Individual monitoring notifications and reports for all facilities**

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

(1) the information reported must include data and results obtained pursuant to Chapter 4731, orders or license conditions, as shown in records maintained by the licensee or registrant.

(2) each notification and report to the individual must:

(a) be in writing;

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

(c) include the individual's exposure information;

B. Each licensee or registrant must advise each worker quarterly of the worker's dose as shown in records maintained by the licensee or registrant pursuant to the provisions of Chapter 4731.0171.

C. Reports received from the NVLAP-accredited individual monitoring device processor must be retained in accordance with 4730.0171.

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

(1) as shown in records maintained by the licensee or registrant pursuant to 4731.0171 for each year the worker was required to be monitored under the provisions of 4731.0125, subp. 2

(2) 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 or registrant, whichever is later.

(3) this report must cover the period of time that the worker's activities involved exposure to radiation or from radioactive material licensed or registered by the commissioner and

must include the dates and locations of licensed or registered activities in which the worker participated during this period.

E. When a licensee or registrant is required by 4731.0163 to report to the commissioner any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted no later than the transmittal to the commissioner and shall comply with the provisions of 4731.0160-4731.0165.

F. End of employment. A licensee or registrant must furnish to a worker who is terminating employment, or to a worker who, while employed by another person, is terminating a work assignment involving radiation dose in the licensee or registrant's facility within a calendar quarter, a report of the worker's dose of radiation . The report must be furnished within 30 days from the time of termination of employment or within 30 days after the exposure of the worker has been determined by the licensee or registrant. The report must cover each calendar quarter in which the worker's activities involved exposure to radiation sources and must include the dates and locations of work under the licensee or registrant in which the worker participated.

Subp. 3. **Individual monitoring requirements for industrial facilities.** In addition to the requirements in subp.1, industrial radiography and accelerator facilities are required to comply with the following items:

A. If a NVLAP-accredited individual device is lost or damaged, the worker must cease work immediately until a replacement NVLAP-accredited personnel device is provided and the dose is calculated for the time period from issuance to loss or damage of the NVLAP-accredited personnel device.

B. The licensee or registrant must not permit an individual operate the equipment unless the individual wears a direct read pocket dosimeter at all times during operations. The following are the requirements for direct read dosimeters:

(1) direct read pocket dosimeters must have a range from zero to 200 milliroentgens (5.16 x 10-5 C/kg).

(2) if a direct read pocket dosimeter is reassigned each day or shift, the direct read pocket dosimeter must be read and recharged daily or at the start of each shift.

(3) if a direct read pocket dosimeter is assigned to only one employee, the direct read pocket dosimeter must be read and recharged when there is a 50 percent elevation in the radiation reading.

(4) direct read dosimeters must be read and the exposures recorded at the beginning and end of each shift

(5) direct read pocket dosimeters must be checked for correct response to radiation at periods not to exceed one year.

(a) acceptable direct read pocket dosimeters must read within plus or minus 20 percent of the actual radiation exposure.

(b) records of the response to the radiation check must be maintained according to 4731.0169, subp. 7.

(6) if an individual's direct read pocket dosimeter is discharged beyond its range, operations by that employee must cease and the employee's NVLAP-accredited personnel dosimeter must be processed immediately. The individual may not return to work with sources

of radiation until a determination of the radiation exposure has been made by the radiation safety officer.

C. In addition, the licensee or registrant must not permit an individual to operate portable industrial radiography equipment or accelerators, unless the individual wears an alarming ratemeter at all times during operations. To ensure correct response to radiation, each alarming ratemeter must:

(1) be tested before use at the start of each shift to ensure that the alarm sounds;

(2) be set to sound at a pre-set exposure rate of 500 mR/hr (1.29 x 10-4 C/kg/hr);

(3) require special means to change the pre-set alarm function;

(4) be calibrated at periods not to exceed one year;

(5) alarm, vibrate, activate a light, or otherwise signal within plus or minus 20 percent of the true radiation exposure rate; and

(6) have records of the tests and calibrations maintained according to 4731.0169, subp. 7.

4731.0131 Radiation Safety Programs

Subpart 1. **General requirements for all facilities**. Each licensee or registrant shall develop, document in accordance with 4731.0169, and implement a radiation safety program commensurate with the scope and extent of licensed or registered activities and sufficient to ensure compliance with the rules below.

A. Each licensee or registrant must have a radiation safety program in place. This program shall ensure that the policies, procedures, reviews, corrective actions, training, notifications, reports and records are all in accordance with this Chapter. The program shall be site-specific.

B. The licensee or registrant shall use to the extent practicable procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as reasonably achievable(ALARA),

C. The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

D. The licensee shall use to implement the ALARA requirement of subp. 1, B, above, and notwithstanding the requirements in 4731.126, subp. 1, a constraint on air emissions or radioactive material to the environment, excluding Radon-222, and its daughter, must be established by licensees such that:

(1) the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem(0.1 mSv) per year from these emissions.

(2) if the licensee exceeds this dose constraint, the licensee must report the amount of overdose as required by 4731.0163, and

(3) prompt corrective action is taken to ensure against recurrence.

Subp. 2. **Control of access to high radiation areas**

A. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(1) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (l mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

(2) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) entryways that are locked except during periods when access to the areas is required, with positive control over each individual entry.

B. In place of the controls required by 4731.0131, subp. 1, A, above, for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

C. A licensee or registrant may apply to the commissioner for approval of alternative methods for controlling access to high radiation areas.

D. The licensee or registrant must establish the controls required by 4731.0131, subp. 2, A and C, above, in a way that does not prevent individuals from leaving a high radiation area.

E. Control is not required for each entrance or address point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation (DOT) provided that:

(1) the packages do not remain in the area longer than 3 days; and

(2) the dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

F. Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that:

(1) there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in 4731.0124 - 4631.0126; and

(2) there are personnel to operate within the ALARA provisions of the licensee's or registrants radiation protection program.

G. When a high or very high radiation area is established for 30 calendar days or less, direct surveillance to prevent unauthorized entry may be substituted for the devices required by this subpart.

Subp 3. **Control of access to very high radiation areas**
In addition to the requirements in 4731.0131, subp. 2, the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in 1 hour at 1 meter from a radiation source or any surface through which the radiation penetrates.

Subp 4. **Healing arts facilities using radiation producing equipment including x-ray.**
In addition to requirements in subp. 1, the licensee or registrant shall include as part of their radiation safety program, must maintain on the premises the following information for each x-

ray system and accelerator for inspection by the commissioner.

(1) the maximum rating of the x-ray tube and generator.

(2) the manufacturer and serial numbers or other permanent identification number of the control console and x-ray tubes.

(3) for diagnostic x-ray systems, the half-value layer of the x-ray beam and the kVp at which the half-value layer was measured.

(4) for diagnostic and therapeutic x-ray systems, records of site-specific radiation safety surveys, radiation leakage measurements, calibrations, equipment performance measurements, maintenance, and equipment modifications performed on the sx-ray system with the names of individuals who performed the services.

(5) mammographic image retention. All mammography images must be retained as required by the Mammography Quality Standards Act of 1992, United States Code, title 42, section 263b, and regulations adopted thereunder.

(6) current copies of delegation agreements form for physicians assistants, and registered physician assistants must be available at the time of inspection by the commissioner. Each delegation agreement must be signed by all supervising physicians.

(7) each facility doing radiographic and fluoroscopic imaging procedures, except dental procedures, must keep a record of the following information:

(a) age of patient, if under age 18;

(b) imaging procedures performed; and

(c) name or initials of person performing the imaging procedure.

4731.0132 Radiation Safety Surveys

Subpart 1. **General Requirements for all facilities**

A. Each licensee or registrant conducting procedures using radiation producing equipment or radioactive materials including source material, special nuclear and NARM must ensure that the radiation safety surveys specified below must be:

(1) site-specific;

(2) performed using calibrated and operational survey instruments in accordance with 4731.0133;

(3) performed at the time of initial installation and after any change in the facility or equipment which might cause a change in radiation hazard.

B. The radiation safety survey for all facilities must include the following:

(1) maintenance and equipment modifications;

(2) shielding plans at installation and when change occurs in shielding, operation or equipment and results from radiation shielding evaluations;

(3) cover any potential radiological hazards that could be present; and

(4) insurance that the surveys were performed according to written procedures established by the radiation safety officer and are in accordance with chapter 4731.

C. If the radiation safety survey results are not in compliance with this chapter, corrective action must be taken and documented.

D. A report of each survey must be prepared, maintained at the facility according to the record requirements in 4731.0169, subp.2, and made available to the commissioner on request.

Subp. 2. **Requirements for all facilities using radioactive material.**

A. In addition to the requirements in subp. 1, the radiation safety survey for facilities using radioactive materials must include the following:

(1) information that may be necessary for the licensee or registrant to comply with the regulations in 4731.0120-4731.0141;

(2) are reasonable under the circumstances to evaluate:

(a) the magnitude and extent of the radiation levels; and

(b) concentrations or quantities of radioactive material.

B. The licensee or registrant must maintain the following records until the commissioner terminates each pertinent license requiring the record:

(1) survey results used to determine the dose from external sources of radiation used in the assessment of the individual dose equivalents in the absence of or in combination with individual monitoring data;

(2) measurement and calculation results used to determine individual intakes of radioactive material and used in the assessment of internal dose.

(3) air sampling, surveys, and bioassays results required in 4731.0123, subp. 1, A, (3), (a) and (b); and

(4) measurements and calculation results used to evaluate the release of radioactive effluents to the environment. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994 must be included.

Subp. 3. **Requirements for facilities using radiation producing equipment, including x-ray.**

In addition to the requirements in subp.1, the radiation safety survey for facilities using radiation producing equipment must include the following:

A. An evaluation of tube housing or source integrity;

B. Equipment calibrations; and

C. Equipment performance measurements.

4731.0133 Requirements For Radiation Safety Survey Instrument Calibration.

Subpart 1. **Requirements for all facilities.** Each radiation survey instrument and any electronic equipment used in radiation safety surveys and in equipment performance tests must be calibrated in a manner traceable to the standard at the National Institute of Standards and Technology (NIST) after each servicing, except for battery changes. The requirement for traceability includes the sensitometer and densitometer equipment used in processing quality assurance testing. Until such time that there is a NIST standard for noninvasive kVp meters, the meters must be returned to the manufacturer for calibration or to an accredited calibration laboratory.

Subp 2. **Industrial facilities.**

A. In addition to subp.1, for industrial facilities that use radioactive materials, to ensure

correct response to radiation, each radiation survey instrument must:

(1) be calibrated:

(a) at energy levels and over a range appropriate for the use;

(b) to an accuracy within plus or minus 20 percent over the applicable range of the instrument;

(c) for linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 2 and 1000 millirems (0.02 and 10 millisieverts) per hour;

(2) for portable industrial radiography and well logging equipment, at periods not to exceed six months;

(3) for equipment other than portable industrial radiography and well logging equipment, at periods not to exceed one year; and

(4) be of a type that does not saturate and read zero at high radiation dose rates

(5) have records of the calibrations maintained according to 4731.0169, subp. 3.

B. In addition to subpart 1, for industrial facilities that use radiation producing machines, each radiation survey instrument must be calibrated:

(1) for portable industrial x-ray equipment, at periods not to exceed six months;

(2) for equipment other than portable industrial x-ray equipment, at periods not to exceed one year; and

(3) after each servicing;

(4) at energy levels and over a range appropriate for the use;

(5) to accuracy within plus or minus 20 percent over the applicable range of the instrument; and

(6) have records of the calibrations maintained according to 4730.0169, subp. 3.

Subp. 3. **Industrial irradiator facilities.** In addition to subp.1, the pool water conductivity meter calibrations required by 4731.0706, subp. 2 must be kept for 4 years or until the next inspection by the commissioner.

4731.0134 Leak Testing Requirements

Subpart 1. **All facilities using radioactive material, including medical facilities.**

A. A licensee or registrant in possession of a sealed source must assure that:

(1) the sealed source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the sealed source was tested semiannually before transfer to the licensee or registrant;

(2) the sealed source that is not designed to emit alpha particles is tested for leakage or contamination at least semiannually or at intervals approved by the commissioner;

(3) each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at intervals approved by the commissioner;

(4) leak tests are capable of detecting 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon of 0.001 microcurie

(37 Bq) each 24 hours;

(5) if there is reason to suspect that a sealed source has been damaged, it must be tested for leaks before further use.

(6) when a sealed source is removed from storage for use or transfer to another person, and has not been tested in the past six months, the sealed source must be tested before use or transfer.

(7) a sealed source or detector cell must not be stored for a period of more than ten years without being tested for leakage or contamination.

(8) tests for contamination from radium daughters must be taken on the interior surface of source storage containers and must be capable of detecting the presence of 0.005 microcurie (185 Bq) of a radium daughter which has a half-life greater than four days.

(9) test samples are taken from the sealed sources or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(10) device test samples are taken when the sealed source is in the off or shielded position.

(11) leak tests are analyzed by individuals who are licensed by the commissioner, U.S. NRC, an agreement state or a licensing state to perform leak test services.

B. A licensee or registrant must retain leak test records for 4 years or until the next inspection by the commissioner, in accordance with 4731.0180, B. The records must contain:

(1) the manufacturer's name;

(2) the model and serial numbers of each sealed source tested;

(3) the identity of each sealed source radionuclide and its estimated activity;

(4) the measured activity of each test sample expressed in microcuries (becquerels);

(5) the date of the test; and

(6) the signature of the radiation safety officer or designee.

C. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee must:

(1) immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with these regulations; and

(2) file a report with the commissioner within 5 days of receiving the leak test results, and the action taken.

D. A leak test is not required on the following sealed sources:

(1) sealed sources containing only radioactive material with a half-life of less than 30 days;

(2) sealed sources containing only radioactive material as a gas;

(3) sealed sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; and

(4) sealed sources that are listed on a license from the commissioner for storage only.

Subp 2. **Healing arts facilities using x-ray equipment**

A. The leakage radiation from the diagnostic source assembly measured at a distance of one meter (39.4 inches) in any direction form the source must not exceed 100 mR (25.8uC/kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches)

B. The radiation emitted by a component other than the diagnostic source assembly must not exceed two mR (0.516 uC/kg) in one hour at five centimeters(1.97 inches) from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance must be determined by measurements average over an area of 100 square centimeters 915.5 square inches) with no linear dimension grater than 20 centimeters (7.9 inches).

4731.0135 Storage and Control of Licensed or Registered Sources of Radiation

Subpart 1. **Security of stored sources of radiation and gauges** The licensee or registrant shall secure from unauthorized removal or access licensed or registered radiation sources that are stored in controlled or unrestricted areas.

Subp. 2. **Control of Sources of Radiation Not In Storage** The licensee or registrant shall control and maintain constant surveillance of licensed or registered radioactive material that is in a controlled or unrestricted area and that is not in storage.

4731.0136 Waste Management For Radioactive Material Facilities.

Subpart 1. **General requirements.**

A. A licensee or registrant shall transfer, dispose, discharge, or decay licensed material only:

(1) by transfer to an authorized recipient as specified in 4731.0136, subp. 5 or in 4731.0300- 4731.0320 of these regulations or to the U.S. Department of Energy;

(2) by decay in storage;

(3) by release in effluents within the limits in 4731.0126, subp. 1; or

(4) as authorized in this subpart.

B. A person shall be specifically licensed to receive waste containing licensed material from other persons for:

(1) treatment prior to disposal;

(2) treatment by incineration;

(3) decay in storage;

(4) disposal at a licensed land disposal facility; or

(5) storage until transferred to a storage or disposal facility authorized to receive the waste.

Subp 2. **Method of obtaining approval of proposed disposal procedures**

A licensee, registrant or applicant for a license may apply to the commissioner for approval of proposed procedures, not otherwise authorized in the 4731.0136 of these regulations, to dispose of licensed material generated in the licensee's activities. Each application must

include:

A. A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and

B. An analysis and evaluation of pertinent information on the nature of the environment; and

C. The nature and location of other potentially affected licensed and unlicensed facilities; and

D. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in 4731.0124-4731.0126.

Subp 3. **Disposal by discharge into sanitary sewerage or by incineration**

A. A licensee or registrant may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) the material is readily soluble, or is readily dispersible biological material, in water; and

(2) the quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer age by the licensee does not exceed the concentration listed in 4731.3001, B, Table 3; and

(3) if more than one radionuclide is released, the following conditions must also be satisfied:

(a) the licensee must determine the fraction of the limit in 4731.3001, B, Table 3, represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the license into the sewer by the concentration of that radionuclide listed in 4731.3001, B, Table 3; and

(b) the sum of the fractions for each radionuclide required by 4731.0136, subp. 3, A, (3), (a), above, does not exceed unity; and

(4) the total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (185 GBq) of all other radioactive materials combined.

B. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 4731.0136, subp. 3, A, above.

C. A licensee may treat or dispose of licensed material by incineration only:

(1) as authorized in 4731.0136, subparts 4 and 7;

(2) if the material is in a form and concentration specified in 4731.0136, subp. 4;

(3) as specifically approved by the commissioner pursuant to 4731.0136, subp. 2.

Subp 4. **Disposal of specific wastes**

A. A licensee may dispose of the following licensed material as if it were not radioactive:

(1) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 0.05 microcurie(1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

B. A licensee may not dispose of tissue under 4731.0136, subp. 4, A, (2), above, in a manner that would permit its use as either food for humans or as animal feed.

C. The licensee shall maintain records in accordance with 4731.0184.

Subp 5. **Transfer for disposal and manifests**

A. The requirements of this section and 4731.3001, G, are designed to:

(1) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in 4731.0100, who ships low-level waste either directly or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in 4731.0100.

(2) establish a manifest tracking system, and

(3) supplement existing requirements concerning transfers and record keeping for those wastes.

B. Each licensee shipping radioactive waste intended for ultimate disposal a licensed low-level radioactive waste disposal facility must document the information required in 4731.3004, 12, and transfer this recorded manifest information to the intended consignee in accordance with 4731.3001, G.

C. Each shipment manifest must include a certification by the waste generator as specified in 4731.3001, G , section II

D. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, must comply with the requirements specified in 4731.3001, G, section III..

Subp 6. **Waste classification**

A. Classes of waste.

(1) Class A waste is waste that is usually segregated from other waste classes at the disposal site.

(a) the physical form and characteristics of Class A waste must meet the minimum requirements set forth in 4731.0136, subp. 7, A, it is not necessary to segregate the waste for disposal.

(b) if Class A also meets the stability requirements set forth in 4731.0136, subp, 7, B, it is not necessary to segregate the waste for disposal.

(c) if radioactive waste does not contain any nuclides listed in either Table 1 or 2, below, it is Class A.

(2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in 4731.0136, subp. 7.

(3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in 4731.0136,

subp. 7.

(4) waste that is not generally acceptable for near-surface disposal is waste for which form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this part, such waste must be disposed of in a geologic repository as defined in 10 CFR 60 unless proposals for disposal of such waste in a disposal site licensed pursuant to 4731.0136, subparts 1, 2, and 3, are approved by the commissioner

B. Determination of the classification of radioactive waste for near surface disposal involves the following considerations.

(1) consideration must be given to the concentration of long-lived radionuclides, and their shorter-lived precursors, whose potential hazard will persist long after such precautions as institutional controls. Improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure.

(2) consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(3) consideration must be given to the kind of long-lived radionuclides. If radioactive waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

(a) if the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.

(b) if the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.

(c) if the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.

(d) for wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions rule described in 4731.0136, subp. 6, C, below.

Table 1

Radionuclide	Concentration Curies per cubic meter
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic nuclides with half-life greater than 5 years. **	100

Pu-241	** 3,500
Cm-242	** 20,000

** Units are nanocuries per gram

(4) consideration must be given to short-lived radionuclides. If radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2.

(a) if the concentration does not exceed the value in Column 1, the waste is Class A.

(b) if the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste is Class B.

(c) if the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C.

(d) if the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

(e) for wastes containing mixtures of the nuclides listed in Table 2. The total concentration shall be determined by the sum of fractions rule described in 4731.0136, subp. 6, C, below.

Table 2

Radionuclide	Concentration, curies per cubic meter		
	Col 1	Col 2	Col 3
Total of all nuclides with less than 5 year half-life	700	***	***
H-3	40	***	***
Co-60	700	***	***
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

*** There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other nuclides in Table 2 determine the waste to be Class C independent of these nuclides.

(5) consideration must be given to the kind radioactive waste of long- and short-lived radionuclides. If radioactive waste contains a mixture of radionuclides, some of which are

listed in Table 1, and some of which are listed in Table 2, classification shall be determined as follows:

(a) if the concentration of a nuclide listed in Table 1 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of nuclides listed in Table 2.

(b) if the concentration of a nuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1 but does not exceed the value in Table 1, the waste shall be Class C, provided the concentration if nuclides listed in Table 2 does not exceed the value shown in Column 3 of Table 2.

(6) classification of wastes with radionuclides other than those listed in Tables 1 and 2. If the radioactive waste does not contain any nuclides listed in either Table 1 or Table 2, it is Class A.

C. The sum of the fractions for mixtures for radionuclides. For determining classification for waste that a contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each nuclides's concentration by the appropriate limit and adding the resulting value. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 Ci/m^3 and Cs-137 in a concentration of 22 Ci/m^3. Since the concentrations both exceed the values on Column1, Table 2, they must be compared to Column 2 values. For Sr-90 fraction 50/150 = 0.33; for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

D. Determination of concentration in waste. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of this waste, or weight of the waste if the units are expressed as nanocuries per gram.

Subp 7. **Waste characteristics**

A. The following requirements are minimum requirements for all classes of waste and are intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

(1) waste must not be packaged for disposal in cardboard or fiberboard boxes.

(2) liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of liquid.

(3) solid waste containing liquid must contain as little free standing and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

(4) waste must not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, of explosive reaction with water.

(5) waste must not contain, or be capable of generating, quantities of toxic

gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with 4731.0136, subp. 7, A, (7), below.

(6) waste must not be pyrophoric. Pyrophoric materials contained in waste must be treated, prepared, and packaged to be nonflammable.

(7) waste in a gaseous form must be packaged at a pressure that does not exceed 1.5 atmospheres at 20 degrees centigrade. Total activity must not exceed 100 curies(3.7 TBq) per container.

(8) waste containing hazardous, biological, pathogenic, or infectious material must be treated to reduce the maximum extent practicable the potential hazard from the non-radiological materials.

B. The requirements in 4731.0136, subp. 7 were intended to provide stability of the waste. Stability is intended to ensure that the waste does not structurally degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(1) waste must have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(2) notwithstanding the provisions in 4731.0136, subp. 7, A, (2) and (3), liquid wastes, or wastes containing liquid, must be converted into a form that contains as little free standing noncorrosive liquid as is reasonably achievable, but in no case must them liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

(3) void spaces within the waste and between the waste and its package must be reduced to the extent practicable.

Subp 8. **Labeling waste package** Each package of waste must be clearly labeled to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 4731.0136, subp. 6.

4731. 0137 General Shielding Requirements. The NCRP and ANSI standard reports in rule, 4731.0137- 4731.0141, are incorporated by reference, are not subject to frequent change, and are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system. The licensee or registrant must ensure that the applicable structural shielding requirements specified in 4731.0137 to 4731.0142 are met. If an analysis of operating conditions indicates the possibility of an individual receiving a dose over the limits in 4731.0124, subp. 1 and 4731.0126, the commissioner may require that structural shielding modifications be made.

A. Each installation where radiation is used shall be provided with such primary

barriers or secondary barriers as are necessary to ensure radiation safety. Each installation shall comply with the special shielding requirements applicable to the type of installation under consideration as specified in subsequent parts of this chapter.

(1) primary or secondary barrier requirements must be deemed to be met:

(a) if the thicknesses of such barriers are equivalent to those calculated in accordance with NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10 MeV," National Council on Radiation Protection and Measurements, September 15, 1976, and

(b) where applicable, ANSI N43.3-1993, "American National Standard for General Radiation Safety: Installations Using Nonmedical X-Ray and Sealed Gamma-Ray Sources, Energies up to 10 MeV," American National Standards Institute, January 28, 1993.

(2) an alternative to NCRP Report No. 49 is that the thickness of primary or secondary barriers be sufficient to limit the radiation exposure levels to below 1/10 of those stated in 4731.0124, subp. 1, and 4731.0126 whichever is applicable.

B. Lead barriers shall be mounted in such a manner that they will not sag or cold-flow because of their own weight and shall be protected against mechanical damage.

C. Joints between different kinds of protective materials shall be so designed that the overall protection of the barrier is not impaired.

D. Holes in protective barriers shall be covered so that the overall attenuation is not impaired.

E. Windows, window frames, doors, and door frames shall have the same lead equivalent as that required of the adjacent wall.

F. All records of shielding designs or results of safety surveys must be permanently kept at the facility and as described in 4731.0169, subp.2. Plans and specifications, along with assumptions and calculations on which the shielding design is based, must be continuously maintained at the facility.

G. All portable or mobile x-ray units, CT scanners, and therapy units must comply with the shielding requirements of this chapter.

4731.0138 General Shielding Requirements For Medical, Chiropractic, Podiatric, Osteopathic, and Veterinary Medicine Facilities.

Subpart 1. **Applicability.** This part applies to all medical, chiropractic, podiatric, osteopathic, and veterinary medicine facilities.

Subp. 2. **General shielding requirements for diagnostic radiographic facilities constructed or structurally remodeled six months after September 10, 1991.** For diagnostic radiographic facilities constructed or structurally remodeled six months after September 10, 1991, the requirements of this part apply. In addition, these facilities must meet the criteria for the particular type of installation as presented in:

A. NCRP Report Number 36, "Radiation Protection in Veterinary Medicine" (1970);

B. NCRP Report Number 38, "Protection Against Neutron Radiation" (1971);

C. NCRP Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to Ten MeV" (1976); and

D. NCRP Report Number 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

Subp. 3. **Requirements for lead or lead equivalent shielding for a diagnostic radiographic facility constructed or structurally remodeled six months after September 10, 1991.** The requirements specified in this subpart apply to a diagnostic radiographic facility constructed or structurally remodeled six months after September 10, 1991.

A. Sheet lead must be installed so it is supported to prevent cold flow.

B. All lead lining must extend to a height of seven feet (2.1 meters).

C. If the wall containing a door is shielded, the door must have the same lead equivalency as the adjoining walls.

D. All lead must be installed so that adjoining pieces of lead are overlapped by a minimum of one-half inch (1.3 centimeters). The shielding of the diagnostic radiographic room must be constructed so the protection is not impaired by joints; openings such as ducts and pipes passing through the barriers; or conduits or service boxes embedded in the barriers.

E. All protective barriers that attenuate the primary x-ray beam must be shielded as primary protective barriers. This includes, but is not limited to, areas of walls containing chest cassette holders and upright buckys.

Subp. 4. **Design requirements for a diagnostic radiographic facility.** For a diagnostic radiographic facility constructed or structurally remodeled six months after September 10, 1991, the design requirements specified in subparts 5 to 8 apply.

Subp. 5. **Space requirements for an operator's booth in a diagnostic radiographic facility**. The requirements in items A to D are required for an operator's booth in a diagnostic radiographic facility.

A. The operator must be allotted not less than 7.5 square feet (0.7 square meters) of unobstructed floor space in the operator's booth.

B. The operator's booth may be any geometric configuration provided no dimension is less than two feet (0.6 meters).

C. Space allocated for the operator's booth must exclude any space occupied by the x-ray control panel, including an overhang, cables, or other encroachments.

D. The booth must be located and constructed so the unattenuated direct scattered radiation originating on the examination or treatment table, or at the upright cassette position does not reach the operator's station in the booth and does not exceed the dose limits specified in 4730.0124, subp. 2

Subp. 6. **Structural requirements for an operator's booth in a diagnostic radiographic facility**. The requirements in items A to D apply to an operator's booth in a diagnostic radiographic facility:

A. The booth walls must be permanently fixed barriers of at least seven feet (2.1 meters) high.

B. The booth must not be used as a primary barrier.

C. When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which prevents the exposure when the door or panel is not closed.

D. Shielding must be provided to meet the requirements of 4731.0124 If a facility's workload does not exceed 100 milliampere-minutes per week and all walls in the diagnostic exposure room are shielded with a minimum of 1.6 millimeter lead (1/16th inch or four pounds per square foot) including the protective barrier, then it is not necessary to estimate the shielding requirements necessary to meet the requirements of 4731.0124.

Subp. 7. **X-ray control placement for an operator's booth in a diagnostic radiographic facility.** The x-ray control must be fixed within the booth so:

A. The exposure button is at least 39 inches (one meter) from any open edge of the control booth wall which is nearest to the examining table; and

B. The operator is able to use the full viewing window.

Subp. 8. **Viewing system requirements for an operator's booth in a diagnostic radiographic facility.** An operator's booth in a diagnostic radiographic facility must meet the requirements in items A and B.

A. A booth must have at least one viewing device which is placed so the operator:

(1) can view the patient during any exposure;

(2) has full view of any occupant of the room; and

(3) can view any entry into the room.

B. When the viewing system is a window, the requirements in subitems (1) to (4) apply.

(1) the window must have the same lead equivalency as the surrounding barrier.

(2) the viewing area must be at least eight inches (20.32 cm) by ten inches (25.4 cm).

(3) the booth must be designed so the operator's expected viewing position is at least 18 inches (0.46 meters) from the edge of the booth.

(4) in diagnostic radiographic facilities constructed or structurally remodeled after September 10, 1991, the minimum window size must be 24 inches high (0.61 meters) X 18 inches wide (0.46 meters) and placed on a five foot two inch (1.57 meters) center with the long dimension of the window in the vertical direction.

4731.0139 General Shielding Requirements for All Dental Radiographic Facilities

Subpart 1. **General requirements**. The structural shielding requirements in this subpart apply to all dental radiographic facilities.

A. Dental rooms containing intraoral radiographic systems must provide barriers at all areas struck by the useful beam. Shielding must meet the criteria in NCRP Report Number 35, "Dental X-Ray Protection," (1970).

B. When dental intraoral radiographic systems are installed in adjacent rooms or areas, protective barriers must be provided between the rooms or areas.

C. Each installation must be provided with a protective barrier for the operator or must be arranged so the operator can stand at least six feet from the patient and the tubehead and not

be in the path of the useful beam.

Subp. 2. **Requirements for new or structurally remodeled facilities**. Dental radiographic facilities constructed or structurally remodeled six months after September 10, 1991, must meet the shielding requirements in this part.

A. For an intraoral dental radiographic facility, the facility must meet the criteria in NCRP Report Number 35, "Dental X-Ray Protection," (1970).

B. For a facility using dental radiographic equipment for extraoral radiographs including but not limited to cephalometric, temporomandibular joint and panoramic radiographs, the general lead or lead equivalent shielding requirements in 4731.0138, subp. 2, apply. In addition, the facility must meet the criteria presented in NCRP Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to Ten MeV" (1976).

4731.0140 General Shielding Requirements For Therapeutic Facilities.

Subpart 1. **Applicability**. All therapeutic facilities must meet the criteria for the particular type of installation as presented in:

A. NCRP Report Number 38, "Protection Against Neutron Radiation" (1971);

B. NCRP Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to Ten MeV" (1976);

C. NCRP Report Number 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977);

D. NCRP Report Number 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range Ten keV to 50 MeV (1981);

E. NCRP Report Number 72, "Radiation Protection and Measurement for Low Voltage Neutron Generators" (1983);

F. NCRP Report Number 79, "Neutron Contamination from Medical Electron Accelerators (1984); and

G. NCRP Report Number 102, "Medical X-ray, Electron Beam and Gamma Ray Protection for Energies Up To 50 MeV (Equipment Design, Performance and Use)" (1989).

Subp. 2. **Shielding requirements for therapeutic systems and accelerators**. Each therapeutic x-ray system and accelerator system installed in a facility must be provided with primary and secondary barriers to ensure compliance with 4730.0124 - 4731.0129.

Subp. 3. **Facility design requirements for therapeutic x-ray systems with energies of 50 kVp and above.** Therapeutic x-ray systems with energies of 50 kVp and above:

A. Must have two-way audio communication between the patient and the operator at the control panel; and

B. Must provide for patient observation using:

(1) a closed circuit television system; or

(2) for systems with energies of 150 kVp or less, a window containing the appropriate lead equivalence so the operator at the control panel may directly observe the patient,

any other individual in the room, and any doorways into the room.

Subp. 4. **Additional requirements for therapeutic systems and accelerators with energies of 150 kVp and above**. In addition to the requirements specified in subp.3, therapeutic systems and accelerators with energies of 150 kVp and above must have protective barriers which are fixed except for entrance doors or beam interceptors and the control panel must be located outside the treatment room.

Subp. 5. **Additional requirements for accelerators in therapy systems**. In addition to the requirements specified in 4731.0140,subparts 3 and 4, facilities with an accelerator must meet the standards in items A to D.

A. Closed circuit television, or an equivalent system, must be provided to permit continuous observation of the patient during irradiation and must be located so the operator may observe the patient from the control panel.

B. Two-way audio communication between the patient and the operator must be provided at the control panel. However, where excessive noise levels or treatment requirements make audio communication impractical, other methods of communication must be used.

C. Treatment room entrances must be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is in the on position.

D. Interlocks or safety devices must be in place so all access into the room is blocked before treatment is initiated or continued. If the useful radiation beam is interrupted by any door opening or tripping of a safety device, it must not be possible to restore the system to operation without closing the door or resetting the safety device and reinitiating irradiation by manual action at the control panel.

4731.0141 General Shielding Requirements For Industrial X-ray, Accelerator, and Sealed Sources Radiography Facilities.

Subpart 1. **Applicability**. This part applies to all new construction and structural remodeling that commences on or after March 1, 1998. All registrants who possess industrial x-ray, industrial accelerator, and sealed source radiography facilities, except industrial cabinet, industrial cabinet baggage, portable industrial x-ray, and analytical radiation producing equipment, must meet the requirements of this part.

Subp. 2. **General shielding and design requirements**.

A. X-ray, sealed source radiography, and industrial accelerator facilities must be designed to meet the occupational dose criteria in 4731.0124.

B. The following documents or equivalent documents must be used in the design process:

(1) National Council on Radiation Protection, Report Number 38, "Protection Against Neutron Radiation" (1971);

(2) National Council on Radiation Protection, Report Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to

10 MeV" (1976); and

(3) National Council on Radiation Protection, Report Number 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

Subp. 3. **Shielding requirements; Class A and industrial accelerator facilities**. Class A stationary industrial radiation producing facilities and stationary accelerator facilities as described in 4731.0600, subp. 2, 4731.0602 and 4731.0900, subp. 1 must have fixed protective barriers, except for entrance doors or beam interceptors. The control panel must be located outside the radiography or accelerator room.

ADMINISTRATIVE PROVISIONS

4731.0150 Employee Qualifications.

Subpart 1. **Certified radiographers.** Industrial facilities using radioactive material must have industrial radiographers that are certified through a program meeting the requirements in 4731.3003, E.

Subp 2. X-ray operators in healing arts facilities using x-ray equipment.

] A. Applicability. Except for an individual licensed under Minnesota Statutes, Chapter147, 150A, or 153, or sections 148.01 to 148.106, and rules adopted thereunder, after January 1, 1997, an individual operating x-ray equipment for use on humans must pass an examination as specified in 4731.0150 supb.2, C-M

B. For the purpose of Chapter 4731 , "individual operating x-ray equipment on humans" means an individual who exposes humans to ionizing radiation by being directly involved with any part of the x-ray procedure from setting the equipment exposure factors through processing the x-ray.

C. Examination requirements. To be approved by the commissioner, an examination must test an individual's knowledge of:

(1) basic radiation safety;
(2) proper use of x-ray equipment;
(3) darkroom and film processing; and
(4) quality assurance procedures.

D. Examination approval. A set of examination questions based on the areas listed in subp. 2, C must be submitted to the commissioner for approval:

(1) at least 60 calendar days before the examination is held;
(2) before the initial examination is used; and
(3) whenever question content is changed or additional questions are added to the question pool.

E. Availability of examinations. An examination must be offered at least three times each calendar year.

F. Reporting examination results. Within 30 calendar days after an examination has been administered, a list of all individuals who have passed the examination and those who have failed the examination must be submitted by the organization administering the examination to the

commissioner.

G. Notice to individual. Written notice to the individual who took the examination on a specific date must be provided by the organization administering the examination within 30 calendar days:

(1) indicating whether the individual passed or failed the examination; and

(2) listing the areas in which the individual failed.

H. Examination security. The identity of an individual taking the examination must be verified by requiring a picture identification at the time of the individual takes the examination.

I. Passing level. The passing level for an examination must be 70 percent.

J. Closed book examination. An examination must be a closed book examination.

K. Validity standards. An examination must met validity standards for educational and psychological testing specified in the American Psychological Association's "Standards for Educational and Psychological Testing"(1996), The "Standards for Education and Psychological Testing" are incorporated by reference, are not subject to frequent change, and are available at the Minnesota State Law Library.

L. Examination questions. An examination must:

(1) consist of a t least 75 multiple choice questions;

(2) include the highest percent of questions on radiation safety; and

(3) vary and reorder questions each time an examination is held.

M. Examination content. An examination must adequately address the topic areas listed in subp.2, item C. Questions for each of the topic areas listed in subp. 2, item C must include the information specified in items (1)-(4):

(1) radiation safety, including:

(a) the biological effects of radiation:

((1)) somatic and genetic effects;

((2)) long-term and short-term effects;

(b) operator protection:

((1)) patient protection; and

((2)) gonad and room shielding and the use of lead aprons and gloves;

(c) beam restriction methods;

(d) personnel monitoring:

((1)) types of monitors available; and

((2)) how to wear monitors;

(e) dose:

((1)) maximum permissible dose for patient and operator; and

((2)) the concept of "as low as reasonably achievable" (ALARA);

(f) radiation terminology:

((1)) meanings; and

((b)) proper use;

(g) restraint and holding procedures and precautions;

(2) the proper use of x-ray equipment, including:

(a) radiographic equipment;

(b) the parts of the x-ray machine and x-ray tube;

(c) the electronics and physics of x-ray generation;
(d) grids and buckys;
(e) automatic exposure controls;
(f) identification of imaging failures;
(g) proper maintenance of x-ray equipment;
(h) image production;
(i) technique factors;
((1)) kVp, mA, mAs, time and distance;
((2)) function and interaction of kVp, mA, mAs, time; and
((3)) density, detail and contrast;
(j) cassettes and film compatibility; and
(k) technique conversion factors;

(3) darkroom and film processing, including:
(a) both automatic or manual chistry;
(b) fog
(c) temperature and time relationship;
(d) identification of artifacts;
(e) handling and storage of film, chemistry, and replenishing;
(f) safelights, types, wattage, and compatibility with film; and
(g) darkroom maintenance;

(4) quality assurance procedures, including:
(a) the importance of quality assurance procedures;
(b) how to do quality assurance procedures for sensitometry and densitometry , screen tests, and fog tests; and
(c) what corrective measures are appropriate.

Subp. 3. **Registrant requirements for facilities using x-ray equipment.**
A registrant in a facility with x-ray equipment used on humans must ensure that:

A. Only an individual who has met the requirements in 4731.0150, subp.2, A and B or 4731.0150, subp 4 is allowed to operate x-ray equipment; and

B. On request of the commissioner, written verification that the individual who operates x-ray equipment has met the requirements in 4731.0150, subp. 2, A and B or 4731.0150, subp. 4 is available for inspection.

Subp. 4. **Equivalent examinations.**

A. General. An individual shall be determined by the commissioner to have met the requirements in 4731.0150 subp.2 A and B if the individual has passed any of the examinations listed below.

B. Radiologic technologist registration examination. If an individual pas passed the radiography examination of the American Registry of Radiologic Technologists, the individual shall be determined to have met the requirements in 4731.0150, subp.2, A and B

C. Chiropractic radiologic technologist registration examination. If an individual has passed the radiography examination of the American Chiropractic Registry of Radiologic

Technologists, the individual shall be determined to have met the requirements in 4731.0150 subp. 2 A and B.

D. Radiologic technologist license from other Unites States jurisdictions. If an individual has passed a full or limited license examination in radiography from other United States jurisdictions, the individual may request that the commissioner review the license examination to determine if the license examination is equivalent to the examination described in 4731.0150 subp.2 A and B If the examination meets the requirements of 4731.0150 subp. 2 C-M, the individual shall be determined by the commissioner to have met the requirements of 4731.0150.

E. Other professional registrations. If an individual has passed a registration examination other than one specified in this part, or an examination not approved under 4731.0150, the individual may request a determination of equivalency according to the procedures and criteria in 4731.0107.

Subp. 5. **Individuals operating x-ray equipment during training.**

A. Exemptions from x-ray machine operator's exam. An individual participating in a training course for physician, dentists, chiropractors, podiatrists, radiologic technologists, chiropractic radiologic technologists, dental hygienists, or dental assistants is exempt from the requirements of 4731.0150 for the duration of the training course. The exemption applies to activities conducted within the scope of the training course. If an individual is operating x-ray equipment for use on humans outside the scope of the training course, the individual must comply with the requirements of 4731.0150 subp.2.

B. Exemption status following training. An individual who successfully completes a training course under subp. 5 A, above is exempt from 4731.0150 until the next applicable national examination is given. The exemption ends on the date that the examination results are released. An individual who fails the examination is no longer exempt from 4731.0150.

4731.0151 Employee Site Specific Training.

Subpart 1. **General requirements for all facilities**

A. In determining individuals subject to the requirements of 4731.0151, licensees and registrants 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 or registered facility. The extent of the instructions must be commensurate with potential radiological health protection problems present in the work place.

B. All individuals who in the course of employment are likely to receive in a year an occupational dose must:

(1) receive initial and annual instruction

(2) be kept informed of the storage, transfer, or use of radiation and/or radioactive material;

(3) be instructed in the health protection problems and bioeffects 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;

(4) be instructed in, and required to observe, to the extent within the workers

control, the applicable procedures, provisions of Chapter 4731, licenses and registrations for the protection of personnel from exposure to radiation and/or radioactive material;

(5) be instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of Chapter 4731, of unnecessary exposure to radiation and/or radioactive material;

(6) be instructed in the significance of the various radiation warning signs, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on a certain piece of equipment and the extra precautions required in such a case;

(7) be 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

(8) be advised as to the radiation exposure reports which workers may request pursuant to 4731.0124.

Subp. 2. **Industrial radiography facilities using radioactive materials.** In addition to the requirements in subp.1, radiographers and assistant radiographers must be trained in:

A. The operating and emergency procedures of the license's license or registration by demonstrating the understanding those procedures. For those employed by a licensee, this is demonstrated by successful completion of a written or oral examination covering this material.

B. The use of the licensee's or registrant's radiographic exposure devices, or sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.

C. Refresher safety issues at intervals not to exceed 12 months. The training may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

Subp 3. **Industrial irradiator facilities**. In addition to subp.1, irradiator operators must be trained in:

A. Requirements of 4731.0100-4731.0194 and 4731.0700-4731.0711 that are relevant to the licensee's irradiator;

B. Operation of the licensee's irradiator;

C. The operating and emergency procedures of the licensee's license or registration. Especially the procedures listed in 4731.0708 that the individual is responsible for performing; and

D. Case histories of accidents or problems involving irradiators.

Subp 4. **Well logging facilities**. In addition to subp.1, logging supervisors and assistants must be trained in:

A. The operating and emergency procedures of the licensee's license or registration. For those employed by the licensee, this is demonstrated by successful completion of a written or oral examination covering this material.

B. The use of the licensee's or registrant's licensed materials, remote handling tools, and

radiation survey instruments.

Subp 5. **Industrial accelerator/cyclotron (PET) facilities.** In addition to subp. 1, accelerator operators must be trained in:

A. Requirements of 4731.0100-4731.0194 and 4731.0900-4731.0907 that are relevant to the licensee's accelerator;

B. Operation of the licensee's accelerator;

C. The operating and emergency procedures of the licensee's license or registration. Especially the procedures listed in 4731.0903 that the individual is responsible for performing; and

D. Case histories of accidents or problems involving accelerators.

Subp. 6. **Sealed and unsealed sources used in industrial or research facilities.** In addition to subp. 1, workers using these sources must be trained in:

A. The operating and emergency procedures of the licensee's license or registration. For employees of the licensee, training is demonstrated by successful completion of a written or oral examination covering this material.

B. The use of the licensee's or registrant's licensed materials, remote handling tools, and radiation survey instruments.

Subp. 7. **Healing arts facilities using x-ray.** In addition to subp. 1, all individuals who operate an x-ray system shall be initially instructed and annually retrained in facility-specific and system-specific safe operating procedures, emergency procedures for malfunctioning equipment, and quality assurance procedures. Written safety procedures for the facility and x-ray systems shall be provided by the registrant to the individuals specified in 4731.0151 including:

A. Information on the effects of radiation exposure to the human body and the embryo-fetus;

B. Projections where holding devices cannot be used; and

C. An restrictions of the operating technique required for the safe operation of the particular x-ray system.

D. Each registrant must provide the in-service training program on quality assurance for employees specified in 4731.0151. Employees must sign or initial their attendance on a record to be kept for inspection by the commissioner.

Subp. 8. **Records**. All instruction and training records must be kept for 4 years or until the next inspection by the commissioner in accordance with 4731.0169, subp. 8.

4731.0152 Radiation User Training Requirements

Subpart 1. **General requirements for all users.** The licensee or registrant must include the following subjects in training:

A. Fundamentals of radiation safety including:

(1) characteristics of radiation; internal and external exposure;

(2) units of radiation dose, quantity of radioactivity and dose limits;

(3) hazards of radiation exposure including large doses;
(4) levels of radiation from licensed or registered material;
(5) methods of controlling radiation dose (time, distance, and shielding); and
(6) access to radiation areas

B. radiation detection instruments including:
(1) use, operation, calibration, and limitations of radiation survey instruments;
(2) survey techniques; and
(3) use of personnel monitoring equipment;
(4) equipment to be used including:
(a) operation and control of equipment,
(b) storage, control, and disposal of licensed or registered material and equipment;
(c) inspection and maintenance of equipment.
(d) the requirements of chapter 4731; and
(e) case histories of radiation accidents.

C. for radioactive material, transportation requirements.

D. for radioactive material users, recentness of training
The training and experience specified for a radioactive material license in Chapter 4731 must have been obtained within 7 years preceding the date of licence application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subp 2. **Industrial facilities using radioactive materials.** In addition to requirements in subp 1, the industrial radiography licensee must:

A. Not permit any individual to act as a radiographer until the individual has received training in the subjects in subp. 1, in addition to a minimum of 2 clock-card months of on-the-job training, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in appendix E of 4731.3001.

B. Not permit any individual to act as a radiographer until the individual has:

(1) received copies of and instruction in the requirements described in 4731.0100-4731.0194; in 4731.0300-4731.0399, in 4731.0500-4731.0520, in the applicable parts of this chapter, in applicable DOT regulations as referenced in 4731.1500 to 4731.1514, in the license(s) under which the radiographer will perform industrial radiography, and the licensee's operating and emergency procedures.

(2) demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment by successful completion of a practical examination covering this material.

C. Not permit any individual to act as a radiographer's assistant until the individual:

(1) has received copies of and instruction in the requirements described in 4731.0100-4731.0194; in 4731.0300-4731.0399, in 4731.0500-4731.0520, in the applicable parts of this chapter, in applicable DOT regulations as referenced in 4731.1500 to 4731.1514, in the

license(s) under which the radiographer's assistant will perform industrial radiography, and the licensee's operating and emergency procedures.

(2) has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

(3) has demonstrated understanding of the instructions provided under item 1 by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in item 2 by successful completion of a practical examination on the use of such hardware.

D. Except as provided in item 4, the RSO or designee must conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that Chapter 4731 rules, license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(1) include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(2) provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 4731.0152, subp. 2 and the radiographer's assistant must re-demonstrate knowledge of the training requirements of 4731.0152, subp. 2 by a practical examination before these individuals can next participate in a radiographic operation.

(3) the commissioner may consider alternatives in those situations where the individual serves as both radiographer and RSO.

(4) in those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

E. The licensee must maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with 4731.0186.

F. Records of radiographer certification maintained in accordance with 4731.0186 provide appropriate affirmation of certification requirements specified in item A of this part.

Subp. 3. **Industrial irradiator facilities.** In addition to requirements in subp.1, the industrial irradiator licensee must:

A. Initially, ensure that before an individual is permitted to operate an irradiator without a supervisor present, the individual must:

(1) be instructed in:

(a) how an irradiator is designed to prevent contamination;

(b) other radiation safety features of an irradiator; and

(c) the basic function of the irradiator.

(2) 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.

(3) have received on-the-job training or simulator training in the use of the irradiator as described in the license application, and

(4) demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

B. Annually:

(1) conduct safety reviews and administer a brief written test on the information covered. Each safety review must include, to the extent appropriate, each of the following:

(1) changes in operating and emergency procedures since the last review,

(2) changes in regulations and license conditions since the last review;

(3) reports on recent accidents, mistakes, or problems that have occurred at irradiators;

(4) relevant results of inspections of operator safety performance;

(5) relevant results of the facility's inspection and maintenance checks; and

(6) a drill to practice an emergency or abnormal event procedure.

(2) evaluate the safety performance of each irradiator operator to ensure that regulations, license conditions, and operating and emergency procedures are followed,

(3) discuss the results of the evaluation with the operator and must instruct the operator on how to correct any mistakes or deficiencies observed, and

(4) train and test individuals who must be prepared to respond to alarms required by 4731.0705, subp. 1 and 2; 4731.0706, subp. 2; 4731.0707, subp. 2; 4731.0708, subp. 3 and 4;

C. Ensure that 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, are instructed and tested in:

(1) any precautions they should take to avoid radiation exposure,

(2) any procedures or parts of procedures listed in 4731.0708 that they are expected to perform or comply with, and

(3) their proper response to alarms required in 4731.0705-4731.0708.

Subp. 4 **Well logging facilities.** In addition to requirements in subp. 1, the well logging licensee must:

A. Not permit an individual to act as a logging supervisor until that person:

(1) has completed training in the subjects outlined in subp. 1;

(2) has received copies of, and instruction in:

(a) the applicable parts of 4731.010-4731.0194 and 4731.0800-4731.0820;

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

(c) the licensee's operating and emergency procedures required by 4731.0803;

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

(4) has demonstrated understanding of the requirements in subp. 1 and this subp. by successfully completing a written test.

B. Not permit an individual to act as a logging assistant until that person:

(1) has received instruction in applicable parts of 4731.0100-4731.0194 and 4731.0800-4731.0820;

(2) has received copies of, and instruction in, the licensee's operating and emergency procedures required by 4731.0803

(3) has demonstrated understanding of the materials listed in subitems 1 and 2 or item B of this subp. by successfully completing a written or oral test; and

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

C. Maintain a record on each logging supervisor's and logging assistant's training and annual refresher safety training. The record must include:

(1) copies of written tests and dates of oral tests given;

(2) training and annual safety reviews, listing the topics discussed; and must be retained until 3 years following the termination of employment.

(3) records of annual safety reviews that list the topics discussed and be retained for 4 years.

Subp 5. **Industrial accelerator/cyclotron (PET) facilities**. In addition to requirements in subp. 1, the accelerator/cyclotron licensee must:

A. Ensure that before an individual is permitted to operate an accelerator without a supervisor present, the individual must:

(1) be instructed in:

(a) how an accelerator or cyclotron is designed to prevent contamination;

(b) other radiation safety features of an accelerator or cyclotron; and

(c) the basic function of the accelerator or cyclotron.

(2) 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 accelerator without supervision.

(3) have received on-the-job training or simulator training in the use of the accelerator or cyclotron as described in the license application, and

(4) also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

B. Annually:

(1) conduct safety reviews for accelerator or cyclotron operators. 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 accelerator;

(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.

(2) evaluate the safety performance of each accelerator or cyclotron operator to ensure that regulations, license conditions, and operating and emergency procedures are followed, and

(3) discuss the results of the evaluation with the operator and must instruct the operator on how to correct any mistakes or deficiencies observed.

C. Ensure that individuals who will be permitted unescorted access to the accelerator or cyclotron, but who have not received the training required for operators and the radiation safety officer, must be instructed and tested (written or oral):

(1) in any precautions they should take to avoid radiation exposure,

(2) any procedures or parts of procedures listed in 4731.0900-4731.0920 that they are expected to perform or comply with, and

(3) their proper response to alarms required in 4731.0901, subp. 2.

Subp 6. **Sealed and unsealed sources used in industrial or research facilities.** In addition to the requirements in subp.1, the licensee must:

A. Ensure that before an individual is allowed to work with industrial sources, the individual must be trained in accordance with 4731.0152, subp 1.

B. Provide the following and have it approved in the license by the commissioner, for licensees who propose to train their own personnel:

(1) instructor qualifications, including training and experience with radioactive materials specifically relating to the topics of instruction;

(2) a detailed training program, including duration of training for each of the topics listed in 4731.0152, subp. 1;

(3) the method of evaluating the training and knowledge of students, such as a written and practical examination, and whether the examination is open or closed book; and

(4) if an examination is used, the passing score, method of retesting students who do not pass and an example of the examination with the correct answers indicated.

C. Maintain records of training during the employment of the individual or 4 years, whichever is greater.

D. Ensure that users of sealed sources in portable devices have a completed a minimum of 8 hours of training from a program approved by the commissioner. The training must include the areas described in 4731.0152, subp. 1.

E. Ensure that users of sealed sources in fixed devices have completed a minimum of 8 hours of training from a program approved by the commissioner. The training must include the areas described in 4731.0152, subp. 1.

F. Ensure that individuals who perform installations, maintenance or service, initial radiation surveys, relocations, or removal from service have completed a minimum of 40 hours of training from a program approved by the commissioner. The training must include the areas described in 4731.0152, subp. 1, and

(1) procedures for performing services; and

(2) actual practice in performing the service.

G. Ensure that individuals who use radioactivity in unsealed form are trained in:

(1) use of fume hoods, glove boxes and hot cells, as appropriate;

(2) waste processing;

(3) animal handling, as appropriate; and

(4) decontamination methods for personnel and the environment.

Subp. 7. **Healing Arts facilities that use radioactive material.** In addition to subp.1, the licensee must ensure the following are followed:

A. Training for authorized medical physicist. Except for 4731.0152, subp. 8, the licensee shall require the authorized medial physicist to be an individual who:

(1). Is certified by a speciality board whose certification process includes all of the training and experience in 4731.0152, subp 7, A, (2), below, and whose certification has been recognized by the commissioner, NRC, or an agreement state; or

(2) holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics or health physics, and has completed 1 year of full time training in therapeutic radiologic physics and an addition year of full time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in 4731.1205, subp. 1, 4731.1208, subp. 6, 4731.1209, subparts 1, 2, and 3, 4731.1210, subparts 1, 2, and 4, and 4731.1211, subp.4, as applicable.

B. Training for an authorized nuclear pharmacist. Except as provided in 4731.0152, subp. 8, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in 4731.0152, subp.7, B,,(2), below, and whose certification has been recognized by the commissioner, NRC, or an agreement state; or

(2) has completed 700 hours in a structured educational program consisting of both:

(a) didactic training in the following areas:

((1)) radiation physics and instrumentation;

((2)) radiation protection;

((3)) mathematics pertaining to the use and measurement of radioactivity;

((4)) chemistry of radioactive material for medical use; and

((5)) radiation biology; and

(b) supervised practical experience in a nuclear pharmacy involving the following:

((1)) shipping, receiving, and performing related radiation surveys;

((2)) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides;

((3)) calculating, assaying, and safely preparing dosages for patients or human research subjects;

((4)) using administrative controls to avoid mistakes in the administration of radioactive material;

((5)) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(3) has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 4731.0152, subp 7, B, (2), and has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

C. Training for experienced nuclear pharmacists. A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 4731.0152, subp.7, B, (2), (a) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement in 4731.152, subp. 7, B, (2), (b), and recentness of training, 4731.0152, subp.1, D, to qualify as an authorized nuclear pharmacist.

D. Records of instruction and training. A licensee shall maintain a record of instructions and training required by 4731.1203, subparts 2, 4, and 6, for four years or until the next inspection by the commissioner. The record must include:

(1) a list of the topics covered;
(2) the date of the instruction or training;
(3) the names(s) of the attendee(s); and
(4) the name(s) of the individual(s) who provided the instruction.

Subp. 8. **Training for experienced RSO, teletherapy or medical physicist, authorized user, and nuclear pharmacist.**

A. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a commissioner, NRC, or agreement state license or permit issued by the commissioner, NRC, or agreement state broad scope licensee or master material license permit or by a master material permittee of broad scope before October 24, 2002 need not comply with the training requirements of 4731.0128, subp. 7, and 4731.0152, subp. 7, A, and B, respectively .

B. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive materials on a license issued by the commissioner, NRC, or agreement state, a permit issued by a commissioner's master material licensee, a permit issued by a commissioner, NRC, or agreement state broad scope licensee, or a permit issued by a commissioner's master material license broad scope permittee before October 24,2002 who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of 4731.1207.

REPORTING REQUIREMENTS

4731.0160 Reserved

4731.0161 Notification and Follow-up Report on Stolen, Lost, Missing Licensed or Registered Sources of Radiation, Including X-ray.

Subpart 1. **Telephone reports.** Each licensee or registrant must report to the commissioner by telephone, the following:

A. Immediately after its occurrence becomes known to the licensee or registrant, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 4731.3001, C, under such circumstances that it appears to the licensee or registrant that an exposure could result to persons in unrestricted areas; or

B. Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee or registrant, all licensed or registered missing material becomes known to the licensee or registrant, all licensed or registered material in a quantity greater than 10 times the quantity specified in 4731.3001, C, that is still missing at this time,

C. 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 used in well logging has been ruptured. The letter must designate the well 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; or

D. Immediately after its occurrence becomes known, a stolen, lost, or missing radiation machine.

Subp 2. **Each licensee or registrant is required to make a written report** under 4731.0161, subp. 1 within 30 days after making the telephone report, setting forth the following information:

A. A description of the licensed material involved, including for radioactive material, the kind, quantity, chemical and physical form and for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

B. A description of the circumstances under which the loss or theft occurred; and

C. A statement of disposition, or probable disposition, of the licensed material involved; and

D. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

E. Actions that have been taken, or will be taken, to recover the source of radiation; and

F. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

Subp 3. **Subsequent to filing the written report**, the licensee or registrant must also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

Subp. 4. **The licensee or registrant must prepare any report** filed with the commissioner as specified in 4731.0161, subp. 1, so that the names of individuals who have received exposure to radiation are stated in a separate and detachable portion of the report.

4731.0162 Notification and Follow-up Report of Incidents or Accidents, Including X-ray. Each licensee or registrant is required to notify and report to the commissioner in the following situations.

Subpart 1. **Notification of incidents to the commissioner**

A. Immediate notification.

(1) each licensee must notify the commissioner by telephone as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation and radioactive materials, including source materials, that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits These events may include fires, explosions, toxic gas release, or similar hazards.

(2) regardless of other requirements for notification, each licensee or registrant must immediately report any event involving a source of radiation possessed by a licensee or registrant that might have caused or threatens to cause any of the following:

(a) an individual to receive:

((1)) a total effective dose equivalent of 25 rems(0.25 Sv) or more;

((2)) a lens dose equivalent of 75 rems (0.75 Sv) or more; or

((3)) a shallow-dose equivalent to the skin or extremities of 250 rads(2.5 Gy) or more; or

(b) the release of radioactive material, inside or outside of a restricted area, so that, if an individual had been present for 24 hours, the individual could have received an intake of five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot cells or process enclosures.

(3) reports of leaking or contaminated sealed sources and gauges.

The licencee must immediately notify the commissioner if the test for leakage or contamination required by 4731.0134 or 4731.1208, subp. 6 indicate for a sealed source the presence of 0.005 microcuries(185 Bq) or more of removable contamination.

(4) in addition to the other reporting requirements in these regulations, each licensee or registrant must notify the commissioner as soon as possible but not later than 4 hours after the discovery of an event, such as fire, explosion, or toxic gas release, that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or to avoid releases of licensed or registered material that could exceed regulatory limits

B. Twenty-four hour notification:.

(1) each licensee must, within 24 hours of discovery of the event, report by telephone to the commissioner any event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions listed below. The telephone reports must include the information available on the :

(a) the caller's name and call back telephone number;

(b) a description of the event, including date and time;

(c) the exact location of the event;

(d) the isotopes, quantities, and chemical and physical form of he licensed or registered material involved;

(e) any personnel radiation exposure data available.

(2) the following conditions must be reported within 24 hours of discovery:

(a) an individual to receive in a period of 24 hours:

((1)) a total effective dose equivalent exceeding 5 rem (0.05 sievert);

((2)) an lens dose equivalent exceeding 15 rem (0.15 sievert); or

((3)) a shallow dose equivalent to the skin or extremities or a total dose equivalent exceeding 50 rem (0.5 sievert); or

(b) the release of radioactive material inside or outside of a restricted area, so that, if an individual had been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations such as hot cells or process enclosures.

(c) an unplanned contamination event that:

((1)) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the areas;

((2)) involves a quantity of material greater than five times the lowest annual limit on intake of materials as specified in 4731.3001 B; and

((3)) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(d) an event in which equipment is disabled or fails to function as designed when:

((1)) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposure to radiation and radioactive material exceeding regulatory limits, or to mitigate the consequences of an accident;

((2)) the equipment is required to be available and operable when it is disabled or fails to function; and

((3)) no redundant equipment is available and operable to perform the required safety function.

(e) an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body;

(f) an unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed materials when:

((1)) the quantity of material involved is five times the lowest annual limit on intake for material specified in 4731.3001 B; and

((2)) the damage affects the integrity of the licensed material or its container.

(g) licensees or registrants having an installed Emergency Notification System must use that system to make the reports required by 4731.0162, subparts 1 and 2, to the

commissioner; all other licensees shall notify the commissioner by telephone.

(h) the provisions of 4731.0162 do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported as specified in 4731.0164.

C. Thirty day notification. The licensee must report the following transportation problems to the commissioner within 30 days:

(1) any instance in which there is significant reduction in the effectiveness of any packaging during use; and

(2) details of any defects with safety significance in the packaging after first use; with the means employed to repair the defects and prevent their recurrence; or

(3) instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

Subp 2. **Preparation and submission of written reports.** Follow-up written reports made by the licensee or registrant in response to the notifications of this section must be made as follows:

A. The licensee must prepare a report of any notifications filed with the commissioner as specified in 4731.0162 so that the names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

B. Each licensee or registrant who makes a notification required by 4731.0162, subparts 1 and 2, must submit a written follow-up report within 30 days of the initial notification. Written reports prepared as required by other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information. These written reports must be sent to the commissioner. The reports must include the following:

(1) a description of the event, including the probable cause and the manufacturer and model number of any equipment that failed or malfunctioned;

(2) the exact location of the event;

(3) the isotopes, quantities, and chemical physical form of the licensed or registered material involved;

(4) date and time of the event;

(5) corrective actions taken or planned and the results of any evaluations or assessments; and

(6) the extent of exposure of individuals to radiation or to radioactive materials without identification of the individuals by name.

Subp. 3. **Industrial radiography notifications.**

A. In addition to the notification requirements specified in 4731.0162, subp.1, each licensee must provide a written report to the commissioner within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) unintentional disconnection of the source assembly from the control cable;

(2) inability to retract the source assembly to its fully shielded position and secure it in this position; or

(3) failure of any component critical to safe operation of the device to properly perform its intended function;

B. The licensee must include the following information in each report submitted under subp.1, and in each report of overexposure submitted under 4731.0163 which involves failure of safety components of radiography equipment:

(1) a description of the equipment problem;

(2) cause of each incident, if known;

(3) name of the manufacturer and model number of equipment involved in the incident;

(4) place, date, and time of the incident;

(5) actions taken to establish normal operations;

(6) corrective actions taken or planned to prevent recurrence; and

(7) qualifications of personnel involved in the incident.

C. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, must notify the commissioner prior to exceeding the 180 days.

Subp 4. **Medical Event Notifications**

A. A licensee must report any event, except for an event that results patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

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

(a) the total dose delivered differs from the prescribed dose by 20 percent or more; or

(b) the total dose dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(c) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

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

(a) an administration of a wrong radioactive drug containing radioactive material;

(b) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(c) an administration of a dose or dosage to the wrong individual or human research subject;

(d) an administration of a dose or dosage delivered by the wrong treatment mode of treatment; or

(e) a leaking sealed source.

(3) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive, i.e. excluding, for permanent implants, seeds

thta were implanted in the correct site but migrated outside the treatment site.

B. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

C. The licensee must notify the commissioner by telephone no later than the next calendar day after discovery of the medical event.

D. The licensee must submit a written report to the commissioner within 15 days after discovery of the medical event.

(1) the written report must include:

(a) the licensee's name;

(b) the name of the prescribing physician;

(c) a brief description of the event;

(d) why the event occurred;

(e) the effect, if any, on the individual(s) who received the administration;

(f) what actions, if any, have been taken or are planned to prevent recurrence; and

(g) certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) the report must not contain the individual's name or any other information that could lead to identification of the individual.

D. The licensee shall submit a written report to the commissioner within 15 days after the discovery of the medical event.

(1) the written report must include:

(a) the licensee's name

(b) the name of the prescribing physician;

(c) a brief description of the event;

(d) why the event occurred;

(e) the effect , if any, on the individual(s) who received the administration;

(f) what actions, if any, have been taken or are planned to prevent recurrence; and

(g) certification that the licensee notified the individual, or the individual's responsible relative or guardian, and if not , why not.

(2) the report may not contain the individual's name or any other information that could lead to identification of the individual.

E. Notification of the individual

(1) the licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful.

(2) the licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within

24 hours, the licensee shall notify the individual as soon as possible thereafter.

(3) the licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the notification requirements in 4731.0162, subp. 4, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian.

(4) if a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. Aside from the notification requirement, nothing in 4731.0162, subp. 4 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

G. A licensee shall:

(1) annotate a copy of the report provided to the commissioner with the:

(a) name of the individual who is the subject of the event; and

(b) social security number or other identification number, if one had been assigned, of the individual who is the subject of the event; and

(2) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of th event.

Subp. 5. **Report of a dose to an embryo/fetus or a nursing child.**

A. A licensee shall report any dose to an embryo-fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from a radioactive material to a pregnant individual unless the dose to the embryo-fetus was specifically approved, in advance, by the authorized user.

B. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast feeding individual that:

(1) is greater than 5 rem (50 mSv) total effective dose equivalent; or

(2) has resulted in unintended permanent functional damage to an organ or a physioogical system of the child, as determined by a physician.

C. The licensee shall notify by telephone the commissioner no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in after discovery of a dose to the embryo/fetus or nursing child that requires a report in 4731.0162, subp. 5, A or B, above.

D. The licensee shall submit a written report to the commissioner no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 4731.0162, subp. 5, A or B, above;

(1) the written report must include:

(a) the licensee's name:

(b) the name of the prescribing physician;

(c) a brief description of the event;

(d) why the event occurred;

(e) the effect, if any, on the embryo/fetus or the nursing child;

(f) what actions, if any, have been taken or are planned to prevent recurrence; and

(g) certification that the licensee notified the pregnant individual or mother, or the mother's or child's responsible relative or guardian, and if not, why not.

(2) the report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

E. Notification of the pregnant individual or mother

(1) the licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 4731.0162, subp. 5, A or B, above, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgement, telling the mother would be harmful.

(2) the licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter.

(3) the licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of 4731.0162, subp5, E, on notification requirements, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother.

(4) if a verbal notification is made, the licensee shall inform the mother or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. A licensee shall:

(1) annotate a copy of the report provided to the commissioner with the:

(a) name of the pregnant individual or the nursing child who is the subject of the event; and

(b) social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of he event.

4731.0163 Notification and follow-up report of exposure, radiation levels, concentration of radioactive materials exceeding limits, and medical events, including x-ray.

Subpart 1. **Reportable Events**. In addition to the notification required by 4731.0162, each licensee or registrant must submit a written report within 30 days after learning of any of the following occurrences:

A. Incidents for which notification is required by 4731.0162; or

B. Doses in excess of any of the following:

(1) the occupational dose limits for adults in 4731.0124, subp. 1;

(2) the occupational dose limits for a minor in 4731.0124, subp. 2;

(3) the limits for an embryo or fetus of a declared pregnant woman in 4731.0124,

subp. 3;

(4) the limits for an individual member of the public in 4731.0126, subp. 6; or

(5) any applicable limit in the license or registration; or

(6) the "as low as reasonably achievable" constraints for air emissions established under 4731.0129, subp. 1, G; or

C. Levels of radiation or concentrations of radioactive material in:

(1) a restricted area in excess of applicable limits in the license or registration; or

(2) an unrestricted area in excess of 10 times the applicable limit set forth in this part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 4731.0126, subp.1; or

(3) for licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

Subp. 2. **Contents of reports.**

A. Each report required by 4731.0163, subp. 1, must describe the extent of exposure of individual to radiation an radioactive material, including as appropriate:

(1) estimates of each individual's dose;

(2) the levels of radiation and concentrations of radioactive material involved;

(3) the cause of the elevated exposures, dose rates, or concentrations; and

(4) corrective steps taken or planned to insure against a recurrence, including the schedule for achieving conformance with applicable limits, "as low as reasonably achievable" constraints, generally applicable environmental standards, and associated license or registration conditions.

B. Each report filed as specified in 4731.0163, subp. 2, must include for each individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in 4731.0124, subp. 3, the identifiers should be those of the declared pregnant woman. The report must be prepared so that this information is stated in a separate and detachable portion of the report.

C. All licenses or registrants who make reports as specified in 4731.0163, subp. 1, shall submit the report in writing to the commissioner.

4731.0164 Reports of Planned Special Exposures, Including X-ray. The licensee or registrant must submit a written report to the commissioner within 30 days following any planned special exposure conducted in accordance with 4731.0124, subp.1, E. This report must inform the commissioner that a planned special exposure was conducted and indicating the date the planned special exposure occurred and information required by 4731.0172.

4731.0165 Notifications and Reports of Individual Monitoring.

A. Requirements for notification and reports to individuals of exposure to radiation of radioactive material are specified in 4731.0101-4731.0195 of these regulations.

B. When a licensee or registrant is required by 4731.0163 to report to the commissioner

any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted no later than the transmittal to the commissioner and shall comply with the provisions of 4731.0101-4731.0195.

C. This part applies to each person licensed by the commissioner to:

(1) possess or use radioactive material for purposes of radiography pursuant to 4731.0300-4731.0320, and 4731.0500-4731.0520;

(2) receive radioactive waste from other persons for disposal under 4731.0136.

(3) possess or use at any time, for processing or manufacturing for distribution pursuant to 4731.0301-4731.0320, and 4731.1200-4731.1220, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Quantity of Radionuclide ** in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

** The commissioner may require as a license condition, or by rule, regulation, or order pursuant to 4731.0300, subp. 5, D, reports from licensees who are licensed to us radionuclides not on the list, in quantities sufficient to cause comparable radiation levels.

D. Each licensee in a category listed in 4731.0166, C, shall submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by 4731.0125, subp. 2, during that year. The licensee may include additional data for individuals for whom monitoring was not required. The licensee shall use form 4731.3004, 1, or other form containing all the information required by 4731.3004, 1.

E. The licensee shall file the report required by 4731.0166, D, covering the preceding year, on or about April 30 of each year. The licensee shall submit the report to the commissioner.

4731.0166 Requirements For Vacating Premises For All Facilities.

Subpart 1. **License termination.** The premises must be left in accord with the requirements in 4731.0301, radiological criteria for license termination.

Subp 2. **X-Ray machine removal from registration.** Removing x-ray machines must be done in accord with 4731.0111, subp. 2. Written notifications to commissioner required in accordance with 4731.0103, subp. 1.

4731.0167 reserved

RECORDKEEPING REQUIREMENTS

The following rules are in addition to other applicable rules in Chapter 4731. If there is a conflict between the commissioner's regulations in 4731.0168-4731.0195, license condition, or other written commissioner approval or authorization pertaining to the retention period for the same type of record, the longest retention period specified takes precedence.

4731.0168 General Requirements For The Format and Retention of Records For All Facilities

Subpart 1. **Retention period conflict**. If there is a conflict between the commissioner's regulations in 4731.0168-4731.0195, license condition, or other written commissioner approval or authorization pertaining to the retention period for the same type of record, the longest retention period specified takes precedence unless the commissioner has granted a specific exemption from the record retention specified in the commissioner's regulations.

Subp. 2. **Maintenance of appropriate records**. Each licensee and registrant must maintain appropriate records, including shipment manifests, and reports, in accordance with 4731.0168-4731.0195, and make the records available at all times for the commissioner. The records must:

A. Be kept in any of the following media and retained for the period specified by the appropriate license condition or rule part:

(1) original or a reproduced copy; or

(2) microform if such reproduced copy or microform is duly authenticated by authorized personnel and is capable of producing a clear and legible copy after storage for the period specified by the commissioner's regulations; or

(3) electronic media storage with the capability for producing legible, accurate, and complete records during the required retention period; and

(4) letters, drawings, and specifications records which include all pertinent information such as stamps, initials, and signatures.

B. Be retained in one of the above formats:

(1) for four years or until the next inspection by the commissioner, unless the commissioner has granted a specific exemption; or

(2) until the license is terminated; or

(3) for the retention period in (1) above, if there is a conflict between the commissioners's regulations, license condition, or other written commissioner approval or authorization pertaining to the retention period for the same type of record,

C. Be clearly marked and use the units; curie, rad, rem, including multiples and subdivisions, with the SI units in parentheses following each of the units.

D. The licensee or registrant must make a clear distinction among the quantities entered on the records required in Chapter 4731, for example, total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed dose equivalent.

E Include maintenance procedures for adequate safeguards against tampering with

and loss of records.

F. If the registrant or licensee ceases operation for any reason, provision must be made for record retention required by this chapter.

G. If a retention period is not otherwise specified by regulation or license condition, the licensee or registrant must retain the record until the commissioner terminates each license or registration that authorizes the activity that is subject to the record keeping requirement.

4731.0169 General Requirements For Keeping Records of Specific Information For All Facilities

Each licensee or registrant is required to keep records of the activities, as indicated below, which are required by chapter 4731 in a manner as indicated in 4731.0168-4731.0195.

Subpart 1. **Records for radiation safety programs**

A. All licensees or registrants must maintain records of radiation safety program, for four years or until the next inspection by the commissioner. The record must include:

(1) the provisions of the program; and

(2) audits, and other reviews of the program content, procedures, and implementation.

B. For radioactive material licensees or registrants the records required by 4731.0169, subp. 1, must be retained until the commissioner terminates each pertinent licensee or registration requiring the record.

C. For healing arts facilities using radiation producing equipment, including x-ray, the radiation safety program records that the licensee or registrant must retain are the records for each x-ray system and accelerator as defined in 4731.0131.

Subp. 2. **Records of radiation safety surveys.**

A. Each licensee or registrant must maintain records of each radiation safety survey conducted in accordance with Chapter 4731 for four years or until the next inspection by the commissioner or as otherwise listed in their license or registration.

B. The licensee must retain each of the following records until the commissioner terminates each pertinent license requiring the record.

(1) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of the individual dose equivalents;

(2) records of the results of measurements and calculations to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) records showing the results of air sampling, surveys, and bioassays required in 4731.0123 A, (3), (a) and (b), and

(4) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

Subp. 3. **Records of radiation survey equipment calibration**

A. Radiation survey instruments. The licensee or registrant must maintain a record of radiation survey instrument calibrations required by 4731.0169, subp. 3 and 4731.1214, subp. 4 for four years or until the next inspection by the commissioner. The record must include:

(1) a description of the calibration procedure;
(2) the date of calibration;
(3) a description of the source used;
(4) the certified exposure rates from the source;
(5) the rates indicted by the instrument being calibrated;
(6) the correction factors deduced from the calibration data; and
(7) the name of the individual who performed the calibration.

B. Alarming ratemeters. To ensure correct response to radiation, each alarming ratemeter must:

(1) be tested before use at the start of each shift to ensure that the alarm sounds;
(2) be set to sound at a pre-set exposure rate of 500 mR/hr (1.29 x 10-4 C/kg/hr);
(3) require special means to change the pre-set alarm function;
(4) be calibrated at periods not to exceed one year;
(5) alarm, vibrate, activate a light, or otherwise signal within plus or minus 20 percent of the true radiation exposure rate; and
(6) have records of the tests and calibrations maintained according to 4731.0169, subp. 3.

Supb. 4. **Records of ambient radiation exposure rate for healing arts facilities using radioactive materials.** The licensee or registrant must retain a record of each survey for ambient radiation exposure rate required by 4731.1206, subp.2, for 4 years or until the next inspection. The record must include:

(1) the date of the survey;
(2) a plan of each area surveyed;
(3) the results of the survey
(4) the instruments used to make the survey or analyze the samples; and
(5) the name of the individual who performed the survey.

Subp. 5. **Records of shielding survey results**. The licensee or registrant must keep all records of shielding designs or results of safety surveys permanently at the facility and as described in 4731.0169 , subp.2.

Subp. 6. **Records of quality assurance program for facilities that use radiation producing equipment. quality control and equipment performance measurements.** The registrant or licensee must maintain records in accordance with 4731.0169, subp. 6, until the next commissioner inspection.

Subp. 7. **Records of individual monitoring device calibration**

Each licensee or registrant must maintain the following exposure records in accordance with

4731.0171.

A. Direct reading dosimeter readings and yearly operability checks required by 4731.0130, subp. 3, item B subtiems 4 and 5.

B. Records of alarming ratemeter calibrations.

C. Reports received from the NVLAP-accredited individual dosimeter processor for the lifetime of the individual worker or for a minimum of 30 years after termination of employment, whichever is less.

D. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged NVLAP-accredited personnel dosimeters, for the lifetime of the individual worker or for a minimum of 30 years after termination of employment, whichever is less.

Subp. 8. **Records of employee training.** The licensee or registrant is required to keep these records in accordance with 4731.0168, subps. 1 and 2 until the next inspection by the commissioner.

4731.0170 reserved

4731.0171 Records of Individual Monitoring Results (175 and 187)

A. Each licensee and registrant must maintain records of doses received by all individuals for whom monitoring was required as specified in 4731.0125, subp. 2, and records of doses received during planned special exposures, accidents, and emergency conditions. The licensee or registrant must retain the required form or record until the commissioner terminates each pertinent license or registration requiring this record. The licensee or registrant must retain and preserve records used in preparing the accumulated dose records for the lifetime of the individual worker or a minimum of 30 years after the individual's termination of employment with the facility, whichever is less. Assessments of dose equivalent and records made using units in effect before the effective date of this rule need not be changed. These records must include when applicable:

(1) the deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

(2) the estimated intake of radionuclides as specified in 4731.0125, subp. 3;

(3) the committed effective dose equivalent assigned to the intake of radionuclides;

(4) the specific information used to assess the committed effective dose equivalent as specified in 4731.0124, subp. 4;

(5) the total effective dose equivalent when required by 4731.0125, subp. 3; and

6) the total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

B. The licensee or registrant must make entries of the records specified in 4731.0171, A, quarterly. The licensee or registrant must maintain the records specified in 4731.0171, A, in clear and legible records containing all the information or on form 4731.3004,1.

C. The licensee or registrant must maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy must also be

kept on file, but may be maintained separately from the dose records.

D. Records of dose to individual members of the public must be maintained to demonstrate compliance with the dose limit for individual members of the public in accordance with 4731.0126, subp. 1.

4731.0172 Records of Any Planned Special Exposure

This part applies to any planned special exposures as described in 4731.0124.subp. 4.
The licensee of registrant must submit a written report to the commissioner within 30 days following any planned special exposure as specified in 4731.0124, subp. 4, informing the commissioner that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 4731.0172.

Subpart 1. **Contents of records**

For each planned special exposure, the licensee or registrant must maintain records that describe:

A. The exceptional circumstances requiring the use of a planned special exposure;

B. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

C. What actions were necessary;

D. Why the actions were necessary;

E. What precautions were taken to assure that doses were maintained ALARA;

F. What individual and collective doses were expected to result; and

G. The doses actually received in the planned special exposure.

Subp 2. **Retention period**

The licensee or registrant shall retain these records until the commissioner terminates each pertinent license or registration requiring these records.

4731.0173 Records of testing entry control devices for very high radiation areas (0300/6)

Warning and control devices; high and very high radiation areas. This subpart applies only to areas of high and very high radiation.

A. Except as provided in item C, each entrance or access point to a high or very high radiation area must be:

(1) equipped with a control device that causes the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems (1.0 mSv) in one hour upon entry into the area;

(2) equipped with a warning device that energizes a visible or audible alarm to alert an individual entering the high or very high radiation area and other nearby nonoccupationally exposed workers; or

(3) maintained locked except during periods when access to the area is required, 0 with access to each individual entry monitored or supervised.

B. The devices required by this subpart must not prevent an individual from leaving a high or very high radiation area.

C. When a high or very high radiation area is established for 30 calendar days or less, direct surveillance to prevent unauthorized entry may be substituted for the devices required by

this subpart.

4731.0174 Records of equipment performance evaluation for x-ray equipment. The licensee or registrant must maintain the records for the equipment performance evaluations in accordance with 4731.0168 until the next inspection by the commissioner.

RADIOACTIVE MATERIAL RECORDS

4731.0180 General Requirements for all facilities using radioactive materials. Each licensee or registrant who uses radioactive material must keep the additional following records:

A. Record of receipt of radioactive material as long as the material is possessed and for four years following the transfer or disposal of the material; and

B. Records of tests for leakage or contamination of sealed sources and devices containing depleted uranium required by these regulations shall be kept in units of microcurie and becquerel and maintained for inspection by the commissioner until the next inspection.

C. Record of the transfer of material. The licensee or registrant that transferred the material must retain the record of each transfer for four years after each transfer unless a specific requirement in another part of Chapter 4731 dictates otherwise; and

D. Record of disposal. The licensee who disposed of the material must retain each record of disposal of radioactive material until the commissioner terminates each license that authorizes disposal of material.

E. Record of transfer or assignment of material to new licensee or registrant. If licensed or registered activities are transferred or assigned in accordance with 4731.0313, subp.2, each licensee or registrant authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, must transfer the following records to the new licensee or registrant and they will be responsible for maintaining these records until the license is terminated:

(1) records of disposal of licensed material made under 4731.0136, subparts 2, 3, 4, and 7; and

(2) records of measurements and calculations as required by 4731.0169, subp. 2, item B subitem 4.

F. Records for license termination Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in unsealed form, must forward the following records to the commissioner:

(1) records of disposal of licensed material made under 4731.0136, subparts 2, 3, 4, and 7;

(2) records of surveys required by 4731.0169, subp, 2; and

(3) records that are required by 4731.0309, subp. 4.

4731.0181 Records of inventory and balance of radioactive material

Subpart 1. **Inventory and balance**

As used in this section terms are specific to inventory and balance:

A. Additions to material in process means receipts of radioactive materials that are opened except for receipts opened only for sampling and subsequently maintained under tamper-safing, and opened sealed sources.

B. Enrichment category for uranium-235 means high-enriched uranium means that uranium whose isotope content is 20 percent or more uranium-235 by weight, and low-enriched uranium means that uranium whose isotope content is less than 20 percent uranium or plutonium.

C. Element means uranium or plutonium.

D. Fissile isotope means:

(1) Uranium-233; or

(2) Uranium-235 by enrichment category.

E. Limit of error means the uncertainty component used in constructing a 95 percent confidence interval associated with a quantity after any recognized bias has been eliminated or its effect accounted for.

F. Material balance means a determination of material unaccounted for (MUF) by subtracting ending inventory (EI) plus removals (R) from beginning inventory (BI) plus additions to inventory (A).

Mathematically,

$$MUF = BI + A - EI - R$$

G. Material in process means any special nuclear material possessed by the licensee except in unopened receipts, sealed sources, and ultimate product maintained under tamper-safing.

H. Physical inventory means determination on a measured basis of the quantity of special nuclear material on hand at a given time. The methods of physical inventory and associated measurements will vary depending on the material to be inventoried and the process involved. Criteria for physical inventories are set out in 10 CFR 70.51 (f).

I. Removals from material in process includes measured quantities of special nuclear material disposed of as discards, encapsulated as a sealed source, or in other ultimate product placed under tamper-safing or shipped offsite.

J. Tamper-safing means the use of devices or containers or vaults in a manner and at a time that ensures a clear indication of any violation of the integrity of previously made measurements of special nuclear material within the container or vault.

K. Ultimate product means any special nuclear material in the form of a product that would not be further processed at that licensed location.

L. Unopened receipts means receipts not opened by the licensee, including receipts of sealed sources, and receipts opened only for sampling and subsequently maintained under tamper-safing.

Subp. 2. **Contents of records and providing copies**

Licensees subject to 4731.0308 and 4731.0312, subp. 6, are exempt from 4731.0181, subp. 2, A - E. Otherwise:

A. Each licensee must keep records showing the receipt, inventory (including location), disposal, acquisition, and transfer of all special nuclear material in his possession, regardless of

its origin or method of acquisition.

B. Each record that is required by 4731.0181 or by license condition must be maintained and retained for the period specified by the appropriate regulation or license condition. .

C. Each record of receipt, acquisition, or physical inventory of special nuclear material must be maintained pursuant to 4731.0181, subp. 2, A, must be retained as long as the licensee retains possession of the material and for four years or until the next inspection following transfer of such material.

D. Each record of transfer of special nuclear material to other persons must be retained by the licensee who transferred the material until the commissioner terminates the licnese authorizing the license's possession of the material . Each record required by 10 CFR 70.51 (e) must be retained for four years or until the next inspection after it is made.

E. Prior to license termination, licensees must forward the following records to the commissioner:

(1) records of disposal of licensed material 4731.0136, subp. 2, (including burials authorized before January 28, 1981 under 10 CFR 20.2003, 20.2004, 20.2005. A previous 10 CFR 20.304 permitted burial of small quantities of licensed material in soil before January 28, 1981, without specific NRC authorization. See 10 CFR 20.304 revised as of January 1, 1981).

(2) records required by 4731.0169, subp.2, B, (4).

(3) records required by 4731.0309, subp. 4.

F. If licensed activities are transferred or assigned in accordance with 4731.0313, subp. 2, the licensee must transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) records of disposal of licensed material made under part 4731.0136, subp. 2, (including burials authorized before January 28, 1981 under 10 CFR 20.2003, 20.2004, and 20.005);

(2) records required by 4731.0169, subp. 2, b, (4); and

(3) records required 4731.0309, subp. 4.

4731.0182 Reserved

4731.0183 Records for Maintenance of Radioactive Waste Transfer

Subpart 1. **Records and reports for licensed activities**

Each licensee must maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations and orders of the commissioner.

A. Each licensee must maintain records of the disposal of licensed materials made under 4731.0136, subparts 3 and 4, 10 CFR 61, and disposal by burial in soil, including burials authorized before January 28, 1981

B. The licensee must retain the records required by 4731.0183, subp. 1, A, above, until the commissioner terminates each pertinent license requiring the record. Requirements for disposition of these records prior to license termination, are located in 4731.0184, subp. 3, for

activities licensed under chapter 4731.

Subp 2. **Records retention period**
Records which are required by the regulations in Chapter 4731 or by license conditions must be maintained for a period specified by the appropriate regulations or by license condition. If a retention period is not otherwise specified, these records must be maintained and transferred to the officials specified in 4731.0183, subp. 5, below, as a condition of license termination unless the commissioner otherwise authorizes their disposition.

Subp 3. **Record of location and quantity of radioactive wastes**
Notwithstanding 4731. 0183, subp. 1, and 4731,0168, F, the licensee must record the location and the quantity of radioactive wastes contained in the disposal site and transfer the records upon license termination to:

A. Chief executive of the nearest municipality,
B. Chief executive of the county in which the facility is located,
C. County zoning board or land development and planning agency,
D. State governor and
E. Other state, local and federal governmental agencies as designated by the commissioner at the time of license termination.

Subp 4. **Record of receipt and acceptance of radioactive waste**
Following receipt and acceptance of a shipment of radioactive waste, the licensee must:

A. Record :
(1) the date that the shipment is received at the disposal facility,
(2) the date of disposal of the waste,
(3) a traceable shipment manifest number,
(4) a description of any engineered barrier or structural overpack provided for disposal of the waste,
(5) the location of disposal at the disposal site,
(6) the containment integrity of the waste disposal containers as received,
(7) any discrepancies between materials listed on the manifest and those received,
(8) the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and
(9) any evidence of leaking or damaged disposal containers or radiation or contamination levels in excess of limits specified in the commissioner's, U.S. DOT or NRC regulations.

B. Briefly describe any repackaging operations of any of the disposal containers included in the shipment, plus any other information required by the commissioner or the NRC as a license condition.

C. Retain these records until the commissioner transfers or terminates the license that authorizes activities described in 4731.0168, A, B(3), and F, and 4731. 0183, subparts 1,3, 4, 5, 6, and 9 .

Subp 5. **Record of safeguards**
Each licensee must comply with the safeguards reporting requirements of 10 CFR 30.55, 40.64, 70.53, and 70.54, if quantities or activities, of materials received or transferred exceed the limits of these sections. Inventory reports required by these sections are not required for materials after disposal.

Subp 6. **Copy of financial report**
Each licensee authorized to dispose of radioactive waste received from other persons must file a copy of its financial report or a certified financial report statement annually with the commissioner in order to update the information base for determining financial qualifications.

Subp 7. **Annual reports to the commissioner**
Each licensee authorized to dispose of waste materials received from other persons, pursuant to 4731.0168, A, B(3), and F, and 4731.0183 subparts 1,3, 4, 5, 6, and 9, shall submit annual reports to the commissioner. Reports must be submitted by the end of the first calendar quarter of each year for the preceding year. The reports must include:

A. Specifications of the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in airborne effluents during the preceding year;

B. The results of the environmental monitoring program;

C. A summary of licensee disposal unit survey and maintenance activities;

D. A summary, by waste class, of activities and quantities of radionuclides disposed of;

E. Any instance in which observed site characteristics were significantly different from those described in the application for a license;

F. Any other information the commissioner may require.

G. If the quantities of radioactive materials released during the reporting period, monitoring results, or monitoring results, or maintenance performed are significantly different from those expected in the materials previously reviewed as part of the licensing action, the report must cover this specifically.

Subp 8. **Report of accidental criticality**
Each licensee must report accidental criticality or loss or theft or attempted theft of special nuclear material in accordance with 10 CFR 70.52.

Subp 9. **Transfer of radioactive materials**
Any transfer of radioactive materials, including source materials and special nuclear materials, by the licensee is subject to the requirements of 4731.0315. Radioactive material, source and special nuclear material mean materials as defined in 4731.0100.

Subp 10. **Electronic recordkeeping system**
The licensee must store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

A. The manifest information that must be electronically stored is:

(1) that required in 4731.3001, G, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

(2) that information required in 4731.0183 subp. 4.

B. As specified in facility license conditions, the licensee must report as stored information, or subsets of this information, on a computer-readable medium.

4731.0184 Records of Receipt, Transfer, and Disposal of Radioactive Material, Including Source Material.

Subpart 1. **Activities that require records**

Each person who receives radioactive material, including source material, pursuant to a license issued pursuant to the regulations in Chapter 4731 must keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

A. The licensee must retain each record of receipt of radioactive material, including source material, as long as the material is possessed and for four years following transfer or disposition of the radioactive source or until the next inspection.

B. The licensee who transferred the material must retain each record of transfer of the radioactive source, including source material, until the commissioner terminates the license that authorizes the activity that is subject to the record keeping requirement.

C. The licensee must retain each record of disposal of radioactive material, including source material, until the commissioner terminates each license that authorizes the activity that is subject to the record keepng requirement.

D. If radioactive material, including source material, is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt, record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in first-out), to make records that are required by 4731.0184 account for 100 percent of the material received.

Subp 2. **Record retention period**

The licensee must retain each record that is required by 4731.0184 or by license condition for the period specified by the appropriate regulation or license condition. Each record must be maintained until the commissioner terminates the license that authorizes the activity that is subject to recordkeeping requirements.

Subp 3. **Prior to license termination**

Prior to license termination, each license authorized to possess radioactive material, including source material, must forward to the following records to the commissioner:

A. For radioactive material in an unsealed form,

(1) records of disposal of licensed material made under 4731.0136, subp. 2 (including burials authorized before January 28, 1981, and burial of small quantities of licensed materials in soil before January 28, 1981 without specific U.S. Nuclear Regulatory Commission authorization.)

(2) records required by 4731.0169, subp. 2, B, (4).

B. For all licensed radioactive material, the records required by 4731.0309, subparts 2,

3, and 4.

Subp 4. **Records for activities that are transferred or assigned**
If licensed activities are transferred or assigned in accordance with 4731.0300, subp. 5, B, each licensee authorized to possess radioactive material, including source material, in an unsealed form, must transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

A. Records of disposal of licensed material made under 4731.0136, subp2, (including burials authorized before January 1981) 4731.0136, subparts 3, 4, and 7.

B. Records required by 4731.0169, subp. 2, B, (4).

4731.0185 Transportation shipment records of radioactive materials

A. Each licensee or registrant must maintain, for a period of 4 years after shipment or until the next inspection, a record of each shipment of licensed material not exempt under 4731.1513 showing, where applicable:

(1) identification of the packaging by model number and serial number;

(2) verification that the packaging, as shipped, had no significant defect;

(3) volume and identification of coolant;

(4) type and quantity of licensed material in each package, and the total; quantity of each shipment;

(5) for each item of irradiated fissile material:

(a) identification by model number and serial number;

(b) irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions, and;

(c) any abnormal or unusual conditions relevant to radiation safety;

(6) date of shipment;

(7) for fissile packages and Type B packages, any special controls exercised;

(8) name and address of the transferee;

(9) address to which the shipment was made; and

(10) results if the determinations required by 4731.1504 and by the conditions of the package approval.

B. The licensee shall make available to the commissioner for inspection, upon reasonable notice, all records required by 4731.0185, A, above and 4731.1500 to 4731.1520. Records are valid only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

C. The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging.

(1) the records to be maintained include records of:

(a) determinations required by 4731.1503;

(b) design, fabrication, and assembly;

(c) results reviews, inspections, tests, and audits;

(d) results of monitoring work performance and materials analyses;

(e) results of maintenance, modification, and repair activities.

(2) inspection, test, and audit records must identify the inspector or data reorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted;

(3) the records must be retained for 4 years or until the next inspection by the commissioner after the life or packaging to which they apply.

4731.0186 Records For Industrial Radiography Uses of Radioactive Material.
Each licensee must maintain copies of records required by this part at the location specified in 4731.0500, subpart 2, item H. In addition to the record requirements in 4731.0500, supb. 3, the following applies.

Subpart 1. **Field stations and temporary jobsites**. Each licensee must have copies of the following documents and records sufficient to demonstrate compliance at all field stations and temporaty jobsites;

A. The radioactive material license authorizing the use of licensed material;

B. A copy of 4731.0100-4731.0194 and 4731.0500-4731.0520;

C. Use logs for each radiographic exposure device as required by 4731.0511;

D. Records of equipment problems identified in daily checks of equipment as required by 4731.0507, subp. 1;

E. Records of alarm system and entrance control checks required by 4731.0507, for permanent radiographic installations;

F. Records of individual monitoring dosimeters as required by 4731.0502;

G. Operating and emergency procedures required by 4731.0505;

H. The latest calibration of the radiation survey instruments in use at the jobsite, as required by 4731.0510;

I.. The latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by 4731.0502;

J. Latest radiation safety survey records required by 4731.0510;

K. The shipping papers for the transportation of radioactive materials required by 4731.0501, subp. 2; and

L. When operating under reciprocity pursuant to 4731.0316 a copy of the Agreement State or NRC license authorizing the use of licensed materials.

Subp. 2. **Records of receipt and transfer of sealed industrial radiography sources.** Each licensee must maintain transportation records showing the receipts and transfers of industrial radiography sources and devices using DU for shielding.

Subp. 3. **Records of quarterly inventory.** Each licensee must maintain records of the quarterly inventory of sealed sources and of devices containing depleted uranium as required by 4731.0511.

Subp. 4. **Utilization logs.** Each licensee must maintain utilization logs for each sealed source.

Subp. 5. **Records of inspection and maintenance of radiographic exposure devices,**

transport and storage containers, associated equipment, source changers, and survey instruments. Each licensee must maintain records specified in 4731.0507 of equipment problems.

Subp. 6. **Records of operator qualifications.** Each licensee must maintain records of radiographer and assistant radiographer training and certification:

A. Records of initial training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

B. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliances observed by the RSO.

4731.0187 Records for Industrial Irradiators. The licensee must maintain the following records at the irradiator:

A. Records of radiation surveys required by 4731.0710;

B. Records of pool water conductivity meter calibrations required by 4731.0709;

C. Records of the results of pool water contamination checks required by 4731.0709;

D. Records of inspection and maintenance checks required by 4731.0709;

E. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment

F. Records on the design checks required by 4731.0702 and the construction control checks as required by 4731.0702, subp. 3.

4731.0188 Records for Well Logging

Subpart 1. **Records required at licensee's facility and field stations.**

Each licensee must maintain the following records at the licensee's facility and each field station:

A. A copy of chapter 4731;

B. The license authorizing the use of licensed material;

C. Operating and emergency procedures required by 4731.0803

D. The record of radiation survey instrument calibrations required by 4731.0807, subp. 2;

E. The record of leak test results required by 4731.0134;

F. Visual inventory records required by 4731.0808;

G. Utilization records required by 4731.0808;

H. Records of inspection and maintenance required by 4731.0805;

I. Training records required by 4731.0152, subp. 4 and

J. Survey records required by 4731.0807.

Subp. 2. **Records required at temporary jobsites..** Each licensee conducting operations at a

temporary jobsite must maintain the following documents and records at the temporary jobsite until the well logging operation is completed:

A. Operating and emergency procedures required by 4731.0803;

B. Evidence of latest calibration of the radiation survey instruments in use at the site required by 4731.0807, subp. 2;

C. Latest survey records required by 4731.0807;

D. The shipping papers for the transportation of radioactive materials required by 4731.1501, supb. 2 of this chapter; and

E. When operating under reciprocity pursuant to 4731.0316, a copy of the Agreement State license authorizing use of licensed materials.

4731.0189 Records for Sealed and Unsealed Sources in Industrial and Research Facilities
Each licensee or registrant must maintain the following records required by 4731.1000, subp. 3:

A. Radioactive material use record

B. Inspection and maintenance checks

C. Routine and emergency surveys

D. Visual inventories of radioactive material.

X-RAY RECORDS

4731. 0190 Records For All Facilities Using X-ray Equipment
Subpart 1. **Individual x-ray systems**. The licensee or registrant must maintain on the premises the following information for each x-ray system and accelerator for inspection by the commissioner.

A. The maximum rating of the x-ray tube and generator.

B. The manufacturer and serial numbers or other permanent identification number of the control console and x-ray tubes.

C. For diagnostic x-rya systems, the half-value layer of the x-ray beam and the kVp at which the half-value layer was measured.

D. For diagnostic and therapeutic x-ray systems, records of site-specific radiation safety surveys, radiation leakage measurements, calibrations, equipment performance measurements, maintenance, and equipment modifications performed on the x-ray system with the names of individuals who performed the services.

E. For industrial ionizing radiation producing equipment and nonmedical accelerators, records as specified in 4731.0168-4731.0174.

Subp. 2. **Mammographic image retention**. All mammography images must be retained as required by the Mammography Quality Standards Act of 1992., United State Code, title 42, section 263b, and regulations adopted thereunder.

Subp. 3. **Recordkeeping**. The licensee or registrant must have available at the time of inspection by the commissioner, records of x-ray equipment and accelerators, and equipment performance measurement for x-ray equipment in accordance with 4731.0168- 4731.0174.

A. Current copies of delegation agreements form physicians assistants and registered physician assistants must be available at the time of inspection by the commissioner. Each delegation agreement must be signed by all supervising physician.

B. Individual monitoring records must be kept in accordance with 4731.0171.

C. At all time, the licensee or registrant is responsible for record retention required by this chapter. If the licensee or registrant ceases operation for any reason, provision must be made for e record retention required by this chapter.

D. Each facility doing radiographic and fluoroscopic imaging procedures, except dental procedures, must keep a record of the following information:

(1) age of patient, if under age 18;

(2) imaging procedures performed; and

(3) name or initials of person performing the imaging procedure.

4731.0191 Records For Industrial Radiation Producing Equipment Facilities
The registrant must ensure that the records in this subpart are maintained for each piece of industrial ionizing radiation producing equipment and accelerators. A copy of the records must be kept with the operating and emergency procedures for the equipment.

A. Except as provided in 4731.0132, subp. 2, item B, the following must be maintained for inspection by the commissioner until the time of the next inspection:

(1) records of the inspection and maintenance of equipment as required by 4731.0601;

(2) records of industrial radiation safety surveys as required by 4731.0601;

(3) records of radiation survey instrument tests and calibrations as required by 4731.0601, supb. 2. Acceptable records include tags or labels affixed to the device or survey meter; and

(4) use logs as required by 4731.0601, subp. 3.

(5) inventories as required by 4731.0129, subp. 8, item B.

B. For records at temporary jobsites, each registrant conducting industrial radiography must have available at the temporary jobsite:

(1) a copy of current registration;

(2) a copy of operating and emergency procedures;

(3) industrial radiation safety survey records as required by 4731.0601;

(4) direct reading pocket dosimeter records for the period of operation at the site; and,

(5) the latest instrument calibration records for instruments in use at the site.

4731.0192 Equipment performance test records. Each licensee or registrant must maintain these records in accordance with 4731.0168-4731.0174 until the next inspection by the commissioner.

4731.0193 Quality Assurance records. Each licensee or registrant must maintain these records in accordance with 4731.0168-4731.0174 until the next inspection by the commissioner.

LICENSING OF RADIOACTIVE MATERIALS

4731.0300 Licensing of Radioactive Material.

Subpart 1. **Applicability.** This part provides for the licensing of radioactive materials. No person shall receive, possess, use, transfer own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part. Unless otherwise specified in these rules or license, no licensee shall use radioactive materials;

A. In or on human beings
B. In field applications where radioactive materials are released to the environment;
C. In animals, plants, or their products which will be used for human consumption; or
D. In plants or animals where their products are released to the environment

Subp 2. **General License Requirements** . A person subject to the regulations in 4731.0300 may not receive title to, own, receive, possess, use, transfer, provide for long-term care, deliver or dispose of radioactive materials, including special nuclear materials or residual radioactive material as defined in 4731.0100 or any source material after removal from its place of deposit in nature, unless authorized in a specific or general license issued by the commissioner under the regulations 4731.0300-4731.0320. General licenses for the possession and use of radioactive material and a general license for ownership of radioactive material must comply with the provisions of 4731-0300-4731.0320.

Subp. 3. **Additional License Requirements.** In addition to the requirements of this part, all licensees are subject to the requirements of 4731.0101 - 4731.0195, 4731, 4731.0700 - 4731.0720 and 4731.1500 - 4731.1518. Licensees engaged in industrial radiographic operations are also subject to the requirements of 4731.0500 - 4731.0520, licensees using radionuclides in the healing arts are subject to the requirements of 4731.1200 - 4731.1220 and licensees engaged in well logging and subsurface tracer studies are subject to the requirements of 4731.0800 - 4731.0820.

Subp. 4. **Modification and revocation of licenses for radioactive material users.**

A. Any license may be revoked, suspended, or modified, in whole or in part, for:

(1) any false statements in the application or any statement of fact required in this rule; or

(2) because of conditions revealed by such application or statement of fact; or

(3) any report, record or inspection; or

(4) other means which would warrant the commissioner to refuse to grant a license on an original application; or

(5) for violation of, or failure to observe any of the terms and provisions of this rule.

B. No license shall be modified, suspended or revoked:

(1) except in cases of willfulness or those in which the public health, interest or safety requires otherwise; or

(2) unless, prior to the institution of such modification, suspension or revocation proceedings, the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

C. Upon revocation, suspension or modification of a license, the commissioner may

immediately take possession of all radioactive material, including source and special nuclear material held by the licensee.

Subp. 5. **Terms and Conditions of Licenses.**

A. Each license issued pursuant to Chapter 4731 shall be subject to all rules, regulations and orders of the commissioner.

B. Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of Chapter 4731.

C. Each person licensed by the commissioner pursuant to the regulations in Chapter 4731 shall confine his possession and use of radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations of Chapter 4731 shall carry with it the right to receive, possess, and use radioactive material . Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of 4731.1500- 4731.1518.

D. The commissioner may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive materials, including special nuclear materials, as the commissioner deems appropriate and necessary in order to:

(1) promote health or to minimize danger of life or property;

(2) guard against the loss or diversion of special nuclear material

(3) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of Chapter 4731.

E. Licensees required to submit emergency plans by 4731.0317 shall follow the emergency plan approved by the commissioner. The licensee may change the approved plan without commissioner approval only if the changes do not decrease the effectiveness of the plan, The licensee shall furnish the change to the commissioner and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease or potentially decrease the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the commissioner.

F. No person may commence operation of a uranium enrichment facility until the commissioner verifies through an inspection that the facility has been constructed in accordance with the requirements of the license. The commissioner shall publish notice of the inspections in the Federal Register.

G. No license for radioactive material issued or granted pursuant to Chapter 4731 and no right to possess or utilize special nuclear material granted by any license issued pursuant to these regulations shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the commissioner shall after securing full information, finds that the transfer is in accordance with the provisions of Chapter 4731, and shall give consent in writing.

H. Bankruptcy

(1) each general licensee that is required to register by 4731.0304, subp. 2, C, (13), and each specific licensee shall notify the commissioner, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 of the United States Code by or against:

(a) the licensee;

(b) an entity that includes person, estate, trust, governmental unit, and United States trustee;

(c) an affiliate which includes an entity or corporation that owns, controls, or holds power to vote 20 percent or more of outstanding voting securities, or a person whose business or substantially all of the property, is operated under a lease or operating agreement by a debtor. For further information see 11 U.S.C. 101(2)

(2) bankruptcy notification must indicate:

(a) the bankruptcy court in which the petition for bankruptcy was filed; and

(b) the date of the filing of the petition

Subp. 6. **Right to Cause the Withholding or Recall of Radioactive Material.** The commissioner may cause the withholding or recall of radioactive material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the commissioner, or who uses such materials in violation of law or regulation of the commissioner, or in a manner other than as disclosed in the application therefor or approved by the commissioner.

Subp. 7. **Right to Grant a Variance to Requirements.** The commissioner may, upon application by a licensee or upon the commissioner's own initiative, grant a variance from the requirements of these regulations if the commissioner determines the variance is authorized by law and would not result in undue hazard to life or property.

4731.0301 Radiological Criteria for License Termination

Subpart 1. **General Provisions and Scope**

A. The criteria in 4731.0301 apply to the decommissioning of facilities licensed under 4731.0300-4731.0320, 4731.0500-4731.0520, 4731.01200-4731.01220, 4731.0700-4731.0720, 4731.0800-4731,0820, 4731.0900-4731.0920, and 4731.1000-4731.1020;

B. The criteria in 4731.0301 do not apply to sites which:

(1) have been decommissioned prior to the effective date of this rule in accordance with criteria identified in the Site Decommissioning Plan action Plan of April 16, 1992 as listed in 57 CFR 13389;

(2) have previously submitted and received the commissioner's approval on a license termination plan or decommissioning plan that is compatible with the Site Decommissioning Plan Action Plan.

(3) after a site has been decommissioned and the license terminated in accordance with the criteria in 4731.0301, the commissioner will require additional cleanup only if based on new information, the commissioner determines that the criteria of 4731.0301 were not met and residual activity remaining at the site could result in significant threat to public health and safety.

(4) The licensee, when calculating the Total Effective Dose Equivalent to the average member of the critical group, must determined the peak annual Total Effective Dose Equivalent dose expected within the first 1000 years after decommissioning..

Subp. 2. **Criteria for unrestricted use after license termination.** A site will be considered acceptable for unrestricted use if:

A. The residual radioactivity that is distinguishable from background radiation, results in

a Total Effective Dose Equivalent to an average member of the critical group that does not exceed 25 rem (0.25 mSv) per year, including that from groundwater sources of drinking water; and

B. The residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the radioactivity levels must take into account consideration of any detriments, such as deaths from transportation accidents involving radioactive materials, expected to potentially result from decontamination and waste disposal.

Subp 3. **Criteria for license termination under restricted conditions**. A site will be considered acceptable for license termination under restricted conditions, if the licensee:

A. Can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 4731.0301, subp. 2:

(1) would result in net public or environmental harm; or

(2) were not being made because the residual levels associated with restricted conditions are as low as reasonably achievable (ALARA). Determination of the radioactivity levels must take into account consideration of any detriments, such as transportation accidents involving radioactive materials, expected to potentially result from decontamination and waste disposal;

B. Has made provisions for legally enforceable institutional controls that provide reasonable assurance that the Total Effective Dose Equivalent from residual radioactivity, distinguishable from background radiation, will not exceed 25 rem (0.25 mSv) per year to an average member of the critical group; and

C. Has provided sufficient financial assurance, in accordance with 4731.0309, subparts 2, 3, and 4, that will enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(1) funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in 4731.0309, subp. 3, D, (1).

(2) surety method, insurance or other guarantee method as described in 4731.0309, subp. 3, D.

(3) a statement of intent in case of federal, state, or local government licensees, as described in 4731.0309, subp 3. D, (4).

(4) an arrangement, which includes the signature of an official of the governmental entity, that is deemed acceptable by such governmental entity when a government entity is assuming custody and ownership of a site,

D. Has arranged, while seeking advice from individuals and institutions in the community who may be affected by the license termination or decommissioning plan, on the issues identified in 4731.0301, subp. 3, E, (1), below provide for:

(1) participation by representatives of a broad cross section of community interests who may be affected by a decommissioning;

(2) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(3) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues; and

E. Has submitted a decommissioning plan or a license termination plan to the commissioner indicating the licensee's intent to decommission in accordance with 4731.0314, subp.1, B, and specifying that the licensee intends to decommission by restricting use of the site.

The licensee shall document in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been brought and incorporated, ss appropriate, following analysis of that advice.

(1). Licensees proposing to decommission by restricting use of the site shall follow 4731.0301, Subp 3, C, above, and obtain information that will:

(a) provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem(0.25 mSv) total effective dose equivalent per year;

(b) be enforceable; and

(c) not impose undue burdens on the local community or other affected parties.

(2) The licensee has provided financial assurance in accord with 4731.0301, subp3, C, above.

F. Has documented that residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the Total Effective Dose Equivalent from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(1) 100 mrem (1 mSv) per year; or

(2) 500 mrem (5 mSv) per year provided that the licensee:

(a) demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem per year (1 mSv per year) value of 4731.0301, subp. 3, F, (1), above, are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(b) makes provisions for durable institutional controls;

(c) provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of 4731.0301, subp. 3, F, and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in 4731.0301,subp. 3, C.

Subp. 4. **Alternative Criteria for License Termination**

A. The commissioner may terminate a license using alternative criteria greater than the dose criterion of 4731.0301, subp. 2, 4731.0301, subp. 3, B, and 4731.0301, subp 3, E, (1), if the licensee:

(1) provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 100 mrem per year (1 mSv per year) limit of 4731.0126, subparts 1 and 2, by submitting an analysis of possible sources of exposure;

(2) has employed to the extent practical restrictions on site use according to the provisions of 4731.0301, subp. 3, in minimizing exposures at the site; and

(3) reduces doses to as low as reasonably achievable (ALARA) levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

(4) has submitted a decommissioning plan or license termination plan to the

commissioner indicating the licensee's intent to decommission in accordance with 4731.0314, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning had been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(a) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(b) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(c) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues.

B. The use of alternate criteria to terminate a license requires the approval of the commissioner after consideration of any comments provided by the U. S. Environmental Protection Agency and any public comments submitted pursuant to 4731.0301, subp. 5.

Subp. 5. **Public Notification and Public Participation in termination.** Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to 4731.0301, subparts 3 or 4, or whenever the commissioner deems such notice to be in the public interest, the commissioner shall:

A. Notify and solicit comments from:

(1) local and state government in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) the Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to 4731.0301, subp. 4.

B. Publish a notice in the State Register and in a forum, such as local newspapers, letters to state and local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

C. Minimization of Contamination. Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize to the extent practicable, the generation of radioactive waste.

4731.0302 Determination of Critical Mass

Subpart 1. **Calculation of total quantity.** For purposes of Chapter 4731 special nuclear material in quantities that are included in a critical mass are determined by uranium enriched with the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear materials in combination shall not exceed unity. For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

[175 (grams contained U-235/350) + (50grams U-233)/200] + (50 grams

Pu/200) = 1

Subp. 2. **Application of critical mass.** The critical mass determination applies to any person in an agreement state who manufactures, produces, receives, possesses, uses, or transfers radioactive material, including source material and special nuclear material in quantities no greater than those listed in Subp.1 above at any particular plant or other authorized location of use. Calculations of special nuclear materials shall include in the quantity computed according to 4731.0302, subp. 1, above, the total quantity of special nuclear material which he is authorized to receive, possess, or use at the plant or other location of use at any one time.

GENERAL LICENSES

4731.0303 General Licenses For Source Material

Subpart 1. **For small quantities of source material:**

A. Commercial and industrial firms, research, educational and medical institutions, and state and local government agencies are issued a general license to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

B. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 4731.0303, subp. 1, A , are exempt from the provisions of 4731.0101-4731.0195, to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to 4731.0300-4731.0320.

C. Persons who receive, possess, use, or transfer source material pursuant to the general license in 4731.0303, subp. 1, A, are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the commissioner in a specific license.

D. Persons are issued a general license authorizing the licensee to receive title to radioactive material or source material without regard to quantity. This general license does not authorize any person to receive, possess, use, deliver or transfer radioactive material source material.

Subp. 2. **Depleted uranium in industrial products and devices.**

A. Persons are issued a general license to receive, acquire, possess, use, or transfer, in accordance with the provisions of 4731.0303, subp. 2, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

B. The general license in 4731.0303, subp. 2, A, applies only to industrial products or devices which have been manufactured or initially transferred either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 4731.0311, subp. 12, or in accordance with a specific license issued to the manufacturer by the commissioner, the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the commissioner, the U.S. Nuclear Regulatory Commission or an agreement state.

C. Information for depleted uranium registration certificate:

(1) persons who receive, acquire, possess, or use uranium pursuant to the general license established by 4731.0303, subp.2, C, (1), shall file form 4731.3004, L, "Registration Certificate –Use of Depleted Uranium Under General License"with the commissioner. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on form 4731.3004, L, the following information and such other information as may be required by that form:

(a) name and address of the general licensee;

(b) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium in 4731.0303, subp. 2, C, (1), and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(c) name, title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 4731.0303, subp. 2, C, (1).

(2) the registrant possessing or using depleted uranium under the general license established by 4731.0303, subp. 2, A, shall report in writing to the commissioner any changes in information furnished by the registrant in the form 4731.3004, L. The report shall be submitted within 30 days after the effective date of such change.

D. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 4731.0303, subp. 2, C, (1):

(1) shall not introduce depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(2) shall not abandon depleted uranium;

(3) shall transfer or dispose depleted uranium only by transfer in accordance with the provisions of 4731.0136, subp. 8.

(a) in the case where the transferee receives the depleted uranium pursuant to the general license established by 4731.0303, subp. 2, C, (1), the transferor shall furnish the transferee a copy of 4731.0300- 4731.0320, and a copy of form 4731.3004, L.

(b) in the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commissions's or agreement state's regulation equivalent to 4731.0303, subp. 2, C, (1), the transferor shall furnish the transferee a copy of 4731.0300- 4731.0320 and a copy of the form 4731.3004, L, accompanied by a note explaining that use of the product of device is regulated by the NRC or agreement state under requirements substantially the same as those in 4731.0101-4731.0195, 4731.0300- 4731.0320, 4731.0501- 4731.0520.

(4) within 30 days of any transfer, shall report in writing to the commissioner the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(5) shall not export such depleted uranium except in accordance with a license issued by the NRC pursuant to 10CFR 110.

E Any person receiving, acquiring, possessing, using or transferring depleted uranium

pursuant to the general license established by 4731. 0303, subp. 2, C, (1), is exempt from the requirements of 4731.0101-4731.0195 with respect the depleted uranium covered by that general license.

4731.0304 General Licenses for radioactive material other than source material. Different general licenses are issued in this subpart, each of which has its own specific conditions and requirements.

Subpart 1. **Certain devices and equipment**. Persons are issued a general license to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured , tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued to the manufacturer by the commissioner, an agreement state, or the U.S. Nuclear regulatory Commission. These devices are:

A. Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5MBq) of polonium-210 per device.

B. Ion generating tube. Devices designed for ionization of air which contain as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries(18.5MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85GBq) of hydrogen-3(tritium) per device.

Subp 2. **Certain measuring, gauging or controlling devices.**

A. Commercial and industrial firms, and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies are issued a general license to own, receive, acquire, possess, use or transfer in accordance with the provisions of 4731.0304, subp. 2, B, C, and D, below, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of:

(1) detecting;
(2) measuring;
(3) gauging, or
(4) controlling thickness, density, level interface location , radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

B. Devices under general license in 4731.0304, subp.2, A

(1) the general license in 4731.0304, subp. 2, A, above, applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in

(a) a specific license issued under 4731.0311, subp. 4, or
(b) an equivalent specific license issued by the NRC or an agreement state.

(2) the devices must have been received from one of the specific licensees described in 4731.0304, subp. 2, B, (1), above or through a transfer made under 4731.0304, subp.2, C, (9), below.

(3) regulations 21CFR 179.21 under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling.

C. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 4731.0304, subp. 2, A:

(1) shall ensure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) shall ensure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however, the following need not be tested for any purpose, devices:

(a) containing only krypton need not be tested for leakage of radioactive material, and

(b) containing only tritium or not more than 100 microcuries(3.7 MBq) of other beta/gamma-emitting material or 10 microcuries(0.37 MBq) of alpha-emitting material, and

(c) held in storage in the original shipping container prior to initial installation;

(3) shall ensure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed in accordance with the instructions provided by the labels, or by a person holding an applicable specific license from, the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such activities;

(4) shall maintain records until the next inspection or until the sealed source is transferred or disposed of. These records are for the following:

(a) compliance with requirements of 4731.0304, subp. 2, C, (2) and (3);

(b) the dates the tests were performed;

(c) the results of the tests;

(d) the names of persons performing the tests, installation, servicing, and removal of radioactive material from installation;

(e) the shielding or containment for radioactive materials

(f) tests for leakage of radioactive materials required by 4731.0304, subp. 2, C, (2);

(g) tests of the "on-off" mechanism and indicator required by 4731.0304, subp. 2, C, (2);

(h) tests of 4731.0304, subp. 2, C, (3), from the date of the recorded event.

(5) shall suspend operation of the device immediately:

(a) if there is a failure of or damage to, or any indication of a possible failure of or damage to:

((1)) the shielding of the radioactive material, or

((2)) the "on-off" mechanism or indicator, or

(b) upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, operation of the device:

((1)) until it has been repaired by the manufacturer or other person holding an applicable specific license from the commissioner, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to repair such devices, or

((2)) until the device and any radioactivity from the device are disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the commissioner, and,

((3)) within 30 days furnish to the commissioner, a report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcuries or more of removable radioactive material or failure of or damage to a source likely to result in contamination of the premises and environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use,

(6) shall not abandon the device containing radioactive material;

(7) shall not export the device containing radioactive material except in accordance with 10CFR110,

(8) shall for the device containing radioactive material:

(a) transfer or dispose of the device containing radioactive material:

((1)) by export only as provided in 4732.0304, subp. 2, C, (7), above,

((2)) to another general licensee as authorized by 4731.0304, subp.2, C, (9),or

((3)) to a person authorized to receive the device by an appropriate specific license issued under Chapter 4731 or under 4731.136 that authorizes waste collection or equivalent regulations issued by the NRC or an agreement state or

((4)) as otherwise approved under 4731.0304, subp. 2, C, (8) (c), below

(b) within 30 days of the transfer, report to the commissioner;

((1)) the identification of the device by manufacturer's, or initial transferor's, name, model number and serial number of the device transferred,

((2)) the name, address, and license number of the person receiving the device, and the name and position of an individual who may constitute a point of contact between the commissioner and the transferee, and

((3)) the date of the transfer

(c) obtain written approval from the commissioner before transferring the device to another specific licensee not specifically identified in 4731.0304, subp. 2, C. 8, (a), above.

(9) shall transfer the device to another general licensee only if:

(a) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of 4731.0161, 4731.0162, 4731.0168, subp. 2, 4731.0180, 4731.0300, subp. 2, 4731.0304, subp. 2, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the

commissioner:

((1)) the manufacturer's, or initial transferor's, name;

((2)) the model number and the serial number of the device transferred;

((3)) the transferee's name and mailing address for the location of use; and

((4)) the name, title, and phone number of the responsible individual identified by the transferee in accordance with 4731.0304, subp. 2, C, (12), to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(b) the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

shall comply with the provisions of 4731.0161 and 4731.0162 for reporting radiation incidents, thefts, or loss of licensed material.

(10) shall comply with the provisions in 4731.0161 and 4731.0162 for reporting radiation incidents, theft, loss of licensed material, but shall be exempt from the remainder of 4731.0101-4731.0195.

(11) shall respond to written requests from the commissioner to provide information relating to the general license within 30 calender days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, the general licensee shall within that same period, request a longer period to supply the information by submitting a letter to the commissioner and provide written justification as to why it cannot comply.

(12) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements . The general licensee , through this individual , shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of the general licensee's responsibility in this regard.

(13) the general licensee:

(a) shall register, in accordance with 4732.0304, subp.2, C, (13), (b) and (c), below, devices containing at least:

((1)) 10 mCi(370 MBq) of cesium-137,

((2)) 0.1mCi(3.7 MBq) of strontium 90,

((3)) 1 mCi(37 MBq) of cobalt-60,

((4)) 1 mCi(37 MBq) of americium-241, or

((5)) any other transuranic, that is, any other atomic number greater than uranium,92, based on the activity indicated on the label.

Each address for a location of use, as described under 4731.0304, subp.2, C, (13), (c), ((4)), represents a separate general licensee and requires a separate registration and fee.

(b) shall, if in possession of a device meeting the criteria of 4731.0304, subp. 2, C, (13), (a), register these devices annually with the commissioner and pay

the fee required in 4731.0103, subp 2. Registration information must be submitted to the commissioner within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition , a general licensee holding devices meeting the criteria of 4731.0304, subp. 2, C, (13),(a), above is subject to the bankruptcy notification requirement

(c) shall, in registering devices, furnish the following information and any other information specifically requested by the commissioner:

((1)) name and mailing address of the general licensee;

((2)) information about each device:

((a)) the manufacturer, or initial transferor;

((b)) model number;

((c)) serial number;

((d)) the radioisotope and activity, as indicated on the label;

((3)) name, title, and telephone number of the responsible person designated as a representative of the general licensee under 4731.0304,subp. 2, C, (12).

((4)) address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

((5)) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

((6)) certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(d) persons generally licensed by an agreement state with respect to devices meeting the criteria in 4731.0304, subp.2, C, (13), (a), above, are subject to temporary registration requirements, as required in 4731.0103, subp. 1, D, if the devices are used in areas subject to NRC jurisdiction for a period of less than 180 days in one calendar year. The commissioner may request information from such licensees.

(14) shall report changes to the mailing address for the location of use , including change in name of general licensee, to the commissioner within 30 days of the effective date of the change. For a portable device, a report of address change is required only for a change in the device's primary place of storage.

(15) may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 4731.0304, subp. 2, C, (2), above, need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

D. The general license in 4731.0304, subp.2, A does not authorize the manufacture or import of devices containing radioactive material.

E. General license to install devices generally licensed in 4731.0304, subp. 2,A.

(1) any person who holds a specific license issued by the commissioner

or an agreement state authorizing the holder to manufacturer, install, or service a device described in 4731.0304, subp. 2, A, within such agreement state is hereby granted a:

(a) general license to install and service such device in any non-agreement state,

(b) general license to install and service such device in offshore waters as defined in 4731.0100.

(2) the license holder must ensure that the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the commissioner or agreement state.

(3) the license holder must ensure that any labels required to be affixed to the device under regulations of the commissioner or the agreement state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

Subp. 3. **Luminous safety devices for aircraft.**

A. Persons are issued a general license to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices used in aircraft, provided that:

(1) each device contains not more than 10 curies(370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(2) each device:

(a) has been manufactured, assembled or initially transferred in accordance with a license issued by the U.S. Nuclear Regulatory Commission under the provisions of 4731.0311, or

(b) has been manufactured or assembled in accordance with a specific license issued by the commissioner or any agreement state which authorizes the manufacturer or assembly of such device for distribution to persons generally licensed by the agreement state.

B. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 4731.0304, subp. 3, A, are exempt from the requirements of 4731.0101- 4731.0195, except that they shall comply with 4731 .0161,and 4731.0162.

C. This general license does not authorize the manufacture, assembly, or repair or import of luminous safety devices containing tritium or promethium-147.

D. This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instruments dials.

Subp 4. **Ownership of radioactive material, including special nuclear material.** Persons are issued a general license to receive title to and own radioactive material, including special nuclear material without regard to quantity. Notwithstanding any other provisions of Chapter 4731, a general licensee under 4731.0304, is not authorized to manufacture, acquire, produce, transfer, receive , possess, use, import or export radioactive material, including special nuclear material, except as authorized in a specific license.

Subp 5. **Calibration and reference sources.**

A. Persons listed below are issued a general license to own, receive, acquire,

possess, use, and transfer, in accordance with the provisions of 4731.0304, subp.2, C, and D, and 4731.0304, subp. 5, americium-241 or plutonium in the form of calibration or reference sources:

(1) any person who holds a specific license issued by the commissioner which authorizes the person to receive, possess, use and transfer radioactive material including source material and special nuclear material; and

(2) any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, or an agreement state which authorizes the person to receive, possess, use, and transfer radioactive material including source and special nuclear material.

B. Persons are issued a general license to own, receive, possess, use and transfer plutonium in the form of calibration sources in accordance with the provisions of 4731.0304, subp. 2, C, and D, and 4731.0304, subp. 5, if that person holds a specific license issued by the commissioner and is authorized the person to receive, possess, use, and transfer radioactive material.

C. Persons are issued a general license to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 4731.0304, subp. 5, D, and E, if that person holds a specific license issued by the commissioner which authorizes the person to receive, possess, use and transfer radioactive material, including source and special nuclear material.

D. The general licenses in 4731.0304, subp. 5, A, B, and C, above, apply only to calibration or reference sources which have been:

(1) manufactured or initially transferred in accordance with specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to10 CFR 32.57 or 10CFR 70.39 or

(2) manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the commissioner, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in part 4731.0311, subp. 6.

E. The general license provided in part 4731.0304, subp. 5, A, B, and C, is subject to the provisions of parts 4731.0101- 4731.0195, 4731.0313, 4731.0314, 4731.0315, 4731.1500-4731.1520. In addition, persons who own, receive acquire, possess, use, or transfer one or more calibration or reference sources pursuant to this general license:

(1) shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) if radium-226 in such sources;

(2) shall not receive, possess, use, or transfer such source unless the source, or storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(a) the receipt, possession, use and transfer of this source , Model____, Serial No._____, are subject to a general license and the regulations of the NRC or of a state with which the Commission has entered into an agreement state. Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS (AMERICIUM-

241). (PLUTONIUM) (showing only the name of the appropriate material) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

OR

(b) the receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license and the regulations of a licensing state, Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer of importer

(3) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the commissioner, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to receive the source;

(4) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(5) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

F. These general licenses do not authorize the manufacturer of calibration or reference sources containing americium-241, plutonium, or radium-226.

G. the general license in 4731.0304, subp. 5, A, does not authorize the manufacture, import, or export of calibration or reference sources containing plutonium.

Subp 6. **General license for use of radioactive material for certain in vitro clinical or laboratory testing.**

A. Any physician, veterinarian, clinical laboratory or hospital is issued a general license to receive, acquire, possess, transfer, or use for any of the following stated tests, in accordance with the provisions of 4731.0300, subp. 5, B, C, D, and E, the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(1) Carbon-14, in units not exceeding ten microcuries (370 kBq) each.

(2) Cobalt-57, in units not exceeding ten microcuries (370 kBq) each.

(3) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.

(4) Iodine-125, in units not exceeding ten microcuries (370 kBq) each.

(5) Mock Iodine-125 reference or calibration sources, in units not exceeding .05 microcurie (1.85 kBq) of iodine129 and 0.005 microcurie (185 Bq) of americium-241 each.E

(6) Iodine-131, in units not exceeding ten microcuries (370 kBq) each.

(7) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.

(8) Selenium-75, in units not exceeding ten microcuries (370 kBq) each.

B. No person shall receive, acquire, possess, use or transfer radioactive materials pursuant to the general license established by 4731 .0304, subp. 6, A, until he has filed form 4731.3004, 7, with the commissioner and received from the commissioner a validated copy of form 4731.3004, 7, with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on form part 4731.3004, 7, the following information and such other information as may be required by the form:

(1) name and address of the physician, veterinarian, clinical laboratory or hospital;

(2) the location of use; and,

(3) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized under the general license in 4731.0304, subp. 6, A, and that such tests will be performed only by personnel trained in the use of such instruments and in the handling of the radioactive material.

C. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 4731.0304, subp. 6, A, shall comply with the following:

(1) the general licensee shall not possess at any one time, pursuant to the general license in 4731.0304, subp. 6, A, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).

(2) the general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) the general licensee shall use the radioactive material only for the uses authorized by 4731.0304, subp. 6, A.

(4) the general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the commissioner, the U.S. Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled, shipping container as received from the supplier.

(5) the general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 4731.0304, subp. 6, A, (8), as required by 4731.0136.

D. The general licensee shall not receive, acquire, possess, or use radioactive material:

(1) except as packaged units which are labeled in accordance with the provisions:

(a) of an applicable specific license issued by the NRC, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75,cobalt-57, or mock Iodine-125 to persons generally licensed under 4731.0304, subp. 6, A, or its equivalent, or;

(b) of an applicable specific license pursuant to 4731.0311, subp. 7; and

(2) unless one of the following statements, or a similar statement which contains the information called for in one of the following statements appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) this radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation made from, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or of an agreement state.

_____

Name of Manufacturer

(b) this radioactive material shall be received, acquired, possessed, and used only physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal and external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____

Name of Manufacturer

E. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 4731.0304, subp. 6, A , shall report in writing to the commissioner, any changes in the information provided in the form 4731.3004, 7. The report shall be furnished within 30 days after the effective date of such change.

F. Any person using radioactive material pursuant to the general license of 4731.0304, subp. 6, A, above, is exempt from the requirements of 4731.0101- 4731.0195 with respect to radioactive material covered by that general license, except that such persons using mock iodine 125 described in 4731.0304, subp. 6, A, (5), above, shall comply with the provisions of 4731.0136, subp. 1, 4731.0161 and 4731.0162.

Subp 7. **General license for Strontium-90 in ice detection devices.**

A. Persons are issued a general license to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided that:

(1) each device contains not more than 50 microcuries(1.85 MBq) of strontium-90, and

(2) each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant 4731.0311, subp. 8, or in accordance with the specifications contained in a specific license issued to the manufacturer by the commissioner, the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the agreement state.

B. Persons who own, receive, acquire, possess, use, or transfer strontium- 90 contained in ice detection devices pursuant to the general license in 4731.0311, subp. 7, A, (1):

(1) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license pursuant to 4731.0308-4731.0315 from the commissioner, the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or dispose of the device pursuant to 4731.0136;

(2) shall ensure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(3) are exempt from the requirements of 4731.0100-4731.0195, except that such persons shall comply with 4731.0136, subp. 1, 4731.0161, and 4731.0162.

C. This general license does not authorize the manufacture, assembly, disassembly, repair or import of strontium-90 in ice detection devices.

SPECIFIC LICENCES

4731.0308 Application for Specific Licenses

Subpart 1. **Requirements for Application**

A. Applications for specific licenses shall be filed in duplicate on form 4731.3004, 4.

B. The commissioner may at any time after the filing of the original application, and during the life of the license until the expiration of the license, require further statements in order to enable the commissioner to determine whether the application should be granted or denied or whether a license should be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

D. An application for a license may include a request for a license authorizing one or more activities.

E. In the application, the applicant may incorporate by reference information contained in previous application statements or reports filed with the commissioner, provided such references are clear and specific.

F. Applications and documents submitted to the commissioner may be made available for public inspection except that the commissioner may withhold any document or part thereof from public inspection in accord with 4731.0105.

Subp 2. **Requirements for Application for Certain Types of Sources**

A. Application to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

(1) identify the source or device by manufacturer and model number as registered with the commissioner on form 4731.3004, 8, or with an agreement state; or

(2) contain the information identified in 10CFR32.210 (c).

B. Application for unsealed sources

(1) each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 4731.3003, D must comply with the requirements in 4731.0317;

(2) applications for source material for uranium or thorium milling or byproduct material at sites formerly associated with such milling or disposition of the byproduct material shall comply with 10CFR40.31.

(3) each application to possess uranium hexafluoride in excess of 50 kilograms in a single container or 1000 kilograms total must contain either:

(a) an evaluation showing that the maximum intake of uranium by a member of the public due to release would not exceed 2 milligrams; or

(b) an emergency plan for responding to the radiological hazards of an accidental release of source material and to any associated chemical hazards directly incident thereto that is equivalent to the emergency plan in 4732.0317.

Subp 3. **Application for renewal of licenses.**

A Application for renewal of a specific license must be filed on form part 4731.3004,

13, and in accordance with 4731.0308, subparts 1 and 2, and 4731.0309.

B. If any licensee granted the extension described in 4731.0314, subp.1, A, (2), has a currently pending renewal application of the extended license, that application will be considered withdrawn by the licensee and any renewal fees paid by the licensee for that application will be refunded.

Subp 4. **Application for amendment of licenses**. Application for amendment of license shall be filed on form 4731.3004, 4, in accordance with 4731.0308, subparts 1 and 2, and 4731.0309, and shall specify the respects in which the licensee desires its license to be amended and the grounds for the amendment.

Subp 5. **Commissioner action on applications to renew or amend.** In considering an application by a licensee to renew or amend his license the commissioner will apply the applicable criteria set forth in 4731.0308, subparts 1 and 2, and 4731.0309.

4731.0309 General Requirements for the Issuance of Specific Licenses

Subpart 1. **Application approved by commissioner**. A specific license application may be approved if the commissioner determines that:

A. The applicant is qualified by reason of training and experience to use the radioactive material in question for the purpose requested in accordance with 4731.0101-4731.0195, 4731.0300- 4731.0320, 4731.0500- 4731.0520, and 4731.1500- 4731.1520 in such a manner as to protect health and minimize danger to life, safety or property;

B. The applicant's proposed equipment, facilities, and procedures are used in a manner that will protect health and minimize danger to life and property;

C. The applicant satisfies any applicable special requirements in 4731.0101-4731.0195, 4731.0309, subparts 1, 2, and 3, 4731.0310, 4731.0500-4731.0520, 4731.0800-4731.0820, 4731.1200-4731.1220.

D. The applicant satisfies the conditions that are necessary to obtain a license to receive and possess radioactive material for commercial waste disposal by land burial.

E. The applicant satisfies the conditions that are necessary to obtain a license to receive and possess radioactive material for the conduct of any other activity which the commissioner, using the considerations below, determines will significantly affect the quality of the environment:

(1) evaluation before commencement of construction of the plant or facility in which the activity will be conducted,

(2) weighing the environmental, economic, technical and other benefits against environmental costs,

(3) considering available alternatives that the action called for.

F. The applicant satisfies the conditions that are necessary to obtain a license for construction. Commencement of construction:

(1) means any clearing of land, excavation, or other substantial action which would adversely affect the environment of a site,

(2) does not mean site explorations, necessary roads for site exploration, borings

to determine foundation conditions or the preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

G. Commencement of construction prior to the commissioner's determination as in F, above shall be grounds for denial of a license.

Subp 2. Decommissioning Funding Plan and Certificate for Financial Assurance.

A. Each applicant for a specific license must include a decommissioning funding plan as described in 4731.0309, subp. 3, C, when the license is:

(1) using a combination of isotopes, if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in 4731.3001, H.

(2) authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 4731.3001, H;

(3) authorizing the possession and use of more than 100 mCi (3.7 GBq) of source material in a readily dispersible form.

B. Each applicant for a specific license authorizing possession and use of radioactive material, of half-life greater than 120 days and in quantities specified in 4731.0309, subp. 3, B, or for unsealed special nuclear material in quantities specified in 4731.0309, subp. 3, shall:

(1) submit a decommissioning funding plan as described in 4731.0309, subp. 3, C; or

(2) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 4731.0309, subp. 3, C, using one of the methods described in 4731.0309, subp. 3, D. The certificate must either:

(a) state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material; or

(b) include a copy of the financial instrument obtained to satisfy the requirements of 4731.0309, subp. 3, D, that is submitted to the commissioner. The applicant may either:

((1)) defer execution of the financial instrument until after the license has been issued, and submit a signed original of the financial instrument to satisfy the requirements of 4731.0309, subp. 3, D, to the commissioner before receipt of licensed material; or

((2)) not defer execution of the financial instrument, and submit to the commissioner, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 4731.0309, subp. 3, D.

C. Each applicant for a specific license authorizing possession and use of quantities of source material greater than 10 mCi (370 MBq) but less than or equal to 100 mCi (3.7 GBq) in a readily dispersible form shall either:

(1) submit a decommissioning funding plan as described in 4731.0309, subp. 3, D; or

(2) submit a certification that financial assurance for decommissioning has been provided in the amount of $150,000 using one of the methods described in 4731.0309, subp. 3, D.

The certification must state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. The applicant may either:

(a) defer execution of the financial instrument until after the license has been issued, at which time a signed original of the financial instrument obtained to satisfy the requirements of 4731.0309, subp. 3, D, must be submitted to the commissioner prior to receipt of licensed material, or

(b) not defer execution of the financial instrument, and at the time of application, and shall submit to the commissioner, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 4731.0309, subp. 3, D.

Subp 3. **Financial Assurance for Decommissioning**

A. Each holder:

(1) of a specific license issued before Aug 01, 2003, which is of a type described on 4731.0309, subp. 2, shall provide financial assurance for decommissioning in an amount at least equal in accordance with the criteria set forth in this subpart.

(2) of a specific license issued before Aug 01, 2003, and of a type described in 4731.0309, subp. 2, A, shall submit, on or before Aug 01, 2003,

(a) a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 in accordance with the criteria set forth in this subpart, or

(b) the certification of financial assurance at this time and a decommissioning funding plan in any application for license renewal.

(3) of a specific license issued before Aug 01, 2003, and of a type described in 4731.0309, subp. 2, B, shall submit on or before Aug 01, 2003, a certificate of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subpart.

B. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of 4731.3001, C, in unsealed form.
(For a combination of isotopes, if R, as defined in 4731.0309, subp. 2, A, divided by 10^4 is greater than 1, but R divided by 10^5 is less than or equal to 1).....$750,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of 4731.3001, C, in unsealed form.
(For a combination of isotopes, if R, as defined in

4731.0309, subp. 2, A, divided by 10^3 is greater than 1, but R divided by 10^4 is less than or equal to 1.).....$150,000

Greater than 10^{10} times the applicable quantities of 4731.3001, C.
In sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 4731.0309, subp. 2, A, divided by 10^{10} is greater than 1.) .....$ 75,000

C. Each decommissioning funding plan must contain:

(1) a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 4731.0309, subp. 3, D, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

(2) a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning. A signed original of the financial instrument obtained to satisfy the requirements of 4731.0309, subp. 3, D, below shall accompany the certificate.

D. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) prepayment may be either:

(a) a deposit prior to the start of operation into an account segregated from licensee assets, funds sufficient to pay decommissioning costs. The licensee must have no administrative control of the cash or liquid assets of these funds;

(b) a form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) guarantee method

A surety method, insurance, or other guarantee method may be used to guarantee that decommissioning cost will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit.

(a) a parent company guarantee of funds for decommissioning cost based on a financial test:

((1)) may be used if the guarantee and test are as contained in 4731.3001 J.

((2)) may not be used in combination with other financial methods to satisfy the requirements of this subpart.

(b) commercial corporations:

((1)) that issue bonds that have a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 4731.3001 K.

((2)) that do not issue bonds that have a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 4731.3001, L.

(c) nonprofit entities, such as colleges, universities, and nonprofit

hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are contained in 4731.3001, M.

(d) a guarantee by the applicant may not be used:

((1)) in combination with other financial methods used to satisfy the requirements this subpart, or

((2)) in any situation where the applicant or licencee has a parent company holding majority control of the voting stock of the company.

(e) any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

((1)) be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the commissioner, the beneficiary, and the licencee of its intention not to renew.

((2)) provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the commissioner within 30 days after receipt of notification of cancellation.

((3)) be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the commissioner. An acceptable trustee includes an appropriate state or federal government's agency or an entity which has authority to act as a trustee and whose trust operation are regulated and examined by a federal or state agency.

((4)) must remain in effect until the commissioner has terminated the license.

(3) an external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund:

(a) is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected.

(b) may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 4731.0309, subp. 3, D, (4).

(4) in case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in 4731.0309, subp. 3, B, and indicating that funds for decommissioning will be obtained when necessary.

Subp 4. **Recordkeeping for Decommissioning.** Each person licensed under 4731.0300-4731.0320 shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use.

A. Before licensed activities are transferred or assigned in accordance with 4731.0300,

subp. 5, licensees shall transfer all records described in this subpart to the new licensee.

B. The new licensee will be responsible for maintaining these records until the license is terminated.

C. If records important to the decommissioning of a facility are kept for other purposes, reference of these records and their locations may be used, and

D. Information the commissioner considers important to decommissioning consists of:

(1) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site. These records may be limited to instances when:

(a) contamination remains after any cleanup procedures, or

(b) there is reasonable potential that contamination remains after any cleanup procedures, or

(c) there is reasonable potential that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete, and

(d) these records must include any known information of identification of involved nuclides, quantities, forms, and concentrations.

(2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used, stored, or both, and if locations of possible inaccessible contamination such as buried pipes which may be subject to contamination.

(a) if required drawings are referenced, each relevant document need not be indexed individually.

(b) if drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for the assuring funds if either a funding plan or certification is used.

(4) a single document updated every 2 years, of the following:

(a) all areas designated as restricted areas as defined under 4731.0100;

(b) all areas outside of restricted areas that require documentation under 4731.0309. subp. 4, D, (1);

(c) all areas outside of restricted areas where current and previous wastes have been buried as documented under 4731.0136, subp 5; and

(d) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal in accordance with 4731.0136, subp. 2.

E. Exceptions to information the commissioner considers important to decommissioning:

(1) areas containing depleted uranium used only for shielding or as penetrators in unused munitions,

(2) locations with only sealed sources provided the sources have not leaked or no contamination remains after cleanup of any leak.

4731.0310 Requirements for Specific Licenses of Broad Scope. This subpart contains

requirements for the issuance of specific licenses of broad scope for radioactive material and holders of such licenses. The provisions and requirements of this subpart are in addition to and not in substitution for other requirements of Chapter 4731.

Subpart 1. **Types of broad scope licenses**. The different types of broad scope licenses are as follows:

A. "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities are usually in the multicurie range.

B. "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use , and transfer of any chemical or physical form of radioactive material specified in 4731.3003 C, for any authorized purpose. The possession limit for a Type B license of broad scope:

(1) if only one nuclide is possessed thereunder, is the quantity specified for that radionuclide in 4731.3003 C, Column I.

(2) if two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows:

(a) for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 4731.3003, C, Column I, for that radionuclide.

(b) the sum of all the ratios for all radionuclides possessed under the license shall not exceed unity.

C. "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in 4731.3003 C , for any authorized purpose. The possession limit for a Type C license of broad scope:

(1) if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 4731.3003 C, Column II.

(2) if two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows:

(a) for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 4731.3003 C, Column II, for that radionuclide.

(b) the sum of all ratios for all radionuclides possessed under the license shall not exceed unity.

Subp. 2. **Application for a Type A specific license of broad scope.** An application for a Type A specific license of broad scope may be approved if:

A. The applicant satisfies the general requirements specified in 4731.0309;

B. The applicant has engaged in several different types of activities involving the use of radioactive material; and

C. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

(1) the establishment of a radiation safety committee composed of such persons

as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials;

(2) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters;

(3) the establishment of appropriate administrative procedures to ensure:

(a) control of procurement and use of radioactive material;

(b) completion of safety evaluations of proposed uses of radioactive material which take into consideration of such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(c) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 4731.0310, subp. 2, C, (3), prior to use of the radioactive material.

Subp. 3. **Application for a Type B specific license of broad scope.** An application for a Type B specific license of broad scope may be approved if:

A. The applicant satisfies the general requirements specified in 4731.0309 ; and

B. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

(1) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(2) the establishment of appropriate administrative procedures to ensure:

(a) control of procurement and use of radioactive material;

(b) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment training and experience of the user, and the operating or handling procedures; and

(c) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 4731.0310, subp. 2, C, (3), prior to use of the radioactive material.

Subp. 4. **Application for a Type C specific license of broad scope .** An application for a Type C specific license of broad scope may be approved if:

A. The applicant satisfies the general requirements specified in 4731.0309.

B. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(1) a college degree at the bachelor level, or equivalent training and experience, in the biological sciences or in engineering; and

(2) at least 40 hours of training and experience:

(a) in the safe handling of radioactive material,

(b) in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and

(c) in biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(3) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to ensure safe operation.

Subp. 5. **Conditions for specific licenses of broad scope.** Specific licenses of broad scope are subject to the following conditions:

A. Unless specifically authorized, persons licensed pursuant to 4731.0310, shall not:

(1) conduct tracer studies in the environment involving direct release of radioactive material;

(2) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(3) conduct activities for which a specific license issued by the commissioner under 4731.0309, G; 4731.0311, and 4731.0500- 4731.0520 are required;

(4) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

B. Each Type A specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

C. Each Type B specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

D. Each Type C specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 4731.0210 subp. 4.

SPECIFIC LICENSES

4731.0311 Special Requirements for a Specific License To Manufacture, Assemble, Repair, or Distribute Commodites, Products, or Devices Which Contain Radioactive Material Including NARM.

Subpart 1. **Licensing the manufacture of products containing radioactive materials in exempt concentrations.**

A. In addition to the requirements set forth in 4731.0309, subp. 1, A, specific license authorizing the use of radioactive material in a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 4731.3001, D, will be issued if:

(1) the applicant submits a description of the:

(a) product or material into which the radioactive material will be introduced,

(b) intended use of the radioactive material,

(c) product or material into which it is introduced,

(d) method of manufacture

(e) initial concentration of the radioactive material in the product or materials,

(f) control methods to ensure that no more than the specified concentration is introduced into the product or material,

(g) estimated time interval between manufacture and transfer of the product or material, and

(h) estimated concentration of the radioactive material in the product of material at the time of transfer; and

(2) the applicant provides reasonable assurance that the:

(a) concentrations of radioactive material at the time of transfer will not exceed the concentration in 4731.3003 A,

(b) reconcentration of the radioactive material in concentrations exceeding those in 4731.3003 A is not likely,

(c) use of lower concentrations is not feasible, and

(d) product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

B. Records and material transfer reports.

(1) each person licensed under 4731.0311, subp. 1, shall maintain records of transfer of material and file a report with the commissioner.

(2) the report must identify the:

(a) type and quantity of each product or material in which radioactive material has been used during the reporting period;

(b) name and address if the person who owned or possessed the product or material, in which radioactive material has been used, at the time of manufacture;

(c) the type and quantity of radionuclide used in each product or material; and

(d) the initial concentrations of the radionuclide in the product or material at the time of transfer of the radioactive material by the licensee.

(3) the licensee shall file the report within 30 days following:

(a) five years after filing the preceding report; or

(b) filing an application for renewal of the license under 4731.0308, subp. 3; or

(c) notifying the commissioner under 4731.0312, subp. 4,of the licensee's decision to permanently discontinue activities authorized under the license issued under 4731.0311, subp. 1, A.

(4) the report must cover the period between filing of the preceding report and the occurrence specified in 4731.0311, subp. 1, B, (3). If no transfers of radioactive material have

been made under 4731.0311, subp. 1, A, during the reporting period, the report shall so indicate.

(5) the licensee shall maintain the record of a transfer until the next inspection after the event is included in a report to the commissioner.

C. Prohibition of introduction of radioactive material. No person may include the use of radioactive material in a product or material knowing or having reason to believe that it will be transferred to persons that have:

(1) exemption under 4731.3001, D, or

(2) equivalent regulations of an agreement state or the U.S. Nuclear Regulatory Commission, except in accordance with a license issued pursuant to 4731.0311, subp. 1, or

(3) general license provided in 4731.316.

D. Resins containing scandium-46 and designed for sand-consolidation in oil wells: Requirements for license to manufacture, or initially transfer for sale or distribution.

An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to 4731.3001, D, will be approved if:

(1) the applicant satisfies the general requirements specified in 4731.0309;

(2) the product is designed to be used only for sand-consolidation in oil wells

(3) the applicant submits the following information:

(a) the general description of the product to be manufactured or initially transferred;

(b) a description of control procedures to be used to assure that the concentration of scandium-46 in the final product at the time of distribution will not exceed 1.4 x 10^3 microcurie (51.8 kBq)/milliliter.

(4) each container of such product will bear a durable, legible label approved by the commissioner which contains the following information:

(a) the product name;

(b) a statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(c) instructions necessary for proper use; and

(d) the manufacturers's name.

Subp. 2. **Licensing the distribution of naturally occurring and accelerator produced material (NARM) in exempt quantities.** Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements maybe obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

A. An application for a specific license to distribute NARM materials to persons exempted from these rules pursuant to 4731.3001, D will be approved if:

(1) the NARM material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human

being;

(2) the NARM material is in the form of:

(a) processed chemical elements, compounds,

(b) mixtures,

(c) tissue samples,

(d) bioassay samples,

(e) counting standards

(f) plated or encapsulated sources, or

(g) similar substances identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity product or device intended for commercial distribution; and

(3) the applicant submits copies of prototype labels and brochures and the commissioner approves such labels and brochures.

B. The license issued under 4731.0311, subp. 2, is subject to the following conditions:

(1) no more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(2) each exempt quantity shall be separately packaged.

(a) no more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 4731.3001, D

(b) the outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5mSv) per hour.

(c) the immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which identifies the radionuclide and the quantity of radioactivity, and bears the words "Radioactive Material."

(d) in addition to the labeling information required by 4731.0311, subp. 2, B, (2), (c), the label affixed to the immediate container, or an accompanying brochure, shall:

((1)) state that the contents are exempt from licensing state requirements,

((2)) bear the words "Radioactive Material–Not for Human Use"-- Introduction into Foods, Beverage, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited–Exempt Quantities Should Not Be Combined," and

((3)) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, ad disposal of the radioactive material.

Subp 3. **Licensing the incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors.** An application for a specific license authorizing the incorporation of radioactive materials into gas and aerosol detectors to be distributed to persons exempt under 4731.3001, D, will be approved if the application satisfies requirements of 4731.0311, subp. 3, and 4731.0101- 4731.0195, 4731.1500-4731.1520.

The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie(3.7 kBq).

Subp 4. **Radioactive material contained in devices for use under 4731.0304, subp. 2; requirements for license to manufacture, or initially transfer.**

A. An application for a specific license to manufacture or initially transfer devices containing radioactive material, to persons generally licensed under 4731.0304, subp. 2, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state will be approved if:

(1) the applicant satisfies the general requirements of 4731.0309;

(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing. operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(a) the device can be safely operated by persons not having training in radiological protection.

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in 4731.0124- 4731.0126, and

(c) under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in 4731.3002, 4.

(3) each device bears a durable, legible, clearly visible label or labels approved by the commissioner, which contains in a clearly identified and separate statement:

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device. Documents such as operating and service manuals may be identified in the label and used to provide information;

(b) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(c) the information called for in the following statement, in the same or substantially similar form: The receipt, possession, use, and transfer of this device, Model_____, Serial No._____,) are subject to a general license or the equivalent and the regulations of the commissioner, of the U.S. Nuclear Regulatory Commission, or of a state that has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.
(the model , serial number, and name of the manufacturer or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device)

CAUTION– RADIOACTIVE MATERIAL

Name of manufacturer or distributor

(4) each device having a separable source housing that provides shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotopes and quantity , the words, "Caution-radioactive Material," the radiation symbol described in 4731.0122, subp. 1, and the name of the manufacturer or initial distributor.

(5) each device meeting the criteria of 4731.0304, subp. 2, C, bears a permanent, eg. embossed, etched, stamped, or engraved, label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in 4731.0122, subp 1.

B. In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the"on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both.

(1) the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified:

(a) by performance characteristics of the device or similar devices, and

(b) by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator.

(2) the commissioner, in determining the acceptable interval for the test for leakage of radioactive material, will consider information which includes, but is not limited to:

(a) primary containment (source capsule);

(b) protection of primary containment;

(c) method of sealing containment;

(d) containment construction materials;

(e) form of contained radioactive material;

(f) maximum temperature withstood during prototype tests;

(g) maximum pressure withstood during prototype tests;

(h) maximum quantity of contained radioactive material;

(i) radiotoxicity of contained radioactive material; and

(j) operating experience with identical devices or similarly designed and constructed devices.

C. If under the general licensee under 4731.0304, subp. 2, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state:

(1) the applicant desires to be authorized to:

(a) install the device,

(b) collect the sample to be analyzed by a specific licensee for leakage of radioactive material,

(c) service the device,

(d) test the "on-off" mechanism and indicator, or

(e) remove the device from installation,

(2) the applicant shall:

(a) include in the application, written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for these estimates.

(b) submit information to demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in 4731.0308-4731.0315.

D. Device labeling

(1) each device having a separable source housing that provides shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotopes and quantity , the words, "Caution-radioactive Material," the radiation symbol described in 4731.0122, subp. 1, and the name of the manufacturer or initial distributor.

(2) each device meeting the criteria of 4731.0304, subp. 2, C, bears a permanent, eg. embossed, etched, stamped, or engraved, label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in 4731.0122, subp1.

E. Conditions of licenses

(1) if a device containing radioactive material is to be transferred for use under the general license contained in 4731.0304, subp.2, each person that is licensed under 4731.0311, subp.4, shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In case of a transfer through to an intermediate person. The information must also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes:

(a) a copy of the general license contained in 4731.0304, subp.2; if paragraphs C,(2) to C, (4), or C,(13), do not apply to the particular device, these paragraphs may be omitted.

(b) a copy of 4731.0161, 4731.0162, 4731.0168, 4731.0180, 4731.0300, subp. 5.

(c) a list of the services that must be performed only by a specific licensee;

(d) information on acceptable disposal options including estimated costs of disposal; and

(e) an indication that the commissioner's policy is to issue high civil penalties for improper disposal.

(2) if radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an agreement state, each person that is licensed under 4731.0311, subp. 4, shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required

information includes:

(a) a copy of the NRC's or agreement state's regulation equivalent to 4731.0304, subp. 2, 4731.0161, 4731.0162, 4731.0168, 4731.0180, 4731.0300, subp.5., or a copy of 4731.0304, subp. 2, 4731.0161. 4731.0162, 4731.0168, 4731.0180 and 4731.0300, subp. 5. If a copy of the commissioner's regulations is provided to a prospective general licensee in lieu of the NRC's or agreement state's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the NRC, or agreement state; if certain paragraphs do not apply to the particular device, those paragraphs may be omitted.

(b) a list of the services that can be performed only by a specific licensee;

(c) information on acceptable disposal options including estimated costs of disposal; and

(d) the name or title, address, and phone number of the contact at the NRC or agreement state regulatory agency from which additional information may be obtained.

(3) an alternative approach to informing customers may be proposed by the licensee for the approval of the commissioner.

(4) each device that is transferred after August, 2004, 1 year after the effective date of this rule, must meet the labeling requirements in 4731.0311, subp. 4, A, (3) through (5).

(5) if a notification of bankruptcy has been made under 4731.0300, subp. 5, E or the license is to be terminated, each person licensed under 4731.0311, subp.4, shall provide, upon request, to the commissioner and to the NRC or any appropriate agreement state records of final disposition required under, 4731.0311, subp. 4, F, (3).

F. Material transfer reports and records. Each person licensed under 4731.0304, subp, 2, to initially transfer devices to generally licensed persons shall comply with the requirements listed below.

(1) the person shall report all transfers of devices to persons for use under the general license in 4731.0304, subp.2, and all receipts of devices from persons licensed 4731.0304, subp. 2, to the commissioner. The report must be submitted on a quarterly basis on the form in 4731.3004, 15, or in a clear and legible report containing all of the data required by the form.

(a) the required information for transfers to general licensees includes:

((1)) the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

((2)) the name , title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

((3)) the date of transfer;

((4)) the type, model number, and serial number of the device transferred; and

((5)) the quantity and type of radioactive material in the device.

(b) if one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the

same information for both the intended user and the intermediate person, and clearly designate the intermediate person(s).

(c) for devices received from a 4731.0304, subp. 2, general licensee, the report must include the identity of the general licensee by name and address, the type , model number, and serial number of the device received, the date of receipt,, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) if the licensee makes changes to a device possessed by a 4731.0304, subp. 2, general licensee, such that the label must be changed to update the required information, the report must identify the general licensee, the device, and the changes to information on the device label;

(e) the report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(f) the report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) the person shall report all transfers of devices to persons for use under a general license from NRC or an agreement state's regulations that are equivalent to 4731.0304, subp. 2, and all receipts of devices from general licensees in the NRC or agreement state's jurisdiction to the responsible NRC or agreement state agency. The report must be submitted on the form in 4731.3004, 15, or in a clear and legible report containing all of the data required by the form.

(a) the required information for transfers to general licensees includes:

((1)) the identity of each general licensee by name and mailing address for the location of use; if there no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

((2)) the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

((3)) the date of transfer;

((4)) the type, model number, and serial number of the device transferred; and

((5)) the quantity and type of radioactive material contained in the device.

(b) if one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(c) for devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) if the licensee makes changes to a device possessed by a general

licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(e) the report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(f) the report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(g) if no transfers have been made to from the NRC or a particular agreement state during the reporting period, this information shall be reported to the responsible NRC or agreement state agency.

(3) the person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 4731.0311, subp.4, F, above. Records required by 4731.0311, subp. 4, F, (3), must be maintained until the next inspection by the commissioner.

Subp. 5. **Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.**

A. An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under part 4731.0304, subp.3, will be approved if:

(1) the applicant satisfies the general requirements of part 4731.0309; and

(2) the applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(a) chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

(b) details of construction and design;

(c) details of the method of binding or containing the tritium or promethium-147;

(d). procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(e) any quantity control procedures proposed as alternatives to those prescribed in part 4731.0311, subp. 5, C;

(f) any additional information, including experimental studies and tests, required by the commissioner to facilitate a determination of the safety of the device.

(3) each device will contain no more than 10 curies (370 GBq) of tritium or 300 millicuries (111 GBq) of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour (50) mSv per hour) at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

(4) the commissioner determines that:

(a) the method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(b) the tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(c) the device is so designed that it cannot easily be disassembled; and

(d) the device has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR 32.101.

B. Labeling of devices

(1) a person licensed under part 4731.0311, subp. 5, A, to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under part 4731.0304 shall, except as provided in part 4731.0311, subp. 5, B, (2), below, affix to each device a label containing the radiation symbol prescribed by part 4731.0122, subp. 1, such other information as may be required by the commissioner including disposal instructions when appropriate, and the following or a substantially similar statement which contains the following information called for in the following statement:

Devices licensed under 10CFR32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

> The receipt, possession, use, and transfer of this device, Model_____, Serial number_____, containing _____ (Identity and quantity if radioactive material) are subject to a general license or the equivalent and the regulations of the commissioner, the U.S. Regulatory Commission, or of a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
>
> CAUTION–RADIOACTIVE MATERIAL
>
> _____
>
> (Name of manufacturer, assembler, or initial transferor)
>
> (The model, serial number and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in the labeling affixed to the device.)

(2) if the commissioner determines that it is not feasible to affix a label to the device containing all the information called for in part 4731.0311, subp. 5, B, (1), above, the commissioner may waive those requirements and require in lieu thereof that:

(a) a label be affixed to the device identifying:

((1)) the manufacturer, assembler, or initial transferor; and

((2)) the type of radioactive material; and

(b) a leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

((1)) the name of the manufacturer, assembler, of initial transferor,

((2)) the type and quantity of radioactive material,

((3)) the model number,

((4)) a statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the commissioner, the U.S. Regulatory Commission, or of an agreement state, and

((5)) such other information as may be required by the commissioner, including disposal instructions when appropriate.

C. Quality assurance; prohibition of transfer

(1) each person licensed under part 4731.0311, subp. 5, A, shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium-147.

(2) each person licensed under part 4731.0311, subp.5, shall take a random sample of the size required by the table in 10 CFR 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(a) with this procedure:

((1)) each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry.

((2)) absolute pressure of the air above the water shall then be reduced to 1 inch of mercury.

((3)) lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer.

((4)) pressure shall then be increased to normal atmospheric pressure.

((5)) any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit.

(b) the immersion test water from the preceding test in part 4731.0311, subp. 5, C, (2), (a), above shall be measured for tritium or promethium-147 content by an apparatus that has been calibrated to measure tritium of promethium-1247, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-1476 in any device is found to leaked into the immersion test water, the leaking device shall be considered as a defective unit.

(c) the levels of radiation from each device containing promethium-147 shall be measured. Any device which has a radiation level in excess of 0.5 millirad (1 μGy) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, shall be considered as a defective unit.

(3) an application for a license or for amendment of a licence may include a description of procedures proposed as alternatives to those prescribed by part 4731.0311, subp. 5, C, (2), above, and proposed criteria for acceptance under those procedures. The commissioner will approve the proposed alternative procedures if the applicant demonstrates that:

(a) they will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium-147 in any 24-hour period; and

(b) the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent

at the consumer's risk of 0.10.

(4) no person licensed under part 4731.0311, subp. 5, A, shall transfer to persons generally licensed under part 4731.0304:

(a) any luminous safety device which has been rested and found defective under the criteria and procedures specified in part 4731.0311, subp. 5, C, unless the defective units have been repaired or reworked and have then met the tests set out in part 4731.0311, subp. 5, C, (2); or

(b) any inspection lot which has been rejected as a result of the procedures in 10 CFR 32.110 or alternative procedures in part 4731.0311, subp. 5, C, (2).

D. Material transfer reports. Each person licensed under part 4731.0311, subp. 5, A, shall file an annual report with the commissioner which must:

(1) state the total quantity of tritium or promethium-147 transferred to persons generally licensed under part 4731.0304.

(2) identify each general licensee by name, state the kinds and numbers of luminous devices transferred,

(3) specify the quantity of tritium or promethium-147 in each kind of device.

(4) cover the year ending June 30 and must be filed within thirty(30) days thereafter.

Subp. 6. **Special requirements for license to manufacture calibration sources containing Americium-241, Plutonium or Radium-226 for distribution to persons generally licensed under part 4731.0304.**

A. An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under part 4731.0304, will be approved if:

(1) the applicant satisfies the requirements of part 4731.0309; and,

(2) the applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(a) chemical and physical form and maximum quantity of americium-241, plutonium or radium-226 in the source;

(b) details of construction and design;

(c) details of the method of incorporation and binding of the americium-241, plutonium or radium-226 in the source;

(d) procedures for and results of prototype testing of sources, which are designed to contain more than:

((1)) 0.005 microcurie (185 Bq) of americium-241

((2)) 0.005 microcurie (185 Bq) of plutonium,

((3)) 0.005 microcurie (185 Bq) of radium-226, to demonstrate that the americium-241, plutonium, or radium-226, respectively, contained in each source will not be released or be removed from the source under normal conditions of use;

(e) details of quality control procedures to be followed in manufacture of the source;

(f) description of labeling to be affixed to the source or the storage container for the source;

(g) any additional information , including experimental studies and tests, required by the commissioner to facilitate a determination of the safety of the source.

(3) each source will contain no more than 5 microcuries (185 kBq) of americium-241 or 5 microcuries (185 kBq) of plutonium or 5 microcuries (185 kBq) of radium-226.

(4) the commissioner determines, with respect to any type of source containing more than 0.005 microcuries (185 Bq) of americium-241 or 0.005 microcuries (185 Bq) of plutonium or 0.005 microcuries (185 Bq) of radium-226, that:

(a) the method of incorporation and binding of the americium-241, plutonium, or radium-226 in the source is such that the americium-241, plutonium, or radium-226, respectively, will not be released or be removed from the source under normal conditions of use and handling of the source; and

(b) the source has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR 32.102, Schedule C.

(5) for any type of source which is designed to contain more than 0.005 microcuries (185 Bq) of americium-241 or 0.005 microcuries (185 Bq) of plutonium or 0.005 microcuries (185 Bq) of radium-226 the applicant must comply with 10 CFR 70.39 (5).

B. Each person licensed under part 4731.0311, subp. 6, affixes to each source, using the appropriate source name, or storage container for the source, a label which shall:

(1) contain sufficient information relative to safe use and storage of the source, and

(2) include the following statement or a substantially similar statement which contains the same information:

Sources licensed under 10 CFR 32.57 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

The receipt, possession, use and transfer of this source, Model___, Serial No.___, are subject to a general license and the regulations of the commissioner, the U.S. Nuclear Regulatory Commission, or of a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory. Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL– THIS SOURCE CONTAINS AMERICIUM-241 or PLUTONIUM OR RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or initial transferor

C. Leak Testing of each source. Each person licensed under part 4731.0311, subp. 6, shall perform a dry wipe test upon each source containing more than 0.1 microcurie(3.7 kBq) of americium-241, 0.1 microcurie (3.7 kBq) of plutonium, or 0.1 microcurie (3.7 kBq) of radium-

226 prior to transferring the source to a general licensee under part 4731.0304.

(1) this test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure.

(2) the radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie (185 Bq) of americium-241 or plutonium or radium-226.

(3) if any such test discloses more than 0.005 microcurie (185 Bq) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or plutonium or radium-226 and shall not be transferred to a general licensee under 4731.0304.

Subp. 7. **Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license**

A. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 4731.0304, subp. 6, may be approved if:

(1) the applicant satisfies the general requirements of 4731.0309.

(2) the radioactive material is to be prepared for distribution prepackaged units of:

(a) Iodine-125 in units not exceeding 10 microcuries (1.85 MBq) each

(b) Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

(c) Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

(d) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(e) Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

(f) Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

(g) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85kBq) of Iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(h) Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each

(3) each prepackaged unit bears a durable, clearly visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and

(b) indicating that the amount of radioactivity does not exceed:

((1)) 10 microcuries (370 kBq) of iodine-125; iodine-131; carbon-14; cobalt-057; or selenium-75;

((2)) 50 microcuries (1.85 MBq) of hydrogen-3 (tritium);

((3)) 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129, and

((4)) 0.005 microcuries (185 Bq) of americium-241 each; and

(c) displaying the radiation caution symbol described in 4731.0122, subp. 1, and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals."

(4) one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies

the package:

(a) this radioactive material may be received, acquired, possessed and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the commissioner, the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of Manufacturer

(b) this radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material; or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations of a general license of a licensing state.

_____

Name of Manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in4731.0136.

Subp 8. **Ice detection devices containing Strontium-90; licensing the manufacture and distribution of ice detection devices.**

A. License application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution for distribution to persons generally licensed under 4731.0304, subp. 7, will be approved if:

(1) the applicant satisfies the general requirement of 4731.0309;

(2) the applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(a) chemical and physical form and maximum quantity of strontium-90 in the device;

(b) details of construction and design of the source of radiation and its shielding;

(c) radiation profile of a prototype device;

(d) procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling

and use;

(e) details of quality control procedures to be followed in manufacture of the device;

(f) description of labeling to be affixed to the device;

(g) instructions for handling and installation of the device;

(h) any additional information, including experimental studies and tests, required by the commissioner to facilitate a determination of the safety of the device;

(3) each device will contain no more than 50 microcuries(1.85 MBq) of strontium-90 in an insoluble form;

(4) each device will bear durable, legible labeling which includes:

(a) the radiation caution symbol prescribed by 4731.0122, subp. 1,

(b) a statement that the device contains strontium-90 and the quantity thereof;

(c) instructions for disposal;

(d) statements that the device may be possessed pursuant to a general license;

(e) that the manufacturer or civil authorities should be notified if the device is found;

(f) that removal of the labeling is prohibited; and

(g) that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;

(5) the commissioner determines that:

(a) the method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(b) the strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and its shield so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem(5 mSv) in a year under ordinary circumstances of use;

(c) the device is so designed that it cannot be easily disassembled;

(d) the device has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR 32.103; and

(e) quality control procedures have been established to satisfy the requirements of 4731.0311, subp. 8, B, below.

B. Quality assurance; prohibition of transfer

(1) each person licensed under 4731.0311, subp, 8, A, shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(2) each person licensed under 4731.0311, subp. 8, A, shall test each device for possible loss of strontium-90 or for contamination by:

(a) wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or

(b) wiping the entire surface area if it is less than 100 square

centimeters.

(c) determining that the detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(3) each person licensed under 4731.0311, subp. 8, A, shall take a random sample of the size required by the table in 10 CFR 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(a) with this procedure:

((1)) each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90.

((2)) absolute pressure of the air above the water shall then be reduced to 1 inch of mercury.

((3)) lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is longer.

((4)) pressure shall then be increased to normal atmospheric pressure.

((5)) any device which leaks, as evidenced by physical contact between the water and the strontium-90, shall be considered as a defective unit.

(b) the immersion test water from the preceding test in 4731.0311, subp. 8, b, (3), (a), shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90, shall be considered as a defective unit.

(4) an application for a license or for amendment to a license may include a description of procedures proposed as alternatives to those prescribed by 4731.0311, subp. 8, B, (3), and proposed criteria for acceptance under those procedures. The commissioner will approve the proposed alternative procedures if the applicant demonstrates that:

(a) they will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

(b) the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumers risk of 0.10

(5) no person licensed under 4731.0311, subp. 8, A, shall transfer to persons generally licensed under 4731.0304, subp. 7:

(a) any device which has been tested and found defective under the criteria and procedures specified in this rule, 4731.0311, subp. 8, B , unless the defective units have been repaired or reworked and then met the tests set out in 4731.0311, subp. 8, B, (3); or

(b) any inspection lot which has been rejected as a result of the procedures in 10 CFR 32.110 or alternative procedures in 4731.0311, subp. 8, B, (4), unless the defective units have been stored and removed or have been repaired or reworked and have then met the tests set out in 4731.0311, subp. 8, B, (3).

Subp 9. **Manufacture preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under 4731.1200- 4731.1220.**

A. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to 4731.1200- 4731.1220. will be approved if:

(1) the applicant satisfies the general requirements specified in 4731.0309;

(2) the applicant submits evidence that the applicant is at least one of the following:

(a) registered or licensed with the U.S. Food and Drug Administration as a drug manufacturer;

(b) registered or licensed with the State of Minnesota as a drug manufacturer;

(c) licensed as a pharmacy by the Minnesota Board of Pharmacy; or

(d) operating as a nuclear pharmacy within a federal medical institution.

(3) the applicant submits information on the radionuclide:

(a) chemical and physical form

(b) maximum activity per vial syringe, generator, or other container of the radioactive drug; and

(c) shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

(4) the applicant satisfies the following labeling requirements, as appropriate. The label:

(a) is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution;

(b) includes the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL";

(c) provides of the radioactive drug or its abbreviation;

(d) provides the quantity of radioactivity at a specified date and time; for radioactive drugs with a half-life greater than100 days, the time may be omitted on the label; and

(e) is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution.

(f) includes the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL," and

(g) provides an identifier that ensures that the syringe, vial, or other container can be correlated with the,information on the transport radiation shield label.

B. A licensee described in 4731.0311, subp. 9, A, (3) or (4):

(1) may prepare radioactive drugs for medical use, as defined in 4731.1202, subp. 4, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 4731.0311, subp. 9, B, (2) and (4), or an individual under the supervision of an

authorized nuclear pharmacist as specified in 4731.1202, subp. 4.

(2) may allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) this individual qualifies as an authorized pharmacist as defined in 4731.0100, subp.232.

(b) this individual also meets the requirements specified in 4731.0152, subparts 1, D, and 7, B, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(c) this individual is designated as an authorized nuclear pharmacist in accordance with 4731.0311, subp. 9, B, (2), (a) or (c), below.

(3) the actions authorized in 4731.0311, subp. 9, B, (1) and (2), above are permitted in spite of more restrictive language in license conditions.

(4) may designate a pharmacist, with training as in 4731. 0152, subp. 7, B, as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the commissioner under 4731.0311, subp. 9, or equivalent regulations of an agreement state, or the U.S. Nuclear Regulatory Commission.

(5) shall provide to the commissioner no later than 30 days after the date that the licensee allows, as provided in 4731.0311, subp. 9, B, (2), (a), or (c), the individual to work as an authorized nuclear pharmacist, a copy of:

(a) each individual's certification by the Board of Pharmaceutical Specialities, the U.S. Nuclear Regulatory Commission, or agreement state license, or the permit issued by a licensee of broad scope, and

(b) the state pharmacy licensure or registration.

C. A licensee shall:

(1) possess and use instrumentation to measure the radioactivity of radioactive drugs

(2) have procedures for use of the instrumentation.

(3) measure, by direct measurement or a combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution.

(4) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(5) check each instrument for constancy and proper operation at the beginning of each day of use.

D. Nothing in this section relieves the licensee from complying with applicable U.S. Food and Drug Administration, other federal or state requirements governing radioactive drugs.

Subp. 10. **Manufacture and distribution of sources or devices containing radioactive material for medical use**

A. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed as required in 4731.1200-4731.1220 for use as a calibration or reference source or for the uses listed in 4731.1208- 4731.1211 will be

approved if:

(1) the applicant satisfies the general requirements of 4731.0309;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(a) the radioactive material contained, its chemical and physical form and amount,

(b) details of design and construction of the source or device,

(c) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(d) for devices containing radioactive material, the radiation profile of a prototype device,

(e) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(f) procedures and standards for calibrating sources and devices,

(g) legend and methods for labeling sources and devices as to their radioactive content, and

(h) instructions for handling and storing the source or device from a radiation safety standpoint. These instructions are to be:

((1)) included on a durable label attached to the source or device, or

((2)) attached to a permanent storage container for the source or device; or

((3)) summarized on the label, for instructions which are too lengthy for the label in 4731.0311, subp. 10, A, (1), above, and printed in detail on a brochure which is referenced on the label;

(3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the:

(a) radionuclide,

(b) quantity ,

(c) date of assay, and

(d) statement that the commissioner has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in 4731.1200- 4731.1220, as appropriate, and to persons who hold equivalent licenses issued by the U.S. Nuclear Regulatory Commission, or an agreement state.

B. In the event the applicant desires that:

(1) the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by:

(a) performance characteristics of the source or device or similar sources or devices, and

(b) design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) in determining the acceptable interval for test of leakage of radioactive material, the commissioner will consider information that includes but is not limited to:

(a) primary containment (source capsule),
(b) protection of primary containment,
(c) method of sealing containment,
(d) containment construction materials,
(e) form of contained radioactive materials,
(f) maximum temperature withstood during prototype tests,
(g) maximum pressure withstood during prototype tests,
(h) maximum quantity of contained radioactive material,
(i) radiotoxicity of contained radioactive material, and
(j) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

C. If an application was filed with the U.S. Nuclear Regulatory Commission in accord with the requirements of 4731.0311, subp. 10, A, on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution until the commissioner issues the license or notifies the applicant otherwise.

Subp 11. **Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceutical containing radioactive material.**

A. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed in accord with 4731.1202, subp. 4 will be approved if:

(1) the applicant satisfies the general requirements specified in 4731.0309.

(2) the applicant submits evidence that the generator or reagent kit is to be manufactured, labeled, and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service act, including:

(a) a new drug application (NDA) approved by the Food and Drug administration (FDA), or

(b) a "Notice of Claimed Investigational Exemption for a New Drug" (ND) that has been accepted by the FDA ; or

(c) the manufacture and distribution of the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit.

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(a) adequate information pertaining to radiation safety on the

procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(b) a statement that this generator or reagent kit as appropriate, is approved for use by persons licensed by the commissioner for uses listed in the license or equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The labels, leaflets, or brochures required by this section are in addition to the labeling required by the Food and Drug Administration(FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

Subp. 12. **Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.**

A. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 4731.0303, subp. 2, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

(1) the applicant satisfies the general requirements specified in 4731.0309 ;

(2) the applicant submits sufficient information to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in 1 year a radiation dose in excess of 10 percent of the limits specified in 4731.0124-4731.0126 . The information must include:

(a) the design,
(b) manufacture
(c) prototype testing
(d) quality control procedures
(e) labeling or marking
(f) proposed uses, and
(g) potential hazards of the industrial product or device

(3) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product of device.

B. In the case of an industrial product or device whose unique benefits have not been demonstrated, the commissioner will approve an application for a specific license under 4731.0311, subp. 12, only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

C. Each person licensed pursuant to 4731.0311, subp.12, A, above, must:

(1) maintain the level of quality control required by the license in the manufacture of the industrial product or device and in the installation of the depleted uranium into the product or device;

(2) label or mark each unit to:

(a) identify:

((1)) the manufacturer or initial transferor of the product or

device;

((2)) the number of the license under which the product or device was manufactured, or initially transferred ;

((3)) the fact that the product or device contains depleted uranium

((4)) the quantity of depleted uranium in each product or device; and

(b) state that receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and to the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

(3) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(4) furnish a copy of the general license:

(a) described in 4731.0303, subp. 2, and a copy of form 4731.3004, 10, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license described in 4731.0303, subp. 2, or

(b) certificate of the U.S. Nuclear Regulatory Commission's or an agreement state's regulation equivalent to 4731.0303, subp. 2, or

(c) described in 4731.0303, subp. 2, and form 4731.3004, 10, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 4731.0303, subp. 2;

(5) report to the commissioner all transfers of industrial products or devices to persons for use under the general license described in 4731.0303, subp. 2. The report shall be submitted within 30 days after the end of each calendar quarter when such a product is transferred to the general licensee. If no transfers have been made to general licensees under 4731.0303, subp. 2, during the reporting period, the report shall so indicate. Such report shall identify:

(a) each general licensee by name and address

(b) an individual by name or position who may constitute a point of contact between the commissioner and the general licensee

(c) the type and model number of the product or device transferred, and

(d) the quantity of the depleted uranium contained in the product or device.

(6) report:

(a) to the U.S. Nuclear regulatory Commission all transfers of industrial products or devices for use under the general license in 10 CFR 40.25.

(b) to the responsible agreement state agency or U.S. Nuclear Regulatory Commission all transfers of devices manufactured and distributed pursuant to 4731.0311, for use under a general license in that state's rules equivalent to 4731.0303, subp. 2 or

10 CFR 40.25.

(c) of transfers shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the general licensee and shall identify:

((1)) each general licensee by name and address

((2)) an individual or position who may constitute a point of contact between the agreement state or U.S. Nuclear Regulatory Commission and the general licensee,

((3)) the type and model number of the device transferred, and

((4)) the quantity of depleted uranium contained in the product or device.

(7) if no transfers have been made to the U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and

(8) if no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of the agency; and

(9) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 4731.0303, subp. 2, or equivalent regulations for the U.S. Nuclear Regulatory Commission or an agreement state,. The records shall:

(a) be maintained until the next inspection after the transfer

(b) show:

((1)) the date of each transfer,

((2)) the quantity of depleted uranium in each product or device transferred, and

((3)) compliance with the report requirements of 4731.0311, subp. 12.

Subp.13. **A licensee, manufacturer or an initial distributer of a sealed source or device containing a sealed source whose product is intended for use under a general or specific license.** The licensee, manufacturer or initial distributor must submit a request for an evaluation of the sealed source or device containing a sealed source in compliance with 10 CFR 32.210 and obtain a registration from the NRC.

4731.0312 Issuance Of Specific Licenses.

Subpart 1. **License satisfies requirements**. Upon determination that an application meets the requirements of Chapter 4731. The commissioner will issue a specific license authorizing the proposed activity and containing appropriate conditions and limitations as necessary.

Subp. 2. **Special license requirements**. The commissioner may incorporate in any license at the time of issuance, or thereafter, the appropriate rule, regulation or order, and additional requirements and conditions with respect to the license's receipt, possession, use and transfer of

radioactive material as are deemed appropriate or necessary to:

A. Protect health or to minimize danger to life and property.

B. Require reports and keeping of records, and provide for inspection of activities under the license; and

C. Prevent loss or theft of material subject to this part.

D. Submit an emergency plan as required by part 4731.0308, subp. 2, B, (1), (b).

Subp. 3. **License termination date.** The commissioner shall indicate the expiration date on each license. The licensee shall be granted a 90 day extension of the expiration date if written justification is submitted and approved by the commissioner.

Subp. 4. **Emergency Plan.** Licensees required to submit emergency plans by part 4731.0308, subp. 2, B, shall follow the emergency plan approved by the commissioner. The licensee:

A. May change the approved plan without commissioner approval only if the changes do not decrease the effectiveness of the plan.

B. Shall furnish the change to the commissioner and to affected offsite response organizations within six months after the change is made.

C. May not implement proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan without prior application to and prior approval by the commissioner.

Subp. 5. **Preparation of Technetium-99m.** Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall test the generator eluates for molybdenum-99 breakthrough in accordance with 4731.1212, subp. 3. The licensee shall record the results of each test and retain each record for four years after the record is made.

4731.0313 Specific Terms and Conditions of Licenses.

Subpart 1. **Rules for license.** Each license issued pursuant to 4731.0313 shall be subject to all the provisions of 4731.0101-4731.0195, 4731.0300-4731.0320, 4731.500- 4731.0520, 4731.0700-4731.0720, 4731.0800-4731.0820, 4731.0900-4731.0920, 4731.1000-4731.1020, 4731.1200-4731.1220, now or hereafter in effect, and to all rules of the commissioner.

Subp. 2. **License restrictions.** Unless the commissioner, after securing full information about a transfer or right under a transfer, finds that the transfer is in accordance with the provisions of Chapter 4731, and gives consent in writing, no actions are permitted for:

A. A license issued or granted under 4731.0313,

B. The right to possess or utilize radioactive material, including special nuclear material,

C. Neither the license nor the radioactive material shall be transferred, assigned, or disposed of in any manner:

(1) voluntarily or involuntarily,

(2) directly or indirectly, or

(3) through transfer of control to any person.

Subp. 3. **Notification of bankruptcy**. Each licensee shall notify the commissioner in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11(Bankruptcy) of the United States Code (U.S.C.)

A. By or against:

(1) the licensee;

(2) an entity, as that term is used in 4731.0300, Subp 5, H, (1), (b), controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate, as that term is used in the 11 U.S.C. 101(2), of the licensee.

B. This notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition for bankruptcy.

Subp. 4. **Authorized use of radioactive material, including special nuclear material.**

A. Each person licensed by the commissioner pursuant to parts 4731.0101-4731.0195, 4731.0300- 4731.0320, 4731.0500-4731.0520, 4731.0700-4731.0720, 4731.0800-4731.0820, 4731.0900-4731.0920, 4731.1000-4731.1020, 4731.1200- 4731.1220, shall confine use and possession of the licensed radioactive material, including special nuclear material to the locations and purposes authorized on the license. Except as otherwise provided in the license, the license issued pursuant to parts 4731.0101-4731.0195, 4731.0300-4731.0320, 4731.0500-4731.0520, 4731.0700-4731.0720, 4731.0800-4731.0820, 4731.0900-4731.0920, 4731.1000-4731.01020, 4731.1200-4731.1220, shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material shall be accordance with the provisions of parts 4731.1500- 4731.1520.

B. The possession, use, and transfer of any special nuclear material produced by a licensee, in connection with or as a result of use of special nuclear material received under his license, shall be subject to the provisions of the license and the regulations of parts 4731.0300-4731.0320.

Subp. 5. **Separate license required.** A. separate license is required for the following:

A. Each activity as designated by license category in part 4731.0102, subp.1.

B. Facilities for which one or more of the following applies:

(1) the facilities are not contiguous;

(2) the facilities are not under a single radiation safety program; or

(3) the facilities are not under the same management.

C. Each facility operated by an out-of-date licensee under reciprocity as specified in part 4731.0316 and does not meet the definition of a temporary job site.

D. Each large irradiator as defined in part 4731.0100.

Subp. 6. **Work location.** A separate license is not required for temporary job sites or for each facility that is authorized under a broad scope license.

4731.0314 Expiration and Termination of Licenses and Commissioning of Sites and Separate Buildings or Outdoor Area.

Subpart 1. **Final 60 days Preceding Expiration of License**

A. Date of expiration

(1) except as provided in 4731.0300-4731.0320, each specific license shall expire at the end of the specified day in the month and year stated therein.

(2) each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in 4731.0314, subp. 1, C , below, shall be deemed to have an expiration date that is five years after the expiration date stated on the current license.

(3) each specific license revoked by the commissioner expires at end of the day on the date of the commissioner's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by the commissioner's order.

(4) each specific license continues in effect, beyond the expiration date, if necessary, with respect to possession of radioactive material, including special nuclear material, until the commissioner notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(a) limit actions involving radioactive materials to those related to decommissioning; and

(b) continue to control entry to restricted areas until they are suitable for release in accordance 4731.0314, subp. 2, D, (5), or 4731.0314, subp. 3.

(5) the commissioner may grant a request to extend the time periods established in 4731.0314, subp. 1, B, or delay or postpone initiation of the decommissioning process if the commissioner determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 60 days before notification pursuant to 4731.0314, subp. 1, B. The schedule for decommissioning set forth in 4731.0314, subp. 1, B , may not commence until the commissioner has made a determination on the request

B. Action Required Within 60 days of License Expiration Date.

(1) no less than 60 days before the expiration date specified in the license, the licensee shall either submit an application for license renewal on the same form used for the initial application under 4731.0308, or

(2) within 60 days of the occurrence of any of the following, each licensee shall provide notification to the commissioner in writing of such occurrence, and either:

(a) begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Chapter 4731, or

(b) submit within 12 months of notification a decommissioning plan, if required by 4731.0314, subp. 3, B, and begin decommissioning upon approval of that plan, if:

((1)) the license has expired pursuant to 4731.0314, subp. 1, A, (1) or (3); or

((2)) the licensee has decided to permanently cease principal activities, as defined in 4731.0100, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance Chapter 4731 requirements; or

((3)) no principal activities have been conducted for a period of 24 months; or

((4)) no principal activities have been conducted for a period of 24

months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Chapter 4731 requirements.

C. The following specific licenses are not subject to, or otherwise affected by, the provisions of 4731.0314, subp. 1, A, (2):

(1) specific licenses for which an evaluation or an emergency plan is required in accordance with 4731.0308, subp. 2, B, (1), (b) ;

(2) specific licenses whose holders are subject to the financial requirements specified in 4731.0309, subparts 2, 3, and 4 , and the holders either:

(a) have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(b) have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

(3) specific licenses whose holders are listed in SDMP List published in NUREG 1444, Supplement 1 (November 1995).

(4) specific licenses whose issuance, amendment, or renewal, as of February 15, 1996, is not categorical exclusion under 10 CFR 51.22(c)(14), and, therefore, need an environmental assessment or environmental impact statement pursuant to 10 CFR 51, subpart A.

(5) specific licenses whose holders have not had at least one U.S. Nuclear Regulatory Commission inspection of licensed activities before February 15, 1996;

(6) specific licenses whose holders, as the result of the most recent U.S. Nuclear Regulatory Commission inspection of licensed activities conducted before February 15, 2002, have been:

(a) cited for a Severity Level I, II, or III violation in a Notice of Violation;

(b) subject to an Order issued by the Nuclear Regulatory commission; or

(c) subject to a Confirmatory Action Letter issued by the Nuclear Regulatory Commission.

(7) specific licenses with expiration dates before July 1, 1995 for which the holders have submitted applications for renewal under 10 CFR 30.37.

Subp 2. **Termination of License.**

A. The licensee shall notify the commissioner, in writing, if the licensee decides not to apply for license renewal.

B. Each licensee shall notify the commissioner immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. The notification and request for termination of the license must include the reports and information specified in 4731.0314, subp. 2, D and E, below.

C. Coincident with the notification required in 4731.0314, subp. 1, B, and 4731.0314, subp2, C, above, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 4731.0309, subparts 2, 3, and 4, in conjunction with license issuance or renewal or as required by 4731.0311. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established by the licensee pursuant to 4731.0314, subp. 3, C, (1), (f), below.

D. If a licensee does not submit an application for license renewal under 4731.0308, the licensee shall, on or before the expiration date specified in the license:

(1) terminate the use of radioactive material:

(2) remove radioactive contamination to the extent acceptable to the commissioner

(3) properly dispose of the radioactive material;

(4) submit a properly completed 4731.3004, 6; and

(5) submit a radiation survey report to confirm the absence of radioactive materials to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual contamination in some other manner. The licensee shall, as appropriate:

(a) for gamma radiation, report levels of radiation in units of microroentgens per hour at 10 centimeters and at 1 meter from surfaces.

(b) for alpha and beta radiation, report levels of radioactivity in units of transformations per minute or microcuries per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

(c) specify the instruments used and certify that each instrument is properly calibrated or tested.

E. If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The commissioner may notify the licensee, in writing, of the termination of the license.

F. Specific licenses, including expired licenses, may be terminated by written notice to the licensee when the commissioner determines that:

(1) radioactive material, including source and special nuclear materials, have been properly disposed; and

(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) information provided shows:

(a) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 4731.0314; or

(b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release. In accordance with the criteria for decommissioning in 4731.0314.

(4) records required by 4731.0184 and 4731. 0314, subp. 5, have been received.

Subp 3. **Submission of Decommissioning Plan.**

A. If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the commissioner notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of 4731.0314, subp. 3, B, below.

B. In addition to the information submitted under 4731.0314, subp. 2, (4) and (5), above:

(1) the licensee shall submit a plan for decommissioning if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been approved previously by the commissioner and these procedures could increase potential health and safety impacts to workers or the public as in any of the following cases:

(a) procedures would involve techniques not applied routinely during cleanup and maintenance operations;

(b) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(c) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(d) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) the commissioner may approve an alternate schedule for submittal of a decommissioning plan required in 4731.0314, subp. 1, B, if the commissioner determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from the radiation to the public health and safety and is otherwise in the public interest.

(3) procedures such as those listed in 4731.0314, subp. 3, B, (1), with potentially impact health, safety impacts may not be performed prior to obtaining the decommissioning plan approval.

C. The proposed decommissioning plan for the site or separate building or outdoor area:

(1) must include:

(a) a description of the conditions of the site or separate building area sufficient to evaluate the acceptability of the plan;

(b) a description of planned decommissioning activities;

(c) a description of the methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(d) the time required to complete the decommissioning plan;

(e) a description of the planned final radiation survey; and

(f) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(g) for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in 4731.0314, subp. 3, C, (1), (a).

(2) may be approved by the commissioner, if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health an safety of the workers and the public will br adequately protected.

D. Except as provided in 4731.0314, subp. 3, E, below, licensees shall:

(1) complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of

decommissioning.

(2) request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning, when decommissioning involves the entire site.

E. The commissioner may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the commissioner determines that the alternative is warranted by consideration of the following:

(1) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) other site-specific factors which the commissioner may consider appropriate on a case-by-case basis, such as in the regulatory requirements of other governmental agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferring clean-up, and other factors beyond the control of the licensee.

Subp 4. **Completion of Decommissioning.**

A. Upon approval of the decommissioning plan by the commissioner, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in 4731.0314, subp. 2, D, (5), above, and shall:

(1) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed a completed form 4731.3004, 6, or equivalent information; and

(2) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 4731.0314. The licensee shall, as appropriate:

(a) report levels of:

((1)) gamma radiation in units of microroentgen(millisieverts) per hour at one meter from surfaces, and

((2)) radioactivity, including alpha and beta in units of:

((a)) disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters removable and fixed for surfaces,

((b)) microcuries (megabecquerels) per milliliter for water, and

((c)) picocuries (becquerels) per gram for solids such as soils or concrete; and

(b) specify the survey and instrument(s) used and certify that each

instrument is properly calibrated and tested.

B. If the information submitted as specified in 4731.0314, subp. 2, D, (5) or 4731.0314 subp. 4 of this section does not adequately demonstrate that the premises are suitable for release for unrestricted use, the commissioner will inform the licensee of the appropriate further actions required for termination of the license.

C. Each licensee who possesses residual radioactive material under 4731.0314, subp. 3, above, following the expiration date specified in the license shall:

(1) limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) continue to control entry to restricted areas until they are suitable for release for unrestricted use and the department notifies the licensee, in writing, that the license is terminated.

D. As the final step in decommissioning, the licensee shall:

(1) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed form 4731.3004, 6, or equivalent information; and

(2) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 4731.0314. The licensee shall, as appropriate:

(a) report levels of:

((1)) gamma radiation in units of microroentgen (millisieverts) per hour at one meter from surfaces, and

((2)) radioactivity, including alpha and beta, in units of:

((a)) disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters, removable and fixed, for surfaces,

((b)) microcuries (megabecquerels) per milliliter for water, and

((c)) picocuries (becquerels) per gram for solids such as soils or concrete; and

(b) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

Subp 5. **Recordkeeping**.

A. Each licensee shall keep records of information important to the decommissioning of the facility in an identified location until the license is released for unrestricted use .

B. Before licensed activities are transferred or assigned in accordance with 4731.0313 subp. 2, licensees shall transfer all records described in 4731.0314, subp.5, D, (1), to the new licensee.

C. In this case a new licensee will be responsible for maintaining these records until license is terminated.

D. If records of relevant information are kept for other purposes, reference to these records and their location can be used. Records which must be kept include:

(1) spills or contamination

(a) location of spills or other unusual occurrences involving the spread of

contamination in and around the facility, equipment, or site.

(b) any known information on identification of involved nuclides, quantities, forms, and concentrations

(c) instances when contamination remains after cleanup procedures or when contaminants may have spread to inaccessible areas such as possible seepage into porous materials such as concrete.

(2) drawings or appropriate records:

(a) drawings of:

((1)) structures as originally built,

((2)) modifications,

((3)) equipment in restricted areas where radioactive materials are used or stored, and

((4)) locations of possible inaccessible contamination such as buried pipes which can be subject to contamination,

(b) drawings and their location can be referenced if not on site. Each relevant document need not be indexed individually.

(c) if drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) a list contained in a single document, except for areas containing only radioactive materials having half-lives of less than 65 days or sealed sources that either have not leaked or no contamination remains after any leak, and updated every 2 years, of the following:

(a) all areas designated and formerly designated restricted areas as defined 4731.0100.

(b) all areas outside of restricted areas that require documentation under 4731.0314, subp. 5;

(c) all areas outside of restricted areas where current and previous wastes have been buried as documented under 4731.0184; and

(d) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 4731.0314 or apply for approval for disposal under 4731.0136, subp. 2; and

(4) records of the:

(a) cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and

(b) funding method used for assuring funds if either a funding plan or certification is used.

4731.0315 **Transfer of Radioactive Material**

Subpart 1. **Authorization required.** No licensee shall transfer radioactive material, including source material and special clear material, except as authorized pursuant to this section.

Subp. 2. **Approved transfer**. Except as otherwise provided in his licensee and subject to the provisions of 4731.0315, subp. 3, A and C, below, any licensee may transfer radioactive material,

including source material and special nuclear material:

A. To the commissioner after approval from the commissioner;

B. To the U.S. Department of Energy (DOE);

C. To any person exempt from these regulations to the extent permitted under such exemptions;

D. To the agency in any agreement state which regulates radioactive material pursuant to an agreement with the U.S. Nuclear Regulatory Commission (NRC).

E. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issue by the commissioner, the NRC, an agreement state or a licensing state.

F. To any person in an agreement state subject to the jurisdiction of that state who has been exempted form licensing requirements and regulations and regulations of that state, to the extent permitted under such exemptions.

G. As otherwise authorized by the commissioner in writing.

Subp. 3. **Licensee requirements for transfer** . The licensee transferring radioactive material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material, including source material and special nuclear material, to be transferred.

A. Before transferring radioactive material, including source material and special nuclear material, to a specific licensee of the commissioner, the NRC, an agreement state, a licensing state or to a general licensee who is required to register with the commissioner, the NRC, an agreement state or a licensing state.

B. Prior to receipt of the radioactive material, including source material and special nuclear material.

C. Any of the following methods for the verification required by 4731.0315, subp. 3, above, are applicable.

(1) the transferor may possess and read a current copy of the transferee's specific or general license, or registration certificate. The transferor shall retain a copy of each license or certificate until the next inspection.

(2) the transferor may possess a written certification by the transferee that the transferee is authorized by license or registration to receive the type, form, and quantity of radioactive material, including source material and special nuclear material, to be transferred, specifying:

(a) the license or registration certification number,

(b) issuing agency, and

(c) expiration date.

The transferor shall retain a copy of each license or certificate for four years from the date that it was obtained.

(3) for emergency shipments, the transferor may accept oral certification by the transferee, provided that the oral certification is confirmed in writing within 10 days, that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material, including source material and special nuclear material to be transferred, specifying the :

(a) license or registration certificate number,
(b) issuing agency, and
(c) expiration date.

The transferor shall retain the written confirmation of the oral certification for four years from the date of the certification.

Subp.4. **Information for transferor.** The transferor may obtain other information compiled by a reporting service from official records of the commissioner, the U.S. NRC, the licensing agency of an agreement state regarding the identity of licensees or registrants and the scope and expiration dates of the licenses or registrations. The transferor shall retain the compilation of information as a record for four years form the date that it was obtained; or

Subp. 5. **Confirmation for transferor.** The transferor may obtain and record confirmation from the commissioner, the U.S. NRC, the licensing agency of an agreement state or a licensing state that the transferor is licensed to receive the radioactive material, including source material and special nuclear material:

A. When none of the methods of verification described in 4731.0315, subparts 3 and 4, above are readily available, or

B. When a transferor desires to verify that information received by one of such methods is correct or up-to-date. The transferor shall retain the record of confirmation for four years from the date the record is made.

Subp. 6. **Shipment and transport of radioactive material.** Shipment and transport of radioactive material shall be in accordance with the provisions of 4731.1500 - 4731.1520.

4731.0316 Reciprocal Recognition of Licenses for Radioactive Materials, including Source, Naturally- Occurring and Accelerator Produced Radioactive Material, and Special Nuclear Material less than Critical Mass.

Subpart 1. **Provisions for Reciprocity.**

A. Provided that the provisions of part 4731.0316, subp. 2, below have been met, any person who holds a specific license from an agreement state or a specific license from the U.S. Nuclear Regulatory Commission , where the licensee maintains an office for directing the licensed activity and retaining radiation safety records, is issued a general license to conduct the same activity in:

(1) non-agreement states;
(2) areas of Exclusive Federal jurisdiction within agreement states; and
(3) offshore waters.

B. The provisions of 4731.0316, subp. 1, A, do not apply if the specific agreement state license or the U.S. Nuclear Regulatory Commission license limits the authorized activity to a specific installation or location.

Subp 2. **Additional requirements for general licenses and work in federal jurisdictions and in non-agreement states.** Notwithstanding any provisions to the contrary in any specific license

issued by an agreement state or any specific license issued by the U.S. Nuclear Regulatory Commission to a person engaging in activities in a non-agreement state, in an area of exclusive federal jurisdiction within an agreement state, or in offshore waters under the general licenses provided in this section, the general licenses provided in this section are subject to all applicable rules and orders of the commissioner including the provisions of 4731.0101-4731.0195, 4731.0300-4731.0302, 4731.0313, 4731.0315, 4731.0500-.0520, 4731.0800-4731.0820, 4731.1500-1520. In addition, any person engaging in activities in non-agreement states, in areas of exclusive federal jurisdiction within agreement states, or in offshore waters under the general licenses provided in this section shall:

A. At least 3 days before engaging in each activity for the first time in a calendar year, file a submittal containing the form in 4731.3004, 14, 4 copies of its agreement state specific license, or U.S. Nuclear Regulatory Commission specific license, and the appropriate fee as prescribed in 4731.0104 subp 1, with the commissioner.

B. If a submittal cannot be filed 3 days before engaging in activities because of an emergency or other reason, the commissioner may waive the 3-day time requirement provided the licensee:

(1) informs the commissioner by telephone, facsimile, the form in 4731.3004, 14, or a letter of initial activities or revisions to the information submitted on the original form in 4731.3004, 14;

(2) receives oral or written authorization for the activity from the commissioner; and

(3) within 3 days after the notification, files the form in 4731.3004, 14, 4 copies of the agreement state, or U.S. Nuclear Regulatory Commission license, and the fee payment.

C. File an amended form as required in 4731.3004, 14, or letter and the appropriate fee as prescribed in 4731.0104, subp. 1, with the commissioner to request approval for changes in work locations, radioactive material, or work activities different from the information contained on the initial form from 4731.3004, 14,

D. Not transfer or dispose of radioactive material possessed or used under the general licenses provided in 4731.0300-4731.0320, in any non-agreement state, in an area of exclusive federal jurisdiction within an agreement state, or in offshore waters, except by transfer to a person who is:

(1) specifically licensed by the commissioner, to receive this material; or

(2) exempt from the requirements for a license for such material under 4731.3001, D.

E. Not possess or use radioactive materials, or engage in the activities authorized in 4731.0316, subp.1, above, under the general license concerning activities in non-agreement states or in areas of exclusive federal jurisdiction within agreement states, for more than 180 days in any calendar year, except that the general license in 4731.0316, subp. 1, concerning activities in offshore waters authorizes that person to possess or use radioactive materials, or engage in the activities authorized, for an unlimited period of time.

F. Comply with all terms and conditions of the specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state except such terms or conditions as are

contrary to the requirements of 4731.0316.

4731.0317 Emergency Planning.

Subpart 1. **Emergency Plan Requirements**.

A. An emergency plan for responding to a release of the radioactive material submitted under 4731.0308, subp. 2, b, (1), (b), must include the following information:

(1) a brief description of the licensee's facility and area near the site;

(2) an identification of each type of radioactive materials accident for which protective actions may be needed;

(3) a classification system for classifying accidents as alert or site area emergencies;

(4) identification of the means of detecting each type of accident in a timely manner;

(5) a brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment;

(6) a brief description of the methods and equipment to assess releases of radioactive materials;

(7) a brief description of the responsibilities of licensee personnel should an accident occur, including identification notifying offsite responsible organizations and the commissioner; also, responsibilities for developing, maintaining, and updating the plan;

(8) notification and coordination which must include:

(a) provide a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate;

(b) establish a control point;

(c) prepare a plan so that notification and coordination will not result in unavailability of some equipment that could prevent completing the notification and coordination;

(d) commit to notifying the commissioner immediately after notification of the appropriate offsite response organizations and not later than one hour after the license declares an emergency.

(9) a brief description of the types of information of facility status, radioactive releases, and recommended protective actions, if necessary to be given to offsite response organizations and to the commissioner.

(10) training for emergency plan must include the following:

(a) a brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel;

(b) familiarize personnel with site-specific emergency procedures.

(c) thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios;

(11) a brief description of the means of restoring the facility to a safe condition after an accident;

(12) the licensee shall:

(a) make provisions for conducting quarterly communications check with offsite response organizations and biennial onsite exercises to:

((1)) test response to simulated emergencies.

((2)) check and update all necessary telephone numbers.

(b) invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required.

(c) use accident scenarios postulated as most probable for the specific site. The scenarios shall not be known to most exercise participants.

(d) critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate:

((1)) the appropriateness of the plan,

((2)) emergency procedures,

((3)) facilities,

((4)) equipment,

((5)) training of personnel, and

((6)) overall effectiveness of the response.

(e) correct deficiencies found by the critiques.

(13) a certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub L. No. 99-499, if applicable of the applicant's activities at the proposed place of use of the radioactive material.

B. The licensee shall:

(1) allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the department;

(2) provide any comments received within 60 days to the commissioner along with the emergency plan.

Subp 2. **Applications That Require Emergency Planning**

A. Application for license to possess radioactive materials in unsealed form

(1) each applicant to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 4731.3003, D, must contain either:

(a) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed 1 rem (10mSv) effective dose equivalent or 5 rem(50 mSv) to the thyroid; or

(b) an emergency plan for responding to a release of radioactive material.

(2) one or more of the following factors can be used to support an evaluation submitted under 4731.0317, subp.1, of this section:

(a) the radioactive material is physically separated so that only a portion could be involved in an accident;

(b) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(c) the release fraction in the respirable size range would be lower than the release fraction shown in 4731.3003, D, due to the chemical or physical form of the material;

(d) the solubility of the radioactive material would reduce the dose received;

(e) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 4731.3003, D. .

(f) operating restrictions of procedures would prevent a release fraction as large as that shown in 4731.3003, D.

(g) other factors appropriate for the specific facility.

B. Application for license radioactive material in a sealed source or in a device

(1) an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains a sealed source must either:

(a) identify the source or device by manufacturer and model number as registered with NRC under 10 CFR 32.210 or with an agreement state;

(b) contain the information identified in 10 CFR 32.210.

INDUSTRIAL RADIOGRAPHY USING RADIOACTIVE MATERIALS

4731.0500 Requirements for Industrial Radiography Facilities Using Radioactive Materials
Subpart 1. **Applicability.** This part contains requirements for the use of radioactive material in industrial radiography. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

A. Industrial radiography using x-ray machines in 4731.0600 to 4731.0607.

B. Industrial radiography using accelerators in 4731.0900 to 4731.0907.

Subp. 2. **License or registration requirements for industrial radiography use.** The commissioner may approve an application for a specific license or registration for the use of licensed or registered material in industrial radiography if the applicant meets the following requirements. The application must include:

A. Information for meeting the licensing requirements as specified in 4731.0309, as appropriate, and any additional requirements contained in this part.

B. A program for training radiographers and radiographers' assistants and a description of this program that specifies the content of the following:

(1) initial training;

(2) on-the-job training;

(3) semi-annual safety reviews provided by the licensee or registrant;

(4) method for demonstration of the radiographer's knowledge, understanding of and the ability to comply with chapter 4731, licensing or registration requirements, and the applicant's written operating and emergency procedures;

(5) method for demonstration of the radiographers' assistants knowledge, understanding of and the ability to comply with the applicant's written operating and emergency procedures.

C. Procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

D. Written operating and emergency procedures as described in 4731.0504 and 4731.0505.

E. A program for semi-annual review inspections of the job performance of each radiographer to ensure that chapter 4731 requirements, license or registration requirements, and the applicant's written operating and emergency procedures are followed.

F. A description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities, including specified delegations of authority and responsibility.

G. If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 4731.0133, subpart 2.

H. A description and identification of the location(s) of all field stations and permanent radiographic installations.

I. Identifications of the locations where all records and documents required by this part and other parts of this chapter will be maintained.

Subp. 3. **Records**. The licensee or registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0189. Records must be kept for four years or until the next inspection by the commissioner. Each licensee or registrant must maintain copies of records required by this part at the location specified in 4731.0500, subpart 2, item H.

4731.0501 Performance Requirements for Industrial Radiography Equipment.
Subpart 1. **Performance requirements criteria**. Equipment used in industrial radiographic operations must meet the following minimum criteria:

A. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute (ANSI), N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography." The ANSI standard is incorporated by reference, is not subject to frequent change, and is available through the Minitex interlibrary loan system.

B. Notwithstanding Item A of subpart 1, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

C. In addition to the requirements specified in item A of this subpart, the following requirements apply to radiographic devices, source changers, source assemblies and sealed sources. The licensee or registrant must ensure that

(1) each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing:

(a) chemical symbol and mass number of the radionuclide in the device;
(b) activity and the date on which this activity was last measured;
(c) model (or product code) and serial number of the sealed source;
(d) manufacturer's identity of the sealed source;
(e) licensee's or registrant's name, address, and telephone number;
(f) the words: "DANGER–RADIOACTIVE." on each sealed source or source assembly; and
(g) the label may not interfere with the safe operation of the exposure device or associated equipment.

(2) radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of4731.1500 to 4731.1514.

(3) any modification of radiographic exposure devices, source changers, source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

Subp 2. **Additional requirements**. In addition to the requirements specified in items A and C of subpart 1 above, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for

radiographic operations or source changers. The licensee or registrant must ensure that:

A. The coupling between the source assembly and the control cable is designed so that the source assembly will not become disconnected if cranked outside the guide tube.

B. The coupling must not be able to be unintentionally disconnected under normal and foreseeable abnormal conditions.

C. The device automatically secures the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

D. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device are equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

E. The guide tube must be:

(1) able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and

(2) able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(3) used when moving the source out of the device.

(4) equipped with an exposure head connection that is able to withstand the tensile test for control units specified in ANSI N432-1980.

F. An exposure head or similar device that is designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

G. A system is in place for source changers that ensures the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

4731.0502 Individual Monitoring. The licensee or registrant, in accordance with 4731.0130, must require a radiographer or a radiographer's assistant, during radiographic operations, to wear on the trunk of the body, dosimetry as follows:

A. At permanent radiography installations where other alarming or warning devices are in routine use, a direct read dosimeter and a NVLAP-accredited individual dosimeter.

B. At temporary jobsites, a direct reading dosimeter, a NVLAP-accredited individual dosimeter, and an operating alarm ratemeter.

4731.0503 Entrances in Permanent Radiographic Installations. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

A. An entrance control of the type described in 4731.0131, subpart 2 that reduces the radiation level upon entry into the area, or

B. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.

4731.0504 Operating Procedures. Each licensee or registrant must develop and follow written operating procedures. The following operating procedures must include written procedures and record making provisions. Copies of superseded procedures must be retained for four years after the change is made.

Subpart 1. **Basic Operating procedures**. The following operating procedures must include written procedures and record making provisions for the following areas:

A. The handling and use of licensed or registered sources including the use of sources, source assemblies, and radiographic exposure devices.

B. The use of remote handling tools for handling sealed sources.

C. Methods for posting and controlling access to radiographic areas.

D. Methods and list of occasions for locking and securing stored licensed or registered materials.

E. Methods for ensuring radiographer assistants are supervised.

F. Opening, modification, removal and replacement of a sealed source from a source holder, and maintenance on sealed sources or holders.

G. Maintenance of records generated by radiographic personnel including temporary jobsites.

H. Methods and occasions for conducting radiation safety surveys, as required by 4731.0132, and 4731.0510.

I. Methods for testing alarm systems at permanent radiographic installations.

J. Individual monitoring and the use of individual monitoring devices, including alarming ratemeters, in accordance with 4731.0130 and 4731.0502.

K. Identify and report to the NRC product defects and noncompliance as required by 10 CFR 21.21.

Subp 2. **Procedures for Use and Maintenance**

A. Ensure the following in accordance with 4731.1500 - 4731.1514:

(1) transport of licensed or registered materials to field stations or temporary jobsites;

(2) packaging of licensed or registered materials for transport in vehicles;

(3) placarding of vehicles when needed; and

(4) physically securing licensed or registered materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal, in accordance with 4731.1500 - 4731.1514.

B. Get, receive, and open packages containing licensed or registered materials, including depleted uranium (DU) in accordance with 4731.0123, subpart 5.

C. Record the receipt of sealed sources and devices using DU; each licensee must make and maintain transportation records showing the receipts and transfers of sealed sources and devices using DU for shielding. These records must include:

(1) the date;

(2) the name of the individual making the record;

(3) radionuclide;

(4) number of curies (becquerels) or mass (for DU); and

(5) manufacturer, model, and serial number of each sealed source.

D. Conduct inspection, maintenance and operability checks of sealed sources, radiographic exposure devices, storage containers, and transport containers, as required by 4731.0507.

Subp 3. **Specific Operating Procedures**

A. Log the source use, including:

(1) a description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located;

(2) the identity and signature of the radiographer to whom the equipment was assigned; and

(3) the plant or site where used and dates of use, including the dates the equipment was removed and returned to storage.

B. Visual inventory and recording of radioactive material use.

C. Leak testing of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the leak testing of sealed sources, the licensee or registrant must:

(1) establish procedures to be followed;

(2) identify the manufacturers of the leak test kits; and

(3) the model numbers of the leak test kits to be used.

D. Contamination testing of DU shielding.

E. Analysis of wipes taken of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the analysis of the wipe samples, the licensee or registrant must:

(1) establish procedures to be followed; and

(2) 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.

Subp 4. **Procedures at field stations and temporary jobsites**. At all field stations and temporary jobsites, demonstration of maintaining the following records and documents:

A. Operating documents:

(1) the radioactive material license authorizing the use of licensed material;

(2) a copy of 4731.0109 to 4731.0186 and 4731.0500 to 4731.0514;

(3) use logs for each radiographic exposure device as required by 4731.0511;

(4) records of equipment problems identified in daily checks of equipment as required by 4731.0507, subpart 1;

(5) records of alarm system and entrance control checks required by 4731.0507, subpart 2, for permanent radiographic installations;

(6) records of individual monitoring dosimeters as required by 4731.0502; and

(7) operating and emergency procedures required by 4731.0505.

B. Data Records

(1) the latest calibration of the radiation survey instruments in use at the jobsite, as required by 4731.0510;

(2) the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by 4731.0502;

(3) latest radiation safety survey records required by 4731.0510;

(4) the shipping papers for the transportation of radioactive materials required by 4731.1501, subpart 2; and

(5) when operating under reciprocity pursuant to 4731.0316, a copy of the Agreement State or NRC license authorizing the use of licensed materials.

4731. 0505 Emergency Procedures. Each licensee or registrant must develop and follow written emergency procedures. Copies of superceded procedures must be maintained for four years after the change is made.

Subpart 1 **Basic emergency procedures** The following emergency procedures must include written procedures and record making provisions for the following areas:

A. Actions to be taken to minimize personnel exposure

B. Actions to be taken when a self-reading dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

C. Actions to be taken when an entrance alarm sounds.

D. Notifications to be made to the licensee's or registrant's radiation safety officer and the commissioner according to 4731.0162, subpart 1, item A in the event of:

(1) an accident or incident;

(2) an unintentional disconnection of the source assembly from the control cable;

(3) the inability to retract the source assembly to its fully shielded position and secure it in this position; or

(4) a failure of any component required for safe operation of the device.

E. Source recovery procedures.

F. Actions to be taken when leak or contamination tests reveal greater than 0.005 microcuries (185 Bq) of removable radioactive material.

G. Actions to be taken if a sealed source is lodged or damaged, when the source is not ruptured.

H. Actions to be taken if a sealed source is ruptured including:

(1) control of contamination;

(2) minimization of inhalation and ingestion of licensed or registered materials;

(3) decontamination of the work place and environment;

(4) decontamination of equipment before release from the site;

(5) decontamination of individuals before leaving the site.

Subp 2. **Records**. Retention of a record of each action and test required by subpart 1. These records must include:

A. The date of the action or test.

B. An annotated diagram of each area surveyed.

C. Background levels.

D. Measurements:

(1) of dose rates which are keyed to the legend of a diagram, expressed in millirem (microsieverts) per hour; or

(2) of removable contamination, expressed in dpm per 100 square centimeters, or counts per minute if performed with a radiation survey instrument.

E. The serial number and model number of the instrument used to conduct the survey or analyze the samples.

F. Identification of the individual who conducted the survey.

4731.0506 Supervision of Industrial Radiography Operations.

Subpart 1. **Radiographer's assistant**. Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by 4731.0510 to determine that the sealed source has returned to the shielded position after an exposure, the assistant must be under the personal supervision of a radiographer. The personal supervision must include:

A. The radiographer's physical presence at the site where the sealed sources are being used.

B. The availability of the radiographer to give immediate assistance if required.

C. The radiographer's direct observation of the assistant's performance of the operations referred to in this part.

Subp. 2. **Two persons**.

A. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the commissioner.

B. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other certified radiographer or an individual who has at a minimum met the requirements of 4731.0152, subpart 2, item C. The additional trained individual must observe the operations and be capable of providing immediate assistance to prevent unauthorized entry.

4731.0507 Inspection and Maintenance. As required by 4731.0504, subpart 2, each licensee or registrant must have written procedures for the inspection and maintenance of sources, source assemblies and source holders.

Subpart 1. **Inspection requirements**. Procedures must include the following requirements:

A. Before each use of the source:

(1) conduct a visual inspection of the integrity of the source holders, radiographic exposure devices, transport and storage containers, associated equipment and source changers, to ensure that the sources are adequately shielding and that required labeling is present;

(2) conduct an operability inspection to check the functioning of the equipment; and

(3) remove equipment that is inoperable or damaged from service until repaired,

and make and keep a record in accordance with 4731.0168; listing:

(a) date of visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what defects were found; and
(d) what repairs were made.

B. Quarterly during use of the source:

(1) conduct a visual inspection and routine maintenance to ensure that there is no physical damage and the required labeling is legible. This inspection includes source holders, radiographic exposure devices, transport and storage containers, associated equipment and source changers;

(2) equipment that is inoperable or damaged must be removed from service until repaired, and a record must be made listing:

(a) date of the visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what damage was found;
(d) what inspection and maintenance operations were performed; and
(e) any actions taken to correct the damage.

C. Replacement components must meet the design specifications.

Subp 2. **Maintenance requirements**

A. The inspection and maintenance must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval in 4731.1506.

B. The alarm system in 4731.0503, item A must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals.

C. Entrance control devices that reduce the radiation level upon entry as designated in 4731.0503, item B must be tested monthly.

D. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7-calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of 4731.0506, subpart 2 and uses an alarming ratemeter.

E. Each licensee must make and maintain records of alarm system and entrance control device tests and retain each record for 4 years after it is made.

4731.0508 Depleted Uranium (DU) Shielding Contamination. Each exposure device using DU shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months.

A. The licensee or registrant must conduct an analysis that is:

(1) capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample; and

(2) performed by a person specifically authorized by the commissioner, an agreement state, or the NRC to perform the analysis.

B. If such testing reveals the presence of 0.005 microcuries (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made.

C. If the evaluation reveals that the S-tube is worn through, the device may not be used again.

D. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeded 12 months.

E. A record of the DU leak-test must be made in accordance with 4731.0134, subpart 1, item B.

4731.0509 Opening of a Source or Source Holder. The following requirements must be met prior to the opening of a source or source holder:

A. The opening, repair, or modification of any sealed or unsealed source must be performed by persons specifically approved to do so by the commissioner, an agreement state or the NRC.

B. Removal of a sealed source from a source holder, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee or registrant unless a written procedure developed has been approved either by the commissioner or by an agreement state.

C. If a sealed source is stuck in the source holder, emergency actions in 4731.0505, subpart 4 must be followed. The licensee or registrant may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee or registrant is specifically approved by the commissioner, an agreement state or the NRC to perform this operation.

4731.0510 Radiation Safety Surveys. In addition to the radiation safety surveys found in 4731.0132, the licensee or registrant must conduct radiation surveys, including but not limited to the surveys required under subpart 1, for each area where licensed or registered materials are used and stored.

Subpart 1. **Requirements of the surveys**. The surveys must:

A. Be conducted when approaching the radiographic exposure device and the guide tube after each exposure to ensure that the sealed source has returned to its shielded position.

B. Be conducted any time the source is exchanged and whenever a device is placed in a storage area as defined in 4731.0100, to ensure that the source is in its shielded position.

C. Be conducted when the encapsulation of the sealed source could be damaged as a result of operation. The licensee or registrant must conduct a contamination survey during and after the operation.

D. Ensure that the maximum exposure rate for storage containers and source changers do not exceed 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisieverts) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

E. Record information, including:

(1) the date of the survey;

(2) the name of the individual conducting the survey;
(3) the identification number or code of the survey;
(4) the instrument used; and
(5) the location of the survey.

Subp. 2. **Requirements of the radiation survey instruments.** Radiation survey instruments must be:

A. Operable and calibrated in accordance to 4731.0133, subpart 2.

B. Capable of measuring appropriate dose rates.

C. Kept at each location where radioactive material is present to conduct the radiation surveys required by chapter 4731.

4731.0511 Visual Inventory and Records of Radioactive Material Use. Each licensee or registrant must conduct a quarterly visual inventory to account for all licensed or registered material received and possessed under the license or registration. The visual inventory must include the following information:

A. Quantity and kind of licensed or registered material;

B. Make, model number, and a serial number or a description of each sealed source used;

C. Location of the licensed or registered material;

D. Date of use of licensed or registered material;

F. Date of the inventory;

G. Identify of the individual who is responsible for the licensed or registered material;

H. Name of the individual conducting the inventory and use record required in 4731.0504, subpart 3, item A.

4731.0512 Labeling and Posting. The licensee or registrant must ensure the labeling and posting requirements in this part are met and are in addition to the requirements found in 4731.0122. The licensee or registrant:

A. May not use or store a source, source holder, or radiographic exposure device that contains licensed or registered material unless every piece of equipment containing radioactive material bears a durable, legible, and clearly visible marking or label. This marking or label must contain:

(1) radiation symbol as specified in 4731.0122; and

(2) the words "DANGER (or CAUTION) RADIOACTIVE MATERIAL NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

B. May not transport licensed or registered material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with requirements in 4731.1500 to 4731.0514.

C. May not perform industrial radiography unless the area is conspicuously posted as required by 4731.0122. Exceptions listed in 4731.0122, subpart 4 of this chapter do not apply to industrial radiographic operations.

4731.0513 Security During Storage, Transportation and Use. The licensee or registrant must:

A. Store each source containing licensed or registered material in a storage container or transportation package, meeting the following requirements:

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

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

B. Transport the package containing licensed or registered 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 or registered material from the vehicle.

C. Ensure that sources not in storage or being transported are under the constant surveillance and control of the licensee or registrant.

D. Ensure that each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the source from its shielded position.

(1) the exposure device and/or its container must be kept locked, and if a keyed-lock, with the key removed at all times, when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 4731.0503; and

(2) in addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

E. Ensure that each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position.

F. Storage containers and source changers must be kept locked, and if a keyed-lock, with the key removed at all times, when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

4731.0514 Offshore Waters Operations. A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the commissioner, another agreement state, or the NRC.

INDUSTRIAL FACILITIES USING X-RAY

4731.0600 General Requirements for Industrial X-ray Equipment

Subpart 1. **Applicability**. This part establishes standards for the use of x-ray equipment in industrial settings. These requirements are in addition to the requirements of 4731.0100 to 4730.0317. For industrial equipment using radioactive material, refer to 4731.0500 to 4731.0514.

Subp. 2. **Classes**. Industrial facilities using x-ray equipment must be classified as Class A, Class B, Class C, Class D, or Class F equipment. The class of the equipment must be specified by the registrant at the time of registration.

A. Class A is equipment intended for unlimited use of industrial radiation producing equipment used for industrial radiography at maximum capacity in a permanent, shielded enclosure.

B. Class B is portable equipment intended for time-limited use, temporary operation at the facility site or a temporary job site for use of industrial radiography.

C. Class C is an industrial cabinet x-ray system or analytical x-ray equipment housed in a cabinet.

D. Class D is analytical x-ray equipment not housed in a cabinet, not to include electron microscopes manufactured after December 31, 1973.

E. Class F is x-ray equipment used with a product conveyor system, including but not limited to curing, polymer linking, quality control, or measurements of thickness or weight.

Subp. 3. **Operating and emergency procedures**. A copy of a registrant's most current written operating and emergency procedures must be supplied to the registrant's employees. The procedures must include:

A. Operating procedures on how to:

(1) handle and use each source of radiation so no individual is exposed to radiation doses in excess of the limits established in 4731.0124;

(2) conduct radiation safety surveys, in accordance with 4731.0132;

(3) control access to Classes A, B, and D x-ray equipment;

(4) lock and secure Classes A, B, D x-ray equipment;

(5) lock and secure Class C equipment that allows an individual to enter the cabinet;

(6) conduct individual monitoring when required under 4731.0125, subpart 2 or 4731.0130; and

(7) conduct exposure rate surveys after each industrial radiographic exposure to determine that x-rays are not being generated.

B. Emergency procedures on how to:

(1) notify the registrant's radiation safety officer and the commissioner in accordance with 4731.0162, subpart 1, item A, when:

(a) personnel using Class A or Class B equipment has a direct reading pocket dosimeter that goes off-scale;

(b) overexposure or an occupational dose has been exceeded; or

(c) a non-occupational worker or member of the public has been exposed.

(2) minimize the exposure of individuals in the event of an incident.

4731.0601. Inspection and Maintenance of Equipment. The registrant must ensure that the following are completed and the records made and maintained as listed in 4731.0168 to 4731.0188.

Subpart 1. **Inspection and maintenance requirements.**

A. Checks for visual defects in Classes A and B equipment prior to each day or each shift of use.

B. Quarterly inspection of proper functioning of warning devices, control devices, and components important to safety, in compliance with subpart 5 and 4731.0173.

C. Tests of alarming ratemeters to be performed before each shift to ensure they signal properly.

D. Maintenance of equipment in accordance with manufacturer's specifications, recording the name of the individual who performed the service.

E. Removal of equipment from service and labeled as defective equipment when a defect is found in a component critical to radiation safety or the function of the equipment, until repairs are made.

F. In addition to the radiation safety surveys conducted in accordance with 4731.0132; surveys must be conducted and recorded:

(1) annually not to exceed one year; and

(2) after each industrial radiographic exposure to determine that the machine is "off."

Subp 2. **Calibration of radiation survey instruments.** Radiation survey instruments must be accessible and calibrated in accordance with 4731.0133, subpart 2.

Subp. 3. **Use logs**. Each registrant that is required to use individual monitoring devices for their employees must make and maintain use logs until the next inspection by the commissioner. The log must specify:

A. A serial number or other unique identification for each piece of x-ray equipment.

B. The identity of the operator assigned to the equipment.

C. The locations and dates where the equipment was used.

D. The technique factors specifying the voltage, current, exposure time for each radiographic exposure, and number of exposures.

Subp. 4. **Safety device**. The registrant must ensure that a safety device or interlock is:

A. Not bypassed unless:

(1) prior, written approval has been obtained from the radiation safety officer. The approval must be for a specified period of time and require that the bypass terminate as soon as repairs are completed;

(2) a readily discernible sign stating "SAFETY DEVICE NOT WORKING" is posted on the device and at the control panel;

(3) radiation safety surveys are performed after the safety device is removed and after the device is restored, according to 4731.0132; and

(4) a record of the bypass must be made according to 4731.0168 to 4731.0191.

B. Provided to prevent the entry of any portion of an individual's body into the primary x-ray beam path, or causes the beam to be shut off when an object enters its path.

Subp. 5. **Warning devices.**

A. Open-beam configurations must have a readily discernible indication of:

(1) x-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in an "on-off" manner; or

(2) shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in "open-closed" manner.

B. An easily visible warning light labeled with the words "X-RAY ON" or other visible warning indicator that clearly shows the equipment is producing ionizing radiation, must be located near a switch that energizes an x-ray tube and illuminated only when the tube is energized.

C. Warning devices must be labeled so that their purpose is easily identified.

D. On equipment installed on or after March 1, 1998, warning devices must have fail-safe characteristics.

Subp. 6. **Security**. For Class A, Class B and equipment from Class C that allows an individual to enter the cabinet, the registrant must ensure that security systems are designed and used so that no operable industrial x-ray equipment is left unattended unless:

A. The equipment is locked in an inoperable condition.

B. The room or building in which the equipment is located is locked.

Subp. 7. **Records**. The registrant must ensure that the records in this part are kept in accordance with 4731.0168 to 4731.0191.

Subp. 8. **Individual monitoring**. The registrant for Class A or Class B must ensure that the individual monitoring requirements specified in 4731.0130 are met. In addition, there must be:

A. Either an alarming ratemeter that will alarm at an exposure of up to 500 mR/hr (1.29 x 10-4 C/kg/hr) or an alarming ratemeter that also integrates the total exposure up to 5,000 milliroentgens (1.29 x 10-3 C/kg).

B. A hand-held portable radiation survey meter with an audible and visible readout of exposure rate or a fixed area radiation exposure rate monitor with a visible or audible alarming indicator may be substituted for the alarming ratemeter.

C. Each registrant must make and maintain the following exposure records:

(1) direct reading dosimeter readings and yearly operability checks required by 4731.0130;

(2) records of alarming ratemeter calibrations;

(3) reports received from the NVLAP-accredited individual dosimeter processor until the commissioner terminates the license;

(4) records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged NVLAP-accredited personnel dosimeters, until the commissioner terminates the license.

4731.0602. Class A Industrial X-ray Equipment.

Subpart 1. **Applicability**. This part applies to Class A industrial x-ray equipment used for industrial radiography. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp. 2. **Permanent, shielded enclosure**. An x-ray source and the objects exposed must be contained in a permanent shielded enclosure.

A. Except as provided in subpart 5, the enclosure must attenuate primary and secondary radiation so that the exposure rate at any accessible external point does not exceed two milliroentgens (5.16 x 10-7 C/kg) per hour when:

(1) the beam is adjusted to give maximum exposure rate with the generator at maximum; and

(2) the equipment is placed in the shortest equipment-to-wall radiographically usable position.

B. A person must be able to exit the enclosure at all times.

C. No person is permitted to remain within an enclosure while the x-ray generator is in operation.

Subp. 3. **Interlocks**. Interlocks must be provided that either prevent entering the enclosure while the x-ray generator is in operation or terminate the generation of x-rays if the enclosure is entered.

A. Interlocks must be provided so that all entrance doors close before industrial radiographic operations are initiated or continued.

B. If a useful radiation beam is interrupted by a door opening, it must not be possible to restore the system to operation without closing the door and reinitiating irradiation by manual action at the control panel.

Subp. 4. **Visible and audible signals**. A permanent, shielded enclosure must be equipped with internal and external visible and audible signals.

A. Visual signals must be activated on generation of x-rays and remain continuously activated while x-rays are generated.

B. Audible signals must be activated if an interlock is interrupted or opened during operation.

Subp. 5. **Ceiling barrier**. If a ceiling barrier does not attenuate the exposure rate as specified in subpart 2, a posted fence or other barrier must be used to restrict access to the area above the ceiling.

4731.0603. Class B Industrial X-ray Equipment.

Subpart 1. **Applicability**. This part applies to Class B portable radiation equipment used for the time-limited, temporary operation at the facility site or temporary jobsite of industrial radiography. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.
Subp. 2. **Restricted areas.** During the use of Class B equipment in either temporary operations at the facility site or at temporary jobsites, all areas in which the exposure rate exceeds two milliroentgens (5.16 x 10-7 C/kg) per hour, must have a fence, rope, signs, or other suitable personnel barrier used outside the two milliroentgens (5.16 x 10-7 C/kg) per hour iso-line to restrict entry.

4731.0604. Class C Industrial X-ray Equipment.
Subpart 1. **Applicability**. This part applies to Class C industrial radiographic and analytical x-ray systems housed in a cabinet.

A. A registrant who performs and maintains a cabinet or cabinet system certified in accordance with 21 CFR 1020.40 must comply with all design and maintenance requirements of 21 CFR 1020.40, and as subsequently amended.. These requirements are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

B. A registrant who performs industrial radiography or x-ray analysis in a noncertified cabinet,must comply with all requirements of this part and the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp 2. **Individual monitoring requirements**. When a cabinet x-ray system allows an individual or any body part to enter the interior of the cabinet, the individual must wear an alarming ratemeter and NVLAP approved individual monitoring device.

4731.0605 **Class D Industrial X-ray Equipment.**
Subpart 1. **Applicability**. This part applies to Class D analytical radiation producing equipment not housed in a cabinet. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp 2. **Ports**. Unused ports on radiation source housings must be closed to prevent opening by an individual other than the operator.

Subp 3. **Shutters**. For equipment with an open-beam configuration, each port on the radiation source housing must be equipped with a shutter that cannot be operated unless either a collimator or a coupling has been connected to the port.

Subp 4. **Radiation shielding of components**. The registrant must ensure that:

A. An x-ray tube housing or port cover is constructed so that, when all shutters are closed, the radiation measured at a distance of five centimeters (1.97 inches) from the surface of the x-ray tube housing or port cover does not produce a dose in excess of 2.5 millirems (0.025 mSv) in one hour.

B. The 2.5 millirems (0.025 mSv) dose limit is not exceeded at any specified tube rating.

C. Each x-ray generator has a protective cabinet that limits radiation measured at a distance of five centimeters (1.97 inches) from the protective cabinet surface so that the x-ray generator does not produce a dose in excess of 0.5 millirem (0.005 mSv) in one hour.

4731.0606 [Reserved]

4731.0607 Class F Industrial X-ray Equipment.

Subpart 1. **Applicability**. This part applies to Class F x-ray equipment used with a product conveyor system. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp. 2. **Class F Equipment within a housing.** When Class F industrial x-ray equipment is surrounded by a housing, it must comply with the following:

A. The radiation source and the materials being exposed to radiation must be contained within the housing.

B. The housing must attenuate the primary and secondary radiation beam so that the exposure rate through any portion of the housing is less than 0.5 milliroentgen (1.29×10^{-7} C/kg) per hour and the exposure rate through openings in the housing is less than five milliroentgens (1.29×10^{-6} C/kg) per hour at any accessible external point when the equipment is being operated at its maximum potential.

C. Interlocks must be provided on access panels in the housing. The interlocks must terminate the generation of radiation or attenuate the radiation exposure rate to five milliroentgens (1.29×10^{-6} C/kg) per hour if an access panel is opened.

D. The housing must be equipped with visible signals that activate when radiation is generated and remain activated continually while radiation is present.

Subp 3. **Class F Equipment without a housing.** When it is not practical to surround Class F industrial x-ray equipment by a housing, the following requirements apply:

A. The equipment must be equipped with visible signals that activate when radiation is generated and remain activated continually while radiation is generated.

B. All areas in which the exposure rate exceeds two milliroentgens (5.16 x 10-7 C/kg) per hour, must have fencing, a rope, signs, or other suitable personnel barrier used outside the two milliroentgens (5.16 x 10-7 C/kg) per hour iso-line to restrict entry.

IRRADIATOR REQUIREMENTS

4731.0700 Requirements for Industrial Irradiators

Subpart 1. **Applicability.**

A. This part contains requirements for the use of radioactive material in the following types of irradiators using gamma radiation to irradiate objects or materials :

(1) panoramic irradiators that have either dry or wet storage of the radioactive sealed sources;

(2) underwater irradiators in which both the source and the product being irradiated are under water; and

(3) iradiators 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.

B. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

(1) 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) in 4731.1000 to 4731.1010;

(2) medical radiology in 4731.1200 to 4731.1214;

(3) medical teletherapy in 4731.1200 to 4731.1214;

(4) radiography (the irradiation of materials for nondestructive testing purposes) in 4731.0500 to 4731.0514;

(5) gauging in 4731.1000 to 4731.1010; or

(6) open-field (agricultural) irradiations in 4731.1000 to 4731.1010.

Subp. 2. **License requirements for irradiator uses.** The commissioner may approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the general requirements specified in 4731.0309 and the following additional requirements:

A. The applicant must submit to the commissioner a developed program for training irradiator operators that specifies the:

(1) initial training;

(2) on-the-job or simulator training;

(3) annual safety reviews provided;

(4) methods used by the applicant to test each operator's knowledge, understanding of, and ability to comply with chapter 4731 and licensing requirements and the irradiator operating and emergency procedures; and

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

B. Must submit written operating and emergency procedures listed in 4731.0708.

C. Must submit a description of the organizational structure for managing the irradiator, including:

(1) the radiation safety responsibilities and authorities of the radiation safety officer; and

(2) who, within the management structure, has the authority to stop unsafe

operations.

D. Must describe the training and experience required for the position of radiation safety officer.

E. Must ensure compliance with:

(1) access control systems required by 4731.0706, subpart 3 and 4731.0707, subpart 2; and

(2) radiation monitors required by 4731.0705.

F. Provide the method of detecting leaking sources required by 4731.0708, subpart 4, item B, including the sensitivity of the method.

G. Provide a current diagram of the facility that shows the locations of all required interlocks and radiation monitors.

H. Describe the qualifications and training of the personnel and the procedures to be used, if the applicant's personnel are to be loading or unloading sources.

I. Provide a copy of the contract for source loading and unloading at the applicant's facility when it is being done by an organization specifically authorized by the commissioner, an agreement state or the NRC to load or unload irradiator sources.

J. Describe the inspection and maintenance tests, including the frequency, required by 4731.0709 to be performed by the applicant.

Subp. 3. **Applications for proposed alternatives.** Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for industrial irradiation of materials or objects may include proposed alternatives for the requirements of 4731.0700 to 4731.0711. The commissioner may 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.

Subp. 4. **Records.**

A. The registrant must ensure that the records required by 4731.0700 to 4731.0711 are kept in accordance with 4731.0168 to 4731.0187. Records must be kept for four years or until the next inspection by the commissioner.

B. For all irradiators, records must be made and maintained of all tests, major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve irradiators and any required radiation safety equipment for 4 years after repairs are completed and for next inspection by the commissioner.

C. For all irradiators, records must be made and maintained on the design checks required by 4731.0702, subpart 2 and the construction control checks as required by 4731.0702, subpart 3 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

4731.0701 Performance Criteria for Sealed Irradiator Sources. Sealed sources must meet the following performance criteria before use:

A. Have a certificate of registration issued under 10CFR 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-souce-change irradiator.

D. If the sources are for use in irradiator pools, they must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance.

E. In prototype testing of the sealed source, it must 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.

4731.0702 Design and Construction Requirements for Irradiator Facilities.

Subpart 1. **Start of construction.** 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 4731.0104. 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 4731. The term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include:

A. Engineering and design work.

B. Purchase of a site.

C. Site surveys or soil testing.

D. Site preparation, site excavation, construction of warehouse or auxiliary structures.

E. Other pre-construction tasks.

Subp. 2. **Irradiator design requirements.** Irradiators whose construction or manufacture began after July 1, 1993, must meet the design requirements of this part.

A. For all irradiators, these design requirements apply. The licensee must provide the commissioner with assurance that:

(1) foundation design gives consideration to soil characteristics, to ensure it is

adequate to support the weight of the shielded walls, and pool, if applicable;

(2) evaluation of the location and sensitivity of the monitor to detect sources carried by a product conveyor system as required by 4731.0705 is completed;

(3) verification of the design is completed so that the product conveyor stops before a source on the product conveyor would cause a radiation overexposure to any person;

(3) verification of the design is completed so that the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room so that a fire is extinguished without the entry of personnel into the room and that the system is protected from mechanical and radiation damage. The system must have a shut-off valve to control flooding into unrestricted areas;

(4) verification of the electrical wiring and electrical equipment in the radiation room are selected to minimize failures; and

(5) design of the product conveyor system, so that the source rack and the mechanism that moves the rack is protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism, if applicable.

B. For panoramic irradiators, these additional design requirements apply. The licensee must provide the comissioner with assurance that:

(1) verification of the design so that the shielded walls meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielded dose requirements of 4731.0703; 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 shielded walls by the irradiator sources;

(2) the source rack drops due to loss of power will not damage the source rack;

(3) the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds;

(4) the source rack drops due to failure of cables or alternate means of support, will not cause loss of integrity of sealed sources;

(5) review of the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and than, if the rack sticks, a means exists to free it with minimal risk to personnel;

(6) verification of the design and logic diagram indicate the access control system meets the requirements of 4731.0706, subpart 3, and 4731.0707, subpart 2;

(7) verification 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, is completed; and

(8) verification of the design for panoramic irradiators to be built in seismic areas, so that 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.

C. For pool and underwater irradiators, these additional requirements apply. The licensee must provide the commissioner with assurance that:

(1) the design of the pool assures that:

(a) the pool is leak resistant;

(b) the pool is strong enough to bear the weight of the pool water and shipping casks;

(c) a dropped cask would not fall on sealed sources; and

(d) all outlets or pipes meet the requirements of 4731.0706, subpart 1, item D and that metal components are metallurgically compatible with other components in the pool.

(2) the design of the water purification system is adequate to meet the requirements of 4731.0706, subpart 1, item G; the system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored;

(3) the radiation monitoring systems used to detect contamination under 4731.0708, subpart 4, item B, are designed to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate;

(4) 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. 3. **Construction monitoring and acceptance testing.** The requirements of this section must be met for all irradiators constructed or manufactured after July 1, 1993. The requirements must be met prior to loading sources.

A. The licensee must provide the commissioner with assurance that:

(1) there is monitoring of the construction of the foundations to verify that their construction meets design specifications in 4731.0702, subpart 2, item A, subitem (1);

(2) the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 4731.0705, Subpart 1; and

(3) irradiators that use a product conveyor systems, are observed and tested for the operation of the conveyor system to assure that the requirements in 4731.0702, subpart 2, item B, subitems (2) to (5) 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, these additional requirements apply. The licensee must ensure that:

(1) there is monitoring of the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete;

(2) testing of the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly;

(3) testing the ability of the heat and smoke detectors is done to:

(a) detect a fire;

(b) activate alarms; and

(c) cause the source rack to automatically become fully shielded;

(4) testing of the operability of the fire extinguishing system;

(5) that the source racks can be returned to their fully shielded positions without offsite power;

(6) panoramic irradiators that use a computer system to control the access control system, must:

(a) have an access control system that operated properly if offsite power is lost; and

(b) have a computer that has security features to prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable;

(7) that the electrical wiring and electrical equipment were installed meet the design specifications; and

(8) testing the movement of the source racks for proper operation prior to source loading, test must include lowering of the source rack due to simulated loss of power.

C. For pool or underwater irradiators, these additional requirements apply. The licensee must ensure that:

(1) the pool meets design specifications and must test the integrity of the pool;

(2) the outlets and pipes meet the requirements of 4731.0706, subpart 1, item D;

(3) the water purification system, the conductivity meter, and the water level indicators operate properly;

(4) the proper operation of the radiation monitors and the related alarm if used to meet 4731.0708, subpart 4, item B; and

(5) the proper operation of the over-the-pool monitor, alarms, and interlocks required by 4731.0705, subpart 2 for underwater irradiators.

4731.0703 Shielded Dose Rates.

Subpart 1. **For panoramic irradiators**, the radiation dose rate in areas that are normally occupied during operation 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. **For dry-source-storage panoramic irradiators**, the radiation dose rate at 1 meter from the shield 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.

Subp. 3. **For pool irradiators**, the radiation dose at 30 centimeters over the edge of the pool may not exceed 2 millirem (0.02 millisievert) per hour when the sources are in the fully shielded position.

4731.0704 Individual Monitoring.

A. The licensee or registrant, in accordance with 4731.0130, must require each irradiator operator to wear a NVLAP-accredited individual dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator.

B. Non-operating individuals who enter the radiation room of a panoramic irradiator must

wear a dosimeter, which may be a direct reading dosimeter.

(1) for groups of visitors, at least one of every 10 people who enter the radiation room are required to wear dosimeters;

(2) if direct reading dosimeters are used to meet the requirements of item B, 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.

4731.0705 Radiation Monitors.

Subpart 1. **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. These alarms must meet the following requirements:

A. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically.

B. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance.

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

Subp. 2. **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.

C. The alarm must be capable of alerting an individual who is prepared to respond promptly.

4731.0706 Requirements for Irradiator Pools. The following subparts are in addition to 4731.0700 through 4731.0705 and 4731.0708 through 4731.0711.

Subpart 1. **General requirements for** 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 probability of substantial leakage and have a surface designed to facilitate decontamination.

C. Have a method to safely store the sources during repairs of the pool.

D. 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.

E. Be provided with a means to replenish water losses from the pool.

F. Be provided with a water level indicator 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.

G. 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.

H. Be provided with a physical barrier, such as a railing or cover, 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; and

I. Not expose handling areas of tools or poles to radiation dose rates greater than 2 millirem (0.02 millisievert) per hour.

Subp. 2. **Pool water purity.**

A. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances.

B. 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.

C. Conductivity meters must be calibrated at least annually.

Subp. 3. **Access control for underwater irradiators.** Each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by 4731.0122, subpart 2. Additional requirements include:

A. A personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended.

B. Keys to the personnel access barrier may only be accessed by operators and facility management.

C. 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.

4731.0707 Requirements for Panoramic Irradiators. The following subparts are in addition to 4731.0700 through 4731.0705 and 4731.0708 through 4731.0711.

Subpart 1. **Control of panoramic irradiator source movement.**

A. The mechanism that moves the sources must:

(1) require a key to actuate

(a) only one key may be in use at any time, and only operators or facility management may possess it;

(b) the key must be attached to a portable radiation survey meter by a chain or cable;

(c) the lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position;

(d) the door to the radiation room must require the same key as the source mechanism;

(2) cause an audible signal upon activation to indicate that the sources are leaving the shielded position.

B. The console 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.

C. The control console must have a control that promptly returns the sources to the

shielded position.

D. Each control must be clearly marked as to its function.

Subp. 2. **Access control for panoramic irradiators.**

A. Entrance requirements

(1) each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent entry of personnel if the sources are in use. These controls include, but are not limited to, the following:

(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.

(2) 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. These would include:

(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.

(3) 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. This includes the following:

(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 subitem (2);

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

(4) 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.

(5) 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.

(6) 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.

(7) each entrance to the radiation room of a panoramic irradiator must be posted as required by 4731.0122, subitem 2. 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.

B. After entering the irradiator:

(1) 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;

(2) 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;

(3) 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.

4731.0708 Operating and Emergency Requirements For Irradiators.

Subpart 1. **Operating procedure requirements.** The licensee must have and follow written operating procedures. Copies of superseded procedures must be retained for four years after the change is made. These procedures must include the following procedures:

A. Operation of the irradiator, including entering and leaving the radiation room.

B. Use of individual 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 sealed sources done in accordance with 4731.0134, or if an applicant wants to perform leak testing of sealed sources, the applicant must:

(1) establish procedures to be followed;

(2) identify the manufacturers of the leak test kits; and

(3) the model numbers of the leak test kits to be used.

F. Analysis of wipes taken of sealed sources done in accordance with 4731.0134, or if the applicant wants to analyze its own wipe samples, the applicant must:

(1) establish procedures to be followed; and

(2) 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.

G. Inspection and maintenance tests required by 4731.0709.

H. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee.

I. Inspection of movable shielding required by 4731.0707, subpart 2, item B, if applicable.

J. Calibration of all survey instruments and conductivity monitors must be performed at required frequency found in 4731.0133.

Subp. 2. **Attendance during operation** of any irradiator, both an irradiator operator and at least one other individual, who is trained on response procedures 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.

B. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

C. 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 4731.0151, subpart 3 must be onsite.

D. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool.

(1) 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 4731.0151, subpart 3;

(2) static irradiations may be performed without a person present at the facility.

Subp. 3. **Emergency procedure requirements.** The licensee must have and follow emergency or abnormal event procedures, appropriate for the irradiator type. These procedures must cover the following conditions:

A. Notification of the licensee's radiation safety officer and the commissioner according to 4731.0162 when:

(1) sources are stuck in the unshielded position;

(2) personnel are overexposed;

(3) the product exit portal monitor or pool monitor alarms;

(4) leaking sources, pool contamination, or alarm caused by contamination of pool water is detected;

(5) a low or high water level, an abnormal water loss, or leakage form the source storage pool is detected;

(6) electrical power is lost;

(7) a fire alarm or explosion occurs in the radiation room, so that a person who is

prepared to summon assistance can be alerted promptly;

(8) unauthorized entry into the radiation room, area around pool, or another alarmed area is detected;

(9) automatic conveyor systems are jammed;

(10) damage to the source racks;

(11) failure of the cable or drive mechanism used to move the source racks;

(12) inoperability of the access control system;

(13) detection of radioactive contamination attributable to licensed radioactive material; and

(14) structural damage to the pool liner or walls.

B. Power failures for panoramic, pool or underwater irradiators.

C. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility.

D. If pool water conductivity rises above 20 microsiemens per centimeter, the actions by licensee to lower the pool water conductivity and the corrective actions to prevent future recurrences.

E. Actions to be taken if pool water conductivity exceeds 100 microsiemens per centimeter.

Subp. 4 **Emergency situations.** The licensee must follow their written procedures for emergencies and abnormal events as required in 4731.0708, subpart 3. The reports for those activities must be kept for 4 years or until the next inspection by the commissioner.

A. Power failures for irradiators:

(1) if electrical power is lost for longer than 10 seconds, the sources must automatically return to the shielded position;

(2) the lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure;

(3) 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 4731.0705, subpart 2 is operating with backup power;

(4) 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.

B. Detection of leaking sources:

(1) if the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm;

(2) 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;

(3) water from the pool must be checked for contamination each day the irradiator operates; the check may be done either by using:

(a) a radiation monitor on a pool-water circulating system; or

(b) 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.

C. If a leaking source is detected:

(1) the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a licensee of the commissioner, an agreement state or NRC that is authorized to perform these functions;

(2) the licensee must promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination;

(3) 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;

(4) if any personnel are found to be contaminated, decontamination must be performed promptly;

(5) if contaminated equipment, facilities, or products are found, the licensee must arrange to have them decontaminated or disposed of by a licensee of the commissioner, an agreement state or NRC that is authorized to perform these functions;

(6) 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 4731.3001.

Subp. 5. **Revision of operating and emergency procedures**. The licensee may revise operating and emergency procedures without prior commissioner approval only if the licensee can assure the commissioner that:

A. The revisions do not reduce the safety of the facility.

B. The revisions are consistent with or better than the procedures submitted with the license application.

C. The revisions have been reviewed and approved by the radiation safety officer.

D. The users or operators have been instructed and tested on the revised procedures before they are put into use.

4731.0709 Inspection and Maintenance.

A. The licensee must perform the inspection and maintenance tests as required by 4731.0700 to 4731.0711. These tests include:

(1) overall operability tests:

(a) operability of each aspect of the access control system;

(b) functioning of the source position indicator;

(c) operability of the radiation monitor for radioactive contamination in pool water, using a radiation check source, if applicable;

(d) operability of the over-pool radiation monitor at underwater irradiators;

(e) operability of the product exit monitor;

(f) operability of the emergency source return control;

(g) leak-tightness of systems through which pool water circulates visual

inspection;

(h) operability of the heat and smoke detectors and extinguisher system ,but without turning extinguishers on;

(2) specific tests:

(a) operability of the means of pool water replenishment;

(b) operability of the indicators of high and low pool water levels;

(c) operability of the intrusion alarm, if applicable;

(d) functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

(e) condition of the barrier to prevent products from hitting the sources or source mechanism;

(f) volume of additional water needed to determine if the pool is leaking;

(g) integrity electrical wiring on required safety systems for damage;

(h) pool water conductivity measurements and analysis; and

(i) product conveyor system 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. Malfunctions and defects found during inspection and maintenance tests must be repaired without undue delay.

4731.0710 Radiation Safety Surveys. In addition to the radiation safety survey requirements in 4731.0132, these surveys must be conducted and records made by licensees for the appropriate type of irradiators.

Subpart 1. **Requirements of the surveys.**

A. For panoramic irradiators the following radiation surveys must be conducted:

(1) before the facility starts to operate, in areas outside the shielding of the radiation room, with the sources in the exposed position;

(2) at intervals not to exceed three years, by the shielding of the irradiator;

(3) before resuming operation after addition of new sources, and

(4) after any modification to the radiation room shielding or structure that might increase dose rates.

B. For pool irradiators the following radiation surveys must be conducted:

(1) before the facility starts to operate, in areas above the pool, after the sources are loaded;

(2) at intervals not to exceed three years, by the shielding of the irradiator;

(3) before resuming operation after addition of new sources;

(4) after any modification to the radiation room shielding or structure that might increase dose rates;

(5) before release to unrestricted areas, water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination; radioactive concentrations must not exceed those specified in table 2, column 2 or table 3 in appendix B to 4731.3001;

(6) 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. 2. **Requirements of the radiation survey instruments**. Radiation survey instruments must be:

A. Operable and calibrated in accordance to 4731.0133, subpart 3.

B. Capable of measuring appropriate dose rates.

C. Kept at each location where radioactive material is present to conduct the radiation surveys required by chapter 4731.

Subp. 3. **Modification**. If the radiation levels specified in 4731.0703 are exceeded, the facility must be modified to comply with the requirements in 4731.0703.

4731.0711 Irradiation of Explosive or Flammable Materials.

A. 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.

B. 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.

WELL LOGGING REQUIREMENTS

4731.0800 Well Logging Requirements.
Subpart 1. **Applicability.** This part contains requirements for the use of radioactive material including sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well or boring. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

A. The use of sealed sources auxiliary to well logging but not lowered into the wells or borings in 4731.1000 to 4731.1010.

B. The use of licensed material in tracer studies involving multiple wells, such as field flooding studies in 4731.1000 to 4731.1010.

Subp. 2. **License requirements for well logging use.** The commissioner may approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements. The applicant must:

A. Satisfy the general licensing requirements specified in 4731.0309, as appropriate, and any special requirements contained in this part.

B. Develop a program for training logging supervisors and logging assistants and submit to the commissioner a description of this program that specifies the content of the following:

(1) initial training;

(2) on-the-job training;

(3) annual safety reviews provided by the licensee;

(4) demonstration of the logging supervisor's knowledge, understanding of and the ability to comply with chapter 4731, licensing requirements, and the applicant's written operating and emergency procedures;

(5) demonstration of the logging assistant's knowledge, understanding of and the ability to comply with the applicant's written operating and emergency procedures.

C. Create written operating and emergency procedures as described in 4731.0803.

D. Establish a program for annual review inspections of the job performance of each logging supervisor to ensure that chapter 4731 requirements, license requirements, and the applicant's written operating and emergency procedures are followed.

E. Describe the applicant's overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

Subp. 3. **Records.** The registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0186. Records must be kept for four years or until the next inspection by the commissioner.

4731.0801 Design and Performance Criteria for Sealed Sources Other Than Sealed Sources that Contain Licensed Material in Gaseous Form. A licensee may only use sealed sources in well logging that meet the following requirements:

A. Is doubly encapsulated.

B. Contains licensed material whose chemical and physical forms are as insoluble and nondispersible as practical.

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

(1) temperature test, where 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;

(2) impact test, where a 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source;

(3) vibration test, where the test source must be subjected to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes;

(4) puncture test, where a 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source; and

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

4731.0802 Individual Monitoring.

A. The licensee or registrant, in accordance with 4731.0130, must require any individual acting as a logging supervisor or logging assistant to wear, at all times during the handling of licensed radioactive materials, a NVLAP-accredited individual dosimeter.

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

4731.0803 Operating and Emergency procedures. Each licensee must develop and follow written operating and emergency procedures.

Subpart 1. **Operating procedures.** The operating procedures must include the following:

A. Overall procedures:

(1) 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;

(2) the use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

(3) methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 4731.0807;

(4) methods for controlling access to sources;

(5) methods and occasions for locking and securing stored licensed materials;

(6) individual monitoring and the use of individual monitoring equipment;

(7) 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;

(8) picking up, receiving, and opening packages containing licensed materials, in accordance with 4731.0123, subpart 5;

(9) for the use of tracers, decontamination of the environment, equipment, and personnel.

B. Maintenance procedures

(1) 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 4731.0805;

(2) maintenance of records generated by logging personnel at temporary jobsites;

(3) visual inventory and recording of radioactive material use;

(4) leak testing of sealed sources done in accordance with 4731.0134, or if an applicant wants to perform leak testing of sealed sources, the applicant must:

(a) establish procedures to be followed;

(b) identify the manufacturers of the leak test kits; and

(c) identify the model numbers of the leak test kits to be used.

(5) identify and report to the NRC defects and noncompliance as required by 10 CFR 21.21.

C. Analysis of data:

(1) analysis of wipes taken of sealed sources done in accordance with 4731.0134;

(2) if the applicant wants to analyze its own wipe samples, the applicant must:

(a) establish procedures to be followed; and

(b) submit a description of these procedures to the commissioner.

(3) 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.

Subp. 2. **Emergency procedures**. Emergency procedures must include written instructions on events in the following areas:

A. Notifications, in the event of an accident/incident or abandonment of a source, to be made to the licensee's radiation safety officer and the commissioner according to 4731.0162.

B. Actions to be taken if a sealed source is lodged or damaged in a well, boring, or drilled hole, so that the source is not ruptured.

C. Actions to be taken if a sealed source is ruptured, including:

(1) prevention of the spread of contamination;

(2) minimization of inhalation and ingestion of licensed or registered materials;

(3) obtaining and using suitable radiation survey instruments as required by 4731.0807, subpart 2;

(4) monitoring of the mud or water circulated during removal operations for possible radioactive contamination;

(5) decontamination of the environment, if the environment is contaminated;

(6) decontamination of equipment before release from the site for unrestricted use, if the equipment was contaminated; and

(7) decontamination of personnel before leaving the site, in the event of their contamination.

D. Actions to be taken to minimize personnel exposure including exposures from inhalation and ingestion of licensed tracer materials.

E. Actions to be taken, after approval of commissioner, if abandonment of source becomes necessary. Sealing or abandonment of a well or boring must be performed by a contractor licensed by the Minnesota Department of Health according to chapters 4725 ,"Wells and Borings" and 4727 "Explorers and Exploratory Borings", and Minnesota Statutes, chapter 103I "Wells, Borings and Underground Uses".

4731.0804 Radioactive Contamination Control. 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 4731.0803.

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

B. 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.

4731.0805 Inspection and Maintenance. Each licensee must have written procedures for the inspection and maintenance of the source and source holders. This program must include the following requirements:

A. Before each use:

(1) a visual inspection looking for defects of the source holders, logging tools, and source handling tools, to ensure that the equipment is in good working condition and that required labeling is present;

(2) if defects are found, the equipment must be removed from service until repaired, and a record must be made and kept for 4 years or the next inspection by the commissioner, listing:

(a) date of visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what defects were found; and
(d) what repairs were made.

B. Semi-annually:

(1) visual inspection and routine maintenance to ensure that there is no physical damage and the required labeling is legible, this inspection is of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars;

(2) if defects are found, the equipment must be removed from service until repaired, and a record must be made and kept for 4 years or the next inspection by the commissioner, listing:

(a) date of the visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what defects were found;

(d) what inspection and maintenance operations were performed; and
(e) any actions taken to correct the defects.

4731.0806 Opening of a Source or Source Holder.

A. 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 NRC.

B. 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 4731.0803 has been approved either by the commissioner pursuant to chapter 4731 or by an agreement state, or the NRC.

C. 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 NRC to perform this operation.

4731.0807 Radiation Safety Surveys. In addition to the radiation safety surveys found in 4731.0132, the licensee must make a radiation survey, including but not limited to the surveys required under subpart 1, of each area where licensed materials are used and stored.

Subpart 1. **Requirements of the surveys.**

A. 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.

B. 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.

C. 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.

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

Subp. 2. **Requirements of the radiation survey instruments.** The licensee must keep a 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 4731. The radiation survey instrument must be capable of measuring appropriate dose rates.

A. 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, in the event of an emergency.

B. The instruments must be operable and calibrated in accordance to 4731.0133.

Subp. 3. **Records**. The results of surveys required under subpart 1 must be recorded and kept in accordance with 4731.0186 and must include:

A. The date of the survey;
B. The name of the individual making the survey;
C. The identification of the survey;
D. The instrument used; and
E. The location of the survey.

4731.0808 Visual Inventory and Records of Material Use. Each licensee must conduct a semi-annual visual inventory to account for all licensed material received and possessed under the license. The licensee must make and maintain the required records in accordance with 4731.0168 to 4731.0186. This inventory and use record must include the following information:

A. Quantity and kind of licensed material.
B. Make, model number, and a serial number or a description of each sealed source used.
C. Location of the licensed material.
D. Date of use of licensed material.
E. Disposition of any unused sealed and unsealed licensed material.
F. Date of the inventory.
G. Identify of the authorized user who is responsible for the licensed material.
H. Name of the individual conducting the inventory and use record.

4731.0809 Labels, Security During Storage, Transportation and Use. The licensee must ensure the requirements in this part are met and are in addition to the requirements found in 4731.0123.

A. The licensee or registrant may not use or store a source, source holder, or logging tool that contains licensed material unless every piece of equipment containing radioactive material bears a durable, legible, and clearly visible marking or label. This marking or label must contain:

(1) radiation symbol as specified in 4731.0122; and

(2) the words " DANGER (or CAUTION) RADIOACTIVE MATERIAL NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

B. The licensee or registrant may not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with requirements in 4731.1500 to 4731.1514.

C. The licensee or registrant must store each source containing licensed material in a storage container or transportation package, meeting the following requirements:

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

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

D. The licensee or registrant must 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.

E. The license or registrant must ensure the logging supervisor is 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.

F. The licensee or registrant must ensure that during well 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 maintains direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in 4731.0100.

4731.0810 Abandonment of Irretrievable Sources.

Subpart 1. **Agreement with well or boring owner or operator**. A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the well owner or operator that is employing the licensee. This agreement is in addition to other requirements in chapter 4731. The licensee must keep this written agreement with the records for four years following the completion of the work or until the next inspection by the commissioner. The agreement must include the following information and the identification of personnel who will perform 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 4731.0804 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.

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 well logging source must be immobilized and sealed in place;

(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 the following information:

(a) word "CAUTION";

(b) radiation symbol in accordance with 4731.0122 without the color requirement;

(c) date the source was abandoned;

(d) name of the well or boring owner or well or boring operator, as appropriate;

(e) well or boring name and well or boring identification number(s) or other designation;

(f) identification of the sealed source(s) by radionuclide and quantity;

(g) 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."

(4) a report must be sent to the commissioner within 30 days, containing the information in item (3).

F. This 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.

Subp. 2. **Abandonment (sealing) procedures for irretrievable sources**. 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:

A. Notify the commissioner by telephone of the circumstances that resulted in the inability to retrieve the source and obtain approval to implement abandonment procedures of this part.

B. Obtain a variance from the sealing requirements of Minnesota Rules, Chapter 4725 or 4727, and comply with the conditions of the variance.

C. Advise the well or boring owner or operator, as appropriate, of the abandonment procedures under subpart 1.

D. 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.

E. Ensure that sealing or abandonment of a well or boring is performed by a contractor licensed by the Minnesota Department of Health in accordance with Chapters 4725, "Wells and Borings"or 4727, "Explorers and Exploratory Borings" and Minnesota Statutes, Chapter 103I, "Wells, Borings and Underground Uses".

Subp.3. **Commissioner approval**. A licensee may apply, contingent upon approval by the commissioner, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in subpart 2 of this part.

4731.0811 Use of a Sealed Source in a Well or Boring Without a Surface Casing. 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 written procedure for reducing the probability of the source becoming lodged in the well or boring. The procedure must be approved by the commissioner prior to use, in accordance to 4731.0800, subpart 2, item C, by an agreement state or the NRC.

4731.0812 Special Uses in Well Logging.

Subpart 1. **Radioactive markers.** 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 4731.3003, schedule 2 of this chapter and only if a variance is obtained from Minnesota Rules, Chapters 4725 or 4727. The use of markers is subject only to the requirements of 4731.0808.

Subp. 2. **Uranium sinker bars.** The licensee may use a uranium sinker bar in well logging only if it is legibly impressed with the words "CAUTION -- RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

Subp. 3. **Energy compensation source (ECS).** The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

A. For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 4731.0134, 4731.0808.

B. For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 4731.0134, 4731.0808, 4731.0810 and 4731.0811.

Subp. 4. **Tritium neutron generator target source.**

A. Use of a tritium neutron generator target source, containing quantities not exceeding 30 curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of 4731.0800 to 4731.0813, except 4731.0801 and 4731.0810.

B. Use of a tritium neutron generator target source, containing quantities exceeding 30 curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of 4731.0800 to 4731.0813 except 4731.0801.

4731.0813 Subsurface Tracer Studies.

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 a well or boring unless a variance to Minnesota rules, chapter 4725 or 4727, has been approved by the commissioner.

ACCELERATOR/CYCLOTRON REQUIREMENTS

4731.0900 General Requirements for Accelerators and Cyclotrons (Positron Emission Tomography–PET)

Subpart. 1. **Applicability**. This part applies to all accelerators, including but not limited to linear accelerators, cyclotrons, including positron emission tomography (PET), van de Graff generators, and ion implanters. The requirements of this part are in addition to requirements for specific uses found in 4731.0100 to 4731.0173. If an accelerator is used for industrial radiography, the registrant must comply with parts 4731.0900 to 4731.0907 and 4731.0600 to 4731.0607.

Subp. 2. **Records**. The registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0173. Records must be kept for four years or until the next inspection by the commissioner.

4731.0901 Safety and Security

Subpart 1. **Safety and warning lights or devices**. The registrant must ensure that a safety device or interlock is:

A. Provided to prevent the entry of any portion of an individual's body into the accelerator beam path, or causes the beam to be shut off when an object enters its path.

B. Not bypassed unless:

(1) prior, written approval has been obtained from the facility radiation safety officer. The approval must be for a specified period of time and require that the bypass terminate as soon as repairs are completed;

(2) a readily discernible sign stating "SAFETY DEVICE NOT WORKING" is posted on the device and at the control panel;

(3) radiation safety surveys must be performed after the safety device is bypassed or removed and when the device is restored, repaired and replaced according to 4731.0132; and

(4) a record of the bypass must be made and maintained according to 4731.0168 to 4731.0173.

C. Warning lights or devices. The registrant must ensure that:

(1) the entry door to an accelerator room is equipped with readily observable warning lights that indicate when the useful beam is in the "on" position;

(2) in addition, each high radiation area must have an audible warning device that must be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device must be clearly heard in all high radiation areas. This warning device is not required for accelerators used on humans.

Subp. 2. **Security**. The registrant must ensure that security systems and procedures are designed and used so that:

A. No operable accelerator is left unattended unless the:

(1) accelerator is locked in an inoperable condition; or

(2) room or building in which the accelerator is located is locked.

B. High or very high radiation areas using accelerators have:

(1) control devices or alarm system installed in accordance with 4731.0131, subpart 2 and 3; or

(2) unauthorized or accidental entry prevented by use of a lock.

Subp. 3. **Accelerator controls and interlock systems.** The registrant must ensure that the accelerator has:

A. Clearly identified and easily discernible instrumentation, readouts, and controls on the control console, including an indicator of beam on/off status.

B. A safety interlock:

(1) on a circuit that allows an interlock to operate independently of all other safety interlocks;

(2) designed to prevent operation of the accelerator in the event of a defect or component failure in the system;

(3) that, once triggered, makes it possible to resume operation of the accelerator only by first manually resetting the controls at the position where the safety interlock was tripped and then resetting the controls at the main control console.

C. A safety interlock installed at each entrance, including a target room, chamber, or other area, that shuts down the accelerator when the entrance barrier is penetrated.

D. Easily identifiable emergency "off" switches with a manual reset that does not allow the accelerator to be restarted from the control console without resetting the emergency "off" switch.

Subp. 4. **Additional requirements for radiation monitoring of cyclotrons, including positron emission tomography (PET) facilities**. The registrant must ensure that:

A. Radiation levels, including stack releases, in an accelerator facility are continuously monitored.

B. Monitoring devices are electrically independent of the accelerator control and safety interlock system.

C. Means are provided to view the radiation monitoring readout at the control panel.

Subp. 5. **Shielding and safety design requirements**. The registrant must ensure that:

A. Shielding requirements of 4731.0141 are met.

B. Radiation safety survey is made when the accelerator is first capable of producing radiation.

Subp. 6. **Ventilation systems**

A. Ventilation systems must be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in 4731.3001, Appendix B, Table 1 of these regulations.

B. A registrant must not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in 4731.3001, Appendix B, Table II of these regulations, except as authorized pursuant to 4731.0126. Concentrations may be

averaged over a period not greater than one year.

C. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

D. If there is venting of radioactive materials from a stack, a continuous airborne monitor must be in place.

4731.0902 Individual Monitoring. The registrant for must ensure that the individual monitoring requirements specified in 4731.0130 are met. In addition, there must be:

A. Either an alarming ratemeter that will alarm at an exposure of up to 500 mR/hr (1.29 x 10-4 C/kg/hr) or an alarming ratemeter that also integrates the total exposure up to 5,000 milliroentgens (1.29 x 10-3 C/kg); or

B. A hand-held portable radiation survey meter with an audible and visible readout of exposure rate or a fixed area radiation exposure rate monitor with a visible or audible alarming indicator may be substituted for the alarming ratemeter.

4731.0903 Operating and Emergency Procedures. A copy of the registrant's written current operating and emergency procedures must be supplied to the registrant's employees and a copy must be available at all times at the accelerator control panel.

Subpart 1. **Operating procedures**. Operating procedures must include procedures that cover the following:

A. Operating the accelerator so that no individual is exposed to radiation doses in excess of the limits established in 4731.0124.

B. Conducting radiation safety surveys, including smear surveys, according to 4731.0132.

C. Controlling access to accelerators.

D. Locking and securing accelerators, according to 4731.0901.

E. Individual monitoring according to 4731.0902.

F. Exposure rate surveys after each accelerator run to determine that the beam has stopped.

G. Handling of unwanted radioactive material and quality control products.

H. Storage of equipment that has become contaminated with radioactivity through use.

Subp. 2. **Emergency procedures**. Emergency procedures must include procedures that cover the following:

A. Notifications to the registrant's radiation safety officer and the commissioner according to 4731.0162, when:

(1) a direct reading pocket dosimeter goes off-scale;

(2) overexposure or an occupational dose has been exceeded;

(3) a non-occupational worker or member of the public has been exposed; or

(4) stack releases exceed limits specified in 4731.3001, Appendix B, Table II; if applicable.

B. Initiation of emergency call list.

C. Actions to be taken when the emergency "off" switches are triggered.

D. Actions to be taken to minimizing the exposure of individuals in the event of an incident.

E. Actions to be taken if accelerator-produced material is spilled or involved in a transportation accident.

4731.0904 Use Logs. Each registrant with accelerators capable of energies of 500 keV or higher must make and maintain use logs until the next inspection by the commissioner. The log must specify:

A. Serial number or other unique identification for each accelerator.

B. Identity of the operator assigned to the equipment.

C. Locations and dates where the equipment was used.

D. Technique factors specifying the voltage, current, operating time for each run, and number of runs.

E. Release rate of radioactive materials emitted from discharge stacks.

F. Identification of accelerator produced material.

4731.0905 Inspection and Maintenance. The registrant must ensure that the following inspections or tests are completed at the proper frequencies and the records made and maintained as listed in 4731.0168 to 4731.0185.

A. Checking of accelerators and associated equipment for visual defects prior to each day of use.

B. Inspection of accelerators for proper functioning of warning devices, control devices, and components important to safety, in compliance with 4731.0173, at the following frequencies:

(1) inspections for cyclotrons, including PET, shall be done daily;

(2) inspections for human use of accelerators, shall be done monthly;

(3) inspections for all other accelerators, shall be done quarterly.

C. Testing of alarming ratemeters before each shift to ensure they signal properly.

D. Testing of area monitors for functionality when used at a cyclotron facility, including PET, shall be done weekly.

E. Checking of area monitors for functioning when used at all other accelerator facilities shall be done monthly.

F. Maintenance of equipment in accordance with manufacturer's specifications.

G. Calibration of radiation survey instruments and area monitors in accordance with 4731.0133.

H. Conducting of radiation safety surveys in accordance with 4731.0132 and annually not to exceed one year.

I. Providing accessibility to radiation survey instruments to conduct the radiation safety surveys, as needed.

J. Labeling and the removal of defective equipment from service, when defect is found in a component critical to radiation safety or the function of the equipment, until repairs are made.

K. Making available the current electrical circuit diagrams of the accelerator and the associated safety interlock systems and maintained at each accelerator facility.

4731.0906 Radiation Safety Surveys. These are in addition to the radiation safety survey requirements in 4731.0132.

Subpart 1. **Requirements of the surveys.** The following surveys must be performed:

A. Measurements of airborne particulate to determine the amount of radioactivity present:

(1) measurements for cyclotrons, including PET, shall be done daily when operating;

(2) measurements for all other accelerators, shall be done weekly.

B. Smear surveys to determine the degree of contamination done at the following frequencies:

(1) smear surveys for cyclotrons, including PET, shall be done daily when operating;

(2) smear surveys for all other accelerators, shall be done weekly.

Subp. 2. **Requirements of the radiation survey instruments**. The licensee or registrant must keep a radiation survey instrument at each accelerator location to conduct the radiation surveys required by chapter 4731.

A. The radiation survey instrument must be capable of measuring appropriate dose rates.

B. The instruments must be operable and calibrated in accordance to 4731.0132.

4731.0907 Additional Requirement for Accelerators in Medical Treatment Settings. The registrant shall appoint a medical committee of at least four members to evaluate and approve uses of medial accelerators for research on a person. Membership of the committee must include the facility radiation safety officer, a physician expert in therapeutic radiology, and a therapeutic radiologic physicist. Membership may include physicians who are experts in internal medicine and hematology.

SEALED AND UNSEALED SOURCE REQUIREMENTS

4731.1000 Sealed and Unsealed Sources Used in Industrial and Research Facilities
Subpart 1. **Applicability**. This part contains requirements for the use of sealed and unsealed sources in industrial and research settings, including requirements for portable and fixed gauges and laboratories. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

A. Industrial radiography in 4731.0500 to 4731.0513.
B. Well logging in 4731.0800 to 4731.0813.
C. Irradiators in 4731.0700 to 4731.0711.
D. Medical uses in 4731.1200 to 4731.1214.

Subp. 2. **License or registration requirements for specific industrial uses.** The commissioner may approve an application for a specific license or registration for the use of licensed material in industrial and research settings if the applicant meets the following requirements. The application must include:

A. The licensing requirements as specified in 4731.0309, as appropriate, and any additional requirements contained in this part.

B. A program for employee training and a description of this program including instructor qualifications that meets the requirements of 4731.0151, 0152, as appropriate.

C. Written operating and emergency procedures as described in 4731.1003 of this part.

D. Action levels for contamination from unsealed sources and the values requiring decontamination and initiation of emergency procedures.

E. A description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities, including specified delegation of authority and responsibility.

F. A description and identification of the location(s) of all field stations.

G. Radioactive material use record.

Subp. 3. **Records**. The registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0185. Records must be kept for four years or until the next inspection by the commissioner.

4731.1001 Design and Performance Criteria for Sealed Sources. A licensee or registrant may use only sealed sources that are registered in the NRC's sealed source and device registry. Sealed sources that contain radioactive material in gaseous form are not included in the sealed source and device registry.

4731.1002 Individual Monitoring. In addition to 4731.0130, the following must be met.
Subpart 1. **NVLAP-accredited individual monitoring device**. The licensee or registrant must require an individual to wear a NVLAP-accredited individual dosimeter when:

A. Working with the source:
(1) handling licensed or registered sources;
(2) using or assisting with sources, or

(3) maintaining sealed sources.

B. Working around the source in fixed gauges during:

(1) installation;

(2) performance the initial survey;

(3) maintenance;

(4) servicing of the unit;

(5) relocation or removal of the sealed sources.

C. Working with unsealed sources and also provide an additional extremity (ring) dosimeter.

Subp. 2. **Bioassay services**. The licensee must provide bioassay services to individuals using unsealed sources of licensed or registered materials.

4731.1003 Operating and Maintenance Procedures. Each licensee or registrant must develop and follow written operating and maintenance procedures. The licensee's or registrant's operating and maintenance procedures must be posted according to 4731.0122.

Subpart 1. **Operating and maintenance procedures for sealed and unsealed sources**. Procedures for both sealed and unsealed sources must include written procedures for the following areas:

A. Operating procedures, including:

(1) handling and use of licensed materials so that radiation doses do not exceed the limits established in 4731.0124;

(2) methods and list of occasions for conducting radiation safety surveys as in 4731.0132, and surveys for detecting radioactivity contamination, as required by 4731.1007;

(3) methods for controlling access to restricted areas;

(4) methods and list of occasions for locking and securing transport and storage containers and sealed sources;

(5) monitoring of an individual in accord with 4731.1002 and bioassay testing;

(6) ensuring the following in accordance with 4731.1500 - 4731.1513:

(a) transport of licensed materials to field stations or temporary jobsites;

(b) packaging of licensed materials for transport in vehicles;

(c) placarding of vehicles when needed; and

(d) physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal, in accordance with 4731.1500 - 4731.1513;

(7) picking up, receiving, and opening packages containing licensed or registered materials.

B. Maintenance procedures, including:

(1) the inspection, maintenance, and operability checks of sealed and unsealed sources, source holders, survey instruments, transport containers, and storage containers;

(2) maintenance for records of the use and date of use of all of the equipment and radioactive materials utilized at each specific temporary jobsite;

(3) calibration of radiation survey instruments at least annually;

(4) posting and providing for lock-out procedures that prevent employees from entering the radiation beam during maintenance, repairs, or other work in, on, or around the radioactive source;

(5) ensuring that a copy of the operating procedures accompany the sources at all times; and

(6) actions to be taken when a source must be transferred or disposed.

Subp.2. **Special operating procedures for sealed sources** must include written procedures for the following areas:

A. Leak testing of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the leak testing of sealed sources, the licensee or registrant must:

(1) establish procedures to be followed;

(2) identify the manufacturers of the leak test kits; and

(3) the model numbers of the leak test kits to be used.

B. Analysis of wipes taken of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the analysis of the wipe samples, the licensee or registrant must:

(1) establish procedures to be followed; and

(2) 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.

Subp. 3. **Special operating procedures for unsealed sources** must include written instructions in the following areas:

A. Limiting the spread of radioactive materials from unsealed sources. This procedure must include action levels:

(1) for fixed and removable contamination; and

(2) for emergency measures if the action levels are exceeded.

B. Analysis of daily and weekly wipes for contamination. The instructions must include the following:

(1) type of instrument detection system used, in accordance with 4731.1007;

(2) background counting times and average background counts;

(3) sample counting times;

(4) sample of calculation converting results into activity or activity per unit time, if applicable;

(5) calculation of counting efficiency; and

(6) calculation of lower level of detection.

C. Monitoring of the fume hood before and after use.

D. Monitoring of any exhaust or ventilation system of a fume hood before and after use.

4731.1004 Emergency Procedures. Each licensee or registrant must develop and follow written emergency procedures. The licensee's and registrant's emergency procedures must be

posted according to 47831.0122.

Subpart 1. **Emergency procedures for both sealed and unsealed sources**

A. Emergency procedures for both sealed and unsealed sources must include written instructions on events in the following areas:

(1) notifications to be reported to the licensee's radiation safety officer and the commissioner according to 4731.0162 in the event of:

(a) an accident or incident;

(b) abandonment of a source; or

(c) levels of contamination that exceed the emergency action levels;

(2) decontamination survey procedures for equipment and affected areas;

(3) actions to be taken when a source must be transferred or disposed;

(4) retention of a record of each action and survey required by 4731.1007. These records must include:

(a) the date of the survey;

(b) an annotated diagram of each area surveyed;

(c) background levels;

(d) measurements including:

((1)) dose rates which are keyed to the legend of a diagram, expressed in millirem (microsieverts) per hour; or

((2)) removable contamination, expressed in dpm per 100 square centimeters, or counts per minute if performed with a radiation survey instrument;

(e) the serial number and model number of the instrument used to make the survey or analyze the samples; and

(f) identification of the individual who performed the survey.

Subp. 2. **Special emergency procedures for sealed sources** must include written instructions in the following:

A. Actions to be taken if a sealed source is lodged or damaged, when the source is not ruptured.

B. Actions to be taken if a sealed source is ruptured including:

(1) control of contamination;

(2) minimization of inhalation and ingestion of licensed or registered materials;

(3) decontamination of the work place and environment;

(4) decontamination of equipment before release from the site; and

(5) decontamination of individuals before leaving the site.

Subp. 3. **Special emergency procedures for unsealed sources** must include written instructions when contamination reaches emergency levels for actions:

A. To minimize an individual's exposure including exposures from inhalation and ingestion of licensed or registered materials;

B. For decontamination and resurvey procedures:

(1) for fixed contamination;

(2) for removable contamination using the following action levels:

(a) 100 dpm per 100 square centimeters of any alpha-emitting radioactive materials;

(b) 1,000 dpm per 100 square centimeters of any beta- or gamma-emitting radioactive materials;

(c) 50 dpm per 100 square centimeters of any transuranic;

(d) 2,000 dpm per 100 square centimeters of uranium; or

(e) 2,000 dpm per 100 square centimeters of any radioactive material with a half-life of less than 80 hours.

(3) for fume hood or ventilation systems;

(4) for localized areas.

4731.1005 Inspection of Sealed and Unsealed Sources. Each licensee or registrant must have a written program including the procedures for the inspection and maintenance of the each source. These procedures of the program must include the following requirements:

A. Before each use of the source:

(1) conduct a visual inspection of the integrity of the container, indication of obvious spillage or gaseous escape and the required labeling;

(2) conduct an operability inspection to check the functioning of the equipment;

(3) remove equipment that is inoperable or damaged from service until repaired, and make and keep a record in accordance with 4731.0168, listing:

(a) date of the inspection that made the discovery;

(b) name of inspector making the discovery;

(c) equipment involved, and what damage was found; and

(d) what repairs were made.

B. Semi-annually during use of the source:

(1) conduct a visual inspection and routine maintenance to ensure that there is no physical or operational damage and the required labeling is legible;

(2) remove equipment that is inoperable or damaged from service until repaired, and make and keep a record in accordance with 4731.0168, listing:

(a) date of the visual inspection that made the discovery;

(b) name of inspector making the discovery;

(c) equipment involved, and what damage was found;

(d) what inspection and maintenance operations were performed; and

(e) any actions taken to correct the damage.

C. Specifications of the manufacturer must be followed.

4731.1006 Opening of a Source or Source Holder. The following requirements must be followed prior to the opening of a source or source holder:

A. The opening, repair, or modification of any sealed or unsealed source must be performed by persons specifically approved to do so by the commissioner, an agreement state or the NRC.

B. Removal of a sealed source from a source holder, 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 has been approved either by the commissioner or by an agreement state.

C. If a sealed source is stuck in the source holder, emergency actions in 4731.1004must be followed. 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 NRC to perform this operation.

4731.1007 Radiation Safety Surveys. In addition to the radiation safety surveys found in 4731.0132, the licensee or registrant must make the following radiation surveys, for each area where licensed or registered materials are used and stored.

Subpart 1. **Requirements of the surveys for both sealed and unsealed sources.**

A. Surveys must be made when:

(1) installing;
(2) maintaining;
(3) servicing;
(4) at the initial use; or
(5) relocating or removing the source.

B. Surveys for the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the licensed or registered materials must be made before transporting licensed or registered materials.

C. The records of the survey results required under this subpart must be kept in accordance with 4731.0168 and must include:

(1) the date of the survey;
(2) the name of the individual conducting the survey;
(3) the identification number or code of the survey;
(4) the instrument used; and
(5) the location of the survey.

Subp. 2. **Special radiation safety surveys for sealed sources** must be conducted when:

A. The assembly is removed from the source holder before departure from a temporary jobsite. The licensee or registrant must confirm by using a survey meter that the source holder is free of contamination.

B. The encapsulation of the sealed source could be damaged as a result of operation. The licensee or registrant must conduct a contamination survey during and after the operation.

Subp. 3. **Special radiation safety surveys for unsealed sources** must be conducted:

A. Before and after use at a temporary jobsite.

B. At the end of each day using radiation instruments for all areas where materials are used or received.

C. At the end of each day using a wipe survey to locate removable contamination for all areas where radioactive materials are used when survey instruments do not detect contamination.

D. Each week with a radiation survey instrument for all areas where radioactive materials or radioactive waste are stored, including fume hoods and ventilation areas.

E. Each week using a wipe survey for removable contamination for all areas where radioactive materials or waste are routinely used or stored.

F. With an instrument capable of measuring dose rates as low as 0.1 millirem (1 μSv) per hour.

G. To monitor individuals for contamination prior to their leaving the restricted area.

Subp. 4. **Requirements of the radiation survey instruments.**

A. A licensee or registrant who is authorized to use:

(1) portable and fixed gauges must use portable radiation survey instruments with appropriate ranges;

(2) unsealed sources must have instruments that are sensitive enough to detect activity levels required for contamination control and to measure radioactive materials listed on the license.

B. The instruments must be operable and calibrated in accordance with 4731.0133.

4731.1008 Visual Inventory and Records of Radioactive Material Use. Each licensee or registrant must conduct a semi-annual visual inventory and account for all licensed or registered material, sealed or unsealed, received and possessed under the license or registration. The licensee or registrant must make and maintain the required records in accordance with 4731.0168 and 4731.0181. The visual inventory and record of use must include the following information:

A. Quantity and kind of licensed or registered material.

B. Make, model number, and a serial number or a description of each sealed source used.

C. Location of the licensed or registered material.

D. Dates of use of the licensed or registered material.

E. Transfer or disposal of any unused sealed and unsealed licensed or registered material.

F. Date of the inventory.

G. Identification of the individual who is responsible for the licensed material.

H. Name of the individual conducting the inventory and use record.

I. Signature of RSO or designee.

4731.1009 Labels and Security During Storage, Transportation and Use. The licensee or registrant must ensure the requirements in this part are met and are in addition to the requirements found in 4731.0122.

Subpart 1. **Label and package** The licensee or registrant:

A May not use or store a source, source holder, or gauge that contains licensed material unless every piece of equipment containing radioactive material bears a durable, legible, and clearly visible marking or label. This marking or label must contain:

(1) radiation symbol as specified in 4731.0122; and

(2) the words " DANGER (or CAUTION) RADIOACTIVE MATERIAL NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

B May not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with requirements in

4731.1500 to 4731.1513.

Subp. 2 **Storage.** The licensee or registrant must store each radioactive material source in a storage container or transportation package, meeting the following requirements:

A. Container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel.

B. Must store licensed material in a manner which will minimize danger from explosion or fire.

Subp. 3. **Transport of the source.** The licensee or registrant must transport the package containing licensed material in a locked and physically secure condition in the transporting vehicle to prevent:

A. Accidental loss.

B. Tampering.

C. Unauthorized removal of the licensed material from the vehicle.

Subp. 4. **Security.** The licensee or registrant must ensure that sources not in storage or being transported are under the constant surveillance and immediate control of the licensee; or are locked to prevent use, tampering, or removal by unauthorized personnel.

4731.1010 Storage and Control of Volatiles and Gases

A. A licensee or registrant must store volatile radioactive materials and radioactive gases in the shipper's radiation shield and container or an equivalent shield and container.

B. A licensee or registrant must store and use radioactive volatiles and gases in a glove box or fume hood that will maintain airborne concentrations within the limits prescribed by 4731.3001, A, Table I, Column 2, and Table II, Column 1.

C. The glove box or fume hood must provide for collection and decay of the volatile or gas.

D. A licensee or registrant must dispose of radioactive materials in accord with 4731.0136. Monitoring must be performed for materials which have been released through venting from a fume hood or ventilation system.