Department of Health

Adopted Permanent Rules Relating to Radiation Control

4731.0100 DEFINITIONS.

[For text of subps 1 to 4, see M.R.]

Subp. 4a. **Accelerator-produced radioactive material.** "Accelerator-produced radioactive material" means any material made radioactive by a particle accelerator.

[For text of subps 5 to 31, see M.R.]

Subp. 32. **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 using special nuclear material;

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 uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition;

C. any discrete source of radium-226 that is produced, extracted, or converted after extraction for commercial, medical, or research activity, or any material that:

(1) has been made radioactive by use of a particle accelerator; and

(2) is produced, extracted, or converted after extraction for commercial, medical, or research activity; and

D. any discrete source of naturally occurring radioactive material, other than source material, that:

(1) the United States Nuclear Regulatory Commission, in consultation with the Administrator of Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(2) is extracted or converted after extraction for use in a commercial, medical, or research activity.

[For text of subps 33 to 43a, see M.R.]

Subp. 43b. **Consortium.** "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

[For text of subps 44 to 51, see M.R.]

Subp. 51a. **Cyclotron.** "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of ten MeV and is commonly used for production of short half-life radionuclides for medical use.

[For text of subps 52 to 60, see M.R.]

Subp. 60a. **Discrete source.** "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

[For text of subps 61 to 139, see M.R.]

Subp. 140. **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 Gy), but less than or equal to 1,200 rads (12 Gy) per hour at the point or surface where the dose is prescribed.

[For text of subps 141 to 147, see M.R.]

Subp. 147a. **Nationally tracked source.** "Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in part 4731.2820. In this context, a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form, and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

[For text of subps 148 to 163, see M.R.]

Subp. 163a. **Particle accelerator.** "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectron volt (MeV). For purposes of this definition, "accelerator" is an equivalent term.

[For text of subps 164 to 171, see M.R.]

Subp. 171a. **Positron emission tomography (PET) radionuclide production facility.** "Positron emission tomography (PET) radionuclide production facility" is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

[For text of subps 172 to 195, see M.R.]

Subp. 196. **Radioactive waste or waste.** "Radioactive waste" or "waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subpart 32, items B, C, and D.

[For text of subps 197 to 242, see M.R.]

Subp. 243. **Total effective dose equivalent or TEDE.** "Total effective dose equivalent" or "TEDE" means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

[For text of subps 244 to 269, see M.R.]

4731.0355 RECIPROCITY.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **Licenses of radioactive material, source and special nuclear material in quantities not sufficient to form a critical mass.**

[For text of items A and B, see M.R.]

C. The out-of-state licensee must not transfer or dispose of radioactive material possessed or used under the general license under this part except by transfer to a person who is specifically licensed by the NRC or an agreement state to receive the material.

[For text of items D to G, see M.R.]

[For text of subp 4, see M.R.]

4731.1030 EXPOSURE NOTIFICATIONS AND REPORTS.

[For text of subp 1, see M.R.]

Subp. 2. **Frequency of report.** Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of part 4731.2540. The licensee shall provide an annual report to each individual monitored under part 4731.2210 of the dose received in that monitoring year if:

A. The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue; or

B. The individual requests their report.

Subp. 3. **Report to former employee; report to commissioner.**

[For text of items A and B, see M.R.]

C. When a licensee is required under part 4731.2610, 4731.2620, or 4731.2630 to report to the commissioner any exposure of an individual to radiation or radioactive material, the licensee must also provide the individual a report on the individual's exposure data included in the report to the commissioner. The report must be transmitted to the individual no later than the transmittal to the commissioner.

[For text of subp 4, see M.R.]

4731.2020 OCCUPATIONAL DOSE LIMITS FOR ADULTS.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **Assessing dose.** When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the commissioner. 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 ten 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 to

demonstrate compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or if the results of individual monitoring are unavailable.

[For text of subps 4 to 6, see M.R.]

4731.2200 SURVEYS AND MONITORING.

[For text of subp 1, see M.R.]

Subp. 2. **Calibration required.** Except as otherwise required in this chapter, a licensee must ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.

[For text of subp 3, see M.R.]

4731.2360 LEAK TEST REQUIREMENTS.

Subpart 1. **Sealed sources.** Except as otherwise required, sealed sources must be tested for leakage at intervals not to exceed the intervals specified in the certificate of registration issued by the NRC or an agreement state.

Subp. 2. **Sealed source received from another person.** In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the NRC or an agreement state, prior to the transfer, a sealed source received from another person must not be put into use until tested and the test results received.

Subp. 3. **Storage of sealed sources.** Sealed sources, except those containing radium, may be stored for a period of no more than three years without being tested for leakage and contamination. When sealed sources are removed from storage for use or for transfer to another person and have not been tested within the required leak test interval, they must be tested and test results received before use or transfer.

Subp. 4. **Test samples.** Test samples must be taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate.

Subp. 5. **Level of detection.** The leak test must be capable of detecting the presence of 0.005 microcurie (185 becquerel) of radioactive material on the test sample.

If the test reveals the presence of 0.005 microcurie (185 becquerel) or more of removable contamination, a report must be filed with the Department of Health according to part 4731.3110 and the source must be removed immediately from service and decontaminated, repaired, or disposed of according to Department of Health regulations.

Subp. 6. **Tests administered by.** Tests for leakage must be performed by the licensee or by other persons specifically licensed by the NRC or an agreement state to perform these services.

Subp. 7. **Retention of leak test records.** A licensee shall retain leak test records for three years. The records must contain the model number and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerel), the date of the test, and the name or initials of the individual who performed the test.

Subp. 8. **Sources exempt from testing.** A licensee need not perform a leak test on the following sources:

A. sources containing only radioactive material with a half-life of less than 30 days;

B. sources containing only radioactive material as a gas;

C. sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or ten microcuries (0.37 MBq) or less of alpha-emitting material; and

D. seeds of iridium-192 encased in nylon ribbon.

4731.2400 WASTE DISPOSAL.

Subpart 1. **General requirements.** A licensee must dispose of licensed material only:

A. by transfer to an authorized recipient as provided under parts 4731.0525 to 4731.0840, 4731.2450, and 4731.3000 to 4731.3175 or in Code of Federal Regulations, title 10, parts 60, 63, and 72;

B. by decay in storage;

C. by release in effluents within the limits under part 4731.2090; or

D. as authorized under parts 4731.2410 to 4731.2440 or 4731.2460.

[For text of subp 2, see M.R.]

4731.2405 DECAY-IN-STORAGE.

Subpart 1. **Disposal in ordinary trash.** A licensee may hold radioactive material with half-lives of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash if the licensee:

A. monitors radioactive material at the surface before disposal;

B. determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

C. removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they are released from the licensee.

Subp. 2. **Record retention.** The licensee shall retain a record of each disposal for three years. The record must include:

A. the date of the disposal;

B. the date on which the radioactive material was placed in storage;

C. the radionuclide with the longest half-life;

D. the manufacturer's name, model number, and serial number of the survey instrument used, or a unique survey meter identification that can be cross-referenced to a specific manufacturer, model, and serial number;

E. the background radiation level;

F. the radiation level measured at the surface of each waste container; and

G. the name of the individual who performed the disposal.

4731.2450 TRANSFER FOR DISPOSAL; MANIFESTS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. **Shipping byproduct material.** Any licensee shipping byproduct material, as defined in part 4731.0100, subpart 32, items C and D, intended for ultimate disposal at a land disposal facility licensed under Code of Federal Regulations, title 10, part 61, must document the information on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee according to part 4731.2950.

4731.2460 DISPOSAL OF CERTAIN BYPRODUCT MATERIAL.

Subpart 1. **Disposal of licensed material.** Licensed material as defined in part 4731.0100, subpart 32, items C and D, may be disposed of according to Code of Federal Regulations, title 10, part 61, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal under Code of Federal Regulations, title 10, part 61, must meet the requirements of part 4731.2450.

Subp. 2. **Disposal of byproduct material.** A licensee may dispose of byproduct material as defined in part 4731.0100, subpart 32, items C and D, at a disposal facility authorized to dispose of such material according to federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

4731.2510 RECORDS; SURVEYS.

Subpart 1. **Record maintenance; three years.** A licensee must maintain records showing the results of surveys and calibrations required under parts 4731.2200 and 4731.2350, subpart 2, for three years after the record is made. The record must include:

A. the date of the measurements;

B. the manufacturer's name, model number, and serial number for the instrument used to measure radiation levels;

C. the radiation level; and

D. the name or initials of the individual who performed the surveys or calibrations.

[For text of subp 2, see M.R.]

4731.2520 DETERMINATION OF PRIOR OCCUPATIONAL DOSE.

Subpart 1. **Determining occupational dose.** For each individual who is likely to receive in a year an occupational dose requiring monitoring under part 4731.2210, a licensee must determine the occupational radiation dose received during the current year.

[For text of subp 2, see M.R.]

Subp. 3. **Compliance methods.** In complying with the requirements of subparts 1 and 2, a licensee may:

[For text of items A to C, see M.R.]

Subp. 4. **Record keeping.**

A. A licensee must record the exposure history of each individual, as required by subpart 1 or 2, on a cumulative occupational exposure record form prescribed by the commissioner, or other clear and legible record including all of the information required by the commissioner's form. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee must use the dose shown in the report in preparing the exposure record. For any period in which the licensee does not obtain a report, the licensee must place a notation on the record indicating the periods and time for which data are not available.

[For text of items B to E, see M.R.]

[For text of subps 5 and 6, see M.R.]

4731.2640 REPORTS TO INDIVIDUALS; DOSE LIMITS EXCEEDED.

When a licensee is required, under part 4731.2620 or 4731.2630 to report to the commissioner any exposure of an identified occupationally exposed individual or an identified member of the public to radiation or radioactive material, the licensee must also provide the individual a report on the individual's exposure data included in the report to the commissioner. The report must be transmitted at a time no later than the transmittal to the commissioner.

4731.2705 NATIONAL SOURCE TRACKING TRANSACTION REPORTING.

Subpart 1. **Report required.** Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source must complete and submit a National Source Tracking Transaction Report as specified in subparts 2 to 6 for each type of transaction.

Subp. 2. **Manufacturing report requirements.** Each licensee who manufactures a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

A. the name, address, and license number of the reporting licensee;

B. the name of the individual preparing the report;

C. the manufacturer, model, and serial number of the source;

D. the radioactive material in the source;

E. the initial source strength in becquerels or curies at the time of manufacture; and

F. the manufacture date of the source.

Subp. 3. **Transfer report requirements.** Each licensee that transfers a nationally tracked source to another person must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

A. the name, address, and license number of the reporting licensee;

B. the name of the individual preparing the report;

C. the name and license number of the recipient facility and the shipping address;

D. the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

E. the radioactive material in the source;

F. the initial or current source strength in becquerels or curies;

G. the date for which the source strength is reported;

H. the shipping date;

I. the estimated arrival date; and

J. for nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

Subp. 4. **Material received report requirements.** Each licensee that receives a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

A. the name, address, and license number of the reporting licensee;

B. the name of the individual preparing the report;

C. the name, address, and license number of the person that provided the source;

D. the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

E. the radioactive material in the source;

F. the initial or current source strength in becquerels or curies;

G. the date for which the source strength is reported;

H. the date of receipt; and

I. for material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

Subp. 5. **Disassemble report requirements.** Each licensee that disassembles a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

A. the name, address, and license number of the reporting licensee;

B. the name of the individual preparing the report;

C. the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

D. the radioactive material in the source;

E. the initial or current source strength in becquerels or curies;

F. the date for which the source strength is reported; and

G. the disassemble date of the source.

Subp. 6. **Disposal report requirements.** Each licensee who disposes of a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

A. the name, address, and license number of the reporting licensee;

B. the name of the individual preparing the report;

C. the waste manifest number;

D. the container identification with the nationally tracked source;

E. the date of disposal; and

F. the method of disposal.

Subp. 7. **Report submission.** The reports discussed in subparts 2 to 6 must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by:

A. using the online National Source Tracking System;

B. electronically using a computer-readable format;

C. facsimile;

D. mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

E. telephone with follow-up by facsimile or mail.

Subp. 8. **Report corrections.** Each licensee must correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Errors may be detected by a variety of methods including administrative reviews or by physical inventories required by regulation. In addition, each licensee must reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subparts 2 to 6. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

Subp. 9. **Initial inventory.** Each licensee that possesses Category 1 or Category 2 nationally tracked sources must report its initial inventory of Category 1 and Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by subpart 7, items A to D. The initial inventory report must include the following information:

A. the name, address, and license number of the reporting licensee;

B. the name of the individual preparing the report;

C. the manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

D. the radioactive material in the sealed source;

E. the initial or current source strength in becquerels or curies; and

F. the date for which the source strength is reported.

4731.2750 ANNUAL LIMITS ON INTAKE AND DERIVED AIR CONCENTRATIONS.

[For text of subps 1 to 5, see M.R.]

Subp. 6. **List of elements.**

Name	Symbol	Atomic Number (AN)
Actinium	Ac	89
Aluminum	Al	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18
Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27

Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99
Erbium	Er	68
Europium	Eu	63
Fermium	Fm	100
Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafnium	Hf	72
Holmium	Ho	67
Hydrogen	H	1
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25

18.2	Mendelevium	Md	101
18.3	Mercury	Hg	80
18.4	Molybdenum	Mo	42
18.5	Neodymium	Nd	60
18.6	Neptunium	Np	93
18.7	Nickel	Ni	28
18.8	Niobium	Nb	41
18.9	Nitrogen	N	7
18.10	Osmium	Os	76
18.11	Oxygen	O	8
18.12	Palladium	Pd	46
18.13	Phosphorus	P	15
18.14	Platinum	Pt	78
18.15	Plutonium	Pu	94
18.16	Polonium	Po	84
18.17	Potassium	K	19
18.18	Praseodymium	Pr	59
18.19	Promethium	Pm	61
18.20	Protactinium	Pa	91
18.21	Radium	Ra	88
18.22	Radon	Rn	86
18.23	Rhenium	Re	75
18.24	Rhodium	Rh	45
18.25	Rubidium	Rb	37
18.26	Ruthenium	Ru	44
18.27	Samarium	Sm	62
18.28	Scandium	Sc	21
19.1	Selenium	Se	34

Silicon	Si	14
Silver	Ag	47
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantalum	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thallium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54
Ytterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30
Zirconium	Zr	40

Subp. 7. **Table of ALIs and DACs.**

	Table 1			Table 2		Table 3
Atomic Number (AN), Radionuclide, and Class	1	2	3	1	2	
AN 1						

Hydrogen-3						
Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
Gas (HT or T_2) submersion[1]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
AN 4						
Beryllium-7						
W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
Y, oxides, halides, and nitrates	—	2E+4	8E-6	3E-8	—	—
Beryllium-10						
W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	—	—
	LLI (1E+3)	—	—	2E-5	2E-4	—
Y, see ^{7}Be	—	1E+1	6E-9	2E-11	—	—
AN 6						
Carbon-11[2]						
Monoxide	—	1E+6	5E-4	2E-6	—	—
Dioxide	—	6E+5	3E-4	9E-7	—	—
Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
Carbon-14						
Monoxide	—	2E+6	7E-4	2E-6	—	—
Dioxide	—	2E+5	9E-5	3E-7	—	—
Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4

AN 7						
Nitrogen-13[2]						
Submersion[1]	—	—	4E-6	2E-8	—	—
AN 8						
Oxygen-15[2]						
Submersion[1]	—	—	4E-6	2E-8	—	—

[The remainder of the table is unchanged.]

FOOTNOTES:

[1] "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2] These radionuclides have radiological half-lives of less than two hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do not include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but must use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits according to part 4731.2040.

[3] For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor according to part 4731.2020, subpart 5. If the percent by weight (enrichment) of U-235 is not greater than five, the concentration value for a 40-hour work week is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour work week must not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, is:

SA = 3.6E-7 curies/gram U U-depleted

$SA = [0.4 + 0.38\ (\text{enrichment}) + 0.0034\ (\text{enrichment})^2]\ E\text{-}6$, enrichment > 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

[For text of subp 8, see M.R.]

4731.2820 NATIONALLY TRACKED SOURCE THRESHOLDS.

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

	Category 1		Category 2	
Radioactive material	(TBq)	(Ci)	(TBq)	(Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

4731.3025 EXEMPTION; CERTAIN CONCENTRATIONS.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **Introduction by specific licensee.** A manufacturer, processor, or producer of a product or material in an agreement state is exempt from parts 4731.3000 to 4731.7280 to the extent that:

A. the manufacturer, processor, or producer transfers radioactive material contained in a product or material in concentrations not in excess of those specified in part 4731.3140; and

B. the radioactive material is introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. The exemption in this subpart does not apply to the transfer of radioactive material in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

Subp. 4. **Transfer limitations.** No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this part or equivalent regulations of the NRC or an agreement state, except according to a specific license issued under Code of Federal Regulations, title 10, section 32.11.

4731.3030 EXEMPTION; CERTAIN ITEMS CONTAINING RADIOACTIVE MATERIAL.

Subpart 1. **Exempt products.** Except for persons who apply radioactive material to or incorporate radioactive material into the following products or persons who initially transfer for sale or distribution the following products containing radioactive material, a person is exempt from parts 4731.3000 to 4731.7280 to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

A. timepieces or hands or dials of timepieces that:

(1) contain not more than the following specified quantities of radioactive material:

(a) 25 millicuries of tritium per timepiece;

(b) five millicuries of tritium per hand;

(c) 15 millicuries of tritium per dial (bezels, when used, are considered part of the dial);

(d) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;

(e) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;

(f) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per any other timepiece dial (bezels, when used, are considered as part of the dial);

(g) one microcurie (0.037 MBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007; and

[For text of subitem (2), see M.R.]

B. balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007;

C. marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007;

D. ionization chamber smoke detectors containing not more than one microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires;

E. electron tubes. For purposes of this item, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents. The exemption under this item applies only if the levels of radiation from each electron tube containing radioactive material do not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber and if each tube does not contain more than one of the following specified quantities of radioactive materials:

(1) 150 millicuries of tritium per microwave receiver protector tube or ten millicuries of tritium per any other electron tube;

(2) one microcurie of cobalt-60;

(3) five microcuries of nickel-63;

(4) 30 microcuries of krypton-85;

(5) five microcuries of cesium-137; or

(6) 30 microcuries of promethium-147; or

F. ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material. For purposes of this item, an instrument's source may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in part 4731.3145, provided that the sum of the fractions does not exceed unity. For purposes of this item, 0.05 microcurie of

americium-241 is an exempt quantity under part 4731.3145. The exemption under this item applies only if:

(1) each source contains no more than one exempt quantity under part 4731.3145; and

(2) each instrument contains no more than ten exempt quantities.

[For text of subp 2, see M.R.]

4731.3040 EXEMPT QUANTITIES.

Subpart 1. **Exempt quantities.** Except as provided in subparts 3 to 5, a person is exempt from parts 4731.3000 to 4731.7280 to the extent that the person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity in part 4731.3145.

Subp. 2. **Receipt under prior license.** A person who possesses radioactive material received or acquired before September 25, 1971, under the general license then provided under Code of Federal Regulations, title 10, section 31.4, or similar general license of a state, is exempt from parts 4731.3000 to 4731.4360, and 4731.6000 to 4731.7280 to the extent that the person possesses, uses, transfers, or owns such radioactive material.

[For text of subps 3 and 4, see M.R.]

Subp. 5. **Aggregation.** No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in part 4731.3145, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by this part.

4731.3050 EXEMPTION; GAS AND AEROSOL DETECTORS CONTAINING RADIOACTIVE MATERIAL.

Subpart 1. **Specific license exemption.** Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, a person is exempt from parts 4731.1000 to 4731.2090 and 4731.3000 to 4731.7280 to the extent that the person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas or aerosol detectors designed to protect life or property from fires and airborne hazards and manufactured, processed, produced, or initially transferred according to a specific license issued under Code of Federal Regulations, title 10, section 32.26, that authorizes the initial transfer of the product for use under this part. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a state under comparable provisions to Code of Federal Regulations, title 10, section 32.26, authorizing distribution to persons exempt from regulatory requirements.

[For text of subp 2, see M.R.]

4731.3065 SPECIFIC LICENSES; APPLICATION.

[For text of subp 1, see M.R.]

Subp. 2. **Sealed source requirements.** An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must:

A. identify the source or device by manufacturer and model number as registered with the NRC under Code of Federal Regulations, title 10, section 32.210, with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to Code of Federal Regulations, title 10, section 32.210; or

B. contain the information identified in Code of Federal Regulations, title 10, section 32.210 (c); or

C. for sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007, that are not registered with the NRC under Code of Federal Regulations, title 10, section 32.210, or with an agreement state, and for which the applicant is unable to provide all categories of information specified in Code of Federal Regulations, title 10, section 32.210 (c), the applicant must provide:

(1) all available information identified in Code of Federal Regulations, title 10, section 32.210 (c) and this chapter concerning the source, and, if applicable, the device; and

(2) sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. This information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

[For text of subps 3 to 6, see M.R.]

Subp. 7. **Application to produce PET radioactive drugs.** An application from a medical facility, educational institution, or federal facility to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under NRC, or equivalent agreement state requirements must include:

A. a request for authorization for the production of PET radionuclides or evidence of an existing license issued by the NRC, or an agreement state with requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

B. evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in part 4731.3395, subpart 1;

C. identification of individuals authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in part 4731.3395, subpart 2; and

D. information identified in part 4731.3395, subpart 1, on the PET drugs to be noncommercially transferred to members of its consortium.

4731.3075 TERMS AND CONDITIONS OF LICENSES.

[For text of subps 1 to 6, see M.R.]

Subp. 7. **Molybdenum-99 requirement.** A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99 or technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, according to part 4731.4435. The licensee must record the results of each test and retain each record for three years after the record is made.

[For text of subp 8, see M.R.]

Subp. 9. **Authorization to produce PET.** Authorization under part 4731.3065, subpart 7, to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA requirements or other federal and state requirements governing radioactive drugs.

A. Each licensee authorized under part 4731.3065, subpart 7, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must:

(1) satisfy the labeling requirements in part 4731.3395, subpart 1, for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(2) possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in part 4731.3395, subpart 3.

B. A licensee that is a pharmacy authorized under part 4731.3065, subpart 7, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must require that any individual that prepares PET radioactive drugs must be:

(1) an authorized nuclear pharmacist that meets the requirements in part 4731.3395, subpart 2; or

(2) an individual under the supervision of an authorized nuclear pharmacist specified in part 4731.4407.

C. A pharmacy, authorized under part 4731.3065, subpart 7, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, must meet the requirements of part 4731.3395, subpart 2.

4731.3145 EXEMPT QUANTITIES.

Radioactive Material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10

Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 11 (C 11)	1,000
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10

Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H 3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100

Indium 115 (In 115)	10
Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100

Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Nitrogen 13 (N 13)	1,000
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Oxygen 15 (O 15)	1,000
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Radium 226 (Ra 226)	1
Rhenium 186 (Re 186)	100

Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulfur 35 (S 35)	100
Tantalum 182 (Ta 182)	10

Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100

Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive materials	0.1

4731.3150 RADIOACTIVE MATERIALS; EMERGENCY PLAN QUANTITIES.

This part specifies quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Radioactive material[1]	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000

Bismuth-207		0.01	5,000
Bismuth-210		0.01	600
Cadmium-109		0.01	1,000
Cadmium-113		0.01	80
Calcium-45		0.01	20,000
Californium-252		0.001	9 (20 mg)
Carbon-14 (noncarbon dioxide)		0.01	50,000
Cerium-141		0.01	10,000
Cerium-144		0.01	300
Cesium-134		0.01	2,000
Cesium-137		0.01	3,000
Chlorine-36		0.5	100
Chromium-51		0.01	300,000
Cobalt-60		0.001	5,000
Copper-64		0.01	200,000
Curium-242		0.001	60
Curium-243		0.001	3
Curium-244		0.001	4
Curium-245		0.001	2
Europium-152		0.01	500
Europium-154		0.01	400
Europium-155		0.01	3,000
Germanium-68		0.01	2,000
Gadolinium-153		0.01	5,000
Gold-198		0.01	30,000
Hafnium-172		0.01	400
Hafnium-181		0.01	7,000
Holmium-166m		0.01	100

Hydrogen-3		0.5	20,000
Iodine-125		0.5	1
Iodine-131		0.5	10
Indium-114m		0.01	1,000
Iridium-192		0.001	40,000
Iron-55		0.01	40,000
Iron-59		0.01	7,000
Krypton-85		1.0	6,000,000
Lead-210		0.01	8
Manganese-56		0.01	60,000
Mercury-203		0.01	10,000
Molybdenum-99		0.01	30,000
Neptunium-237		0.001	2
Nickel-63		0.01	20,000
Niobium-94		0.01	300
Phosphorus-32		0.5	100
Phosphorus-33		0.5	1,000
Polonium-210		0.01	10
Potassium-42		0.01	9,000
Promethium-145		0.01	4,000
Promethium-147		0.01	4,000
Radium-226		0.001	100
Ruthenium-106		0.01	200
Samarium-151		0.01	4,000
Scandium-46		0.01	3,000
Selenium-75		0.01	10,000
Silver-110m		0.01	1,000

Sodium-22		0.01	9,000
Sodium-24		0.01	10,000
Strontium-89		0.01	3,000
Strontium-90		0.01	90
Sulfur-35		0.5	900
Technetium-99		0.01	10,000
Technetium-99m		0.01	400,000
Tellurium-127m		0.01	5,000
Tellurium-129m		0.01	5,000
Terbium-160		0.01	4,000
Thulium-170		0.01	4,000
Tin-113		0.01	10,000
Tin-123		0.01	3,000
Tin-126		0.01	1,000
Titanium-44		0.01	100
Vanadium-48		0.01	7,000
Xenon-133		1.0	900,000
Yttrium-91		0.01	2,000
Zinc-65		0.01	5,000
Zirconium-93		0.01	400
Zirconium-95		0.01	5,000
Any other beta-gamma emitter		0.01	10,000
Mixed fission products		0.01	1,000
Mixed corrosion products		0.01	10,000
Contaminated equipment, beta-gamma		0.001	10,000

Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material, solid noncombustible	0.001	10,000
Mixed radioactive waste, beta-gamma	0.01	1,000
Packaged mixed waste, beta-gamma[2]	0.001	10,000
Any other alpha emitter	0.001	2
Contaminated equipment, alpha	0.0001	20
Packaged waste, alpha[2]	0.0001	20
Combinations of radioactive materials listed above[1]		

[1]For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in this part exceeds one.

[2]Waste packaged in Type B containers does not require an emergency plan.

4731.3215 GENERAL LICENSE; DETECTING, MEASURING, GAUGING, CONTROLLING, AND OTHER DEVICES.

[For text of subp 1, see M.R.]

Subp. 2. **Applicability.**

A. The general license under subpart 1 applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled according to:

(1) a specific license issued under part 4731.3330;

(2) an equivalent specific license issued by the NRC or an agreement state; or

(3) an equivalent specific license issued by a state with provisions comparable to part 4731.3330.

B. The devices must have been received from one of the specific licensees described in item A or through a transfer made under subpart 3, item M.

Subp. 3. **Requirements.** A person who acquires, receives, possesses, uses, or transfers radioactive material in a device according to the general license issued under subpart 1 must:

[For text of items A to K, see M.R.]

L. obtain written approval from the commissioner before transferring the device to another specific licensee not specifically identified in item J; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(1) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(2) removes, alters, covers, or clearly and unambiguously augments the existing label, otherwise required by subpart 3, item A, so that the device is labeled in compliance with part 4731.2330; however, the manufacturer, model number, and serial number must be retained;

(3) obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license, such as leak testing procedures; and

(4) reports the transfer under item K;

[For text of items M to R, see M.R.]

Subp. 3a. **Registration of generally licensed devices.**

A. A person to whom subpart 3 applies shall register generally licensed devices according to items B and C. These devices contain:

(1) at least ten millicuries (370 MBq) of cesium-137;

(2) at least 0.1 millicurie (3.7 MBq) of strontium-90;

(3) at least one millicurie (37 MBq) of cobalt-60;

(4) at least 0.1 millicurie (3.7 MBq) of radium-226; or

(5) at least one millicurie (37 MBq) of americium-241 or any other transuranic (any other element with an atomic number greater than uranium-92) based on the activity indicated on the label.

[For text of items B and C, see M.R.]

[For text of subp 4, see M.R.]

4731.3230 GENERAL LICENSE; AMERICIUM-241 AND RADIUM-226 CALIBRATION OR REFERENCE SOURCES.

Subpart 1. **License issued; americium-241.** A general license is issued to persons listed in this part to own, receive, acquire, possess, use, and transfer, according to the provisions of subparts 4 and 5, americium-241 or radium-226 in the form of calibration or reference sources:

A. a person who holds a specific license issued by the commissioner that authorizes the person to receive, possess, use, and transfer radioactive material; and

B. a government agency that holds a specific license issued by the NRC that authorizes the person to receive, possess, use, and transfer radioactive material.

Subp. 2. [See repealer.]

Subp. 3. [See repealer.]

Subp. 4. **Calibration or reference source requirements.** The general licenses in subpart 1 apply only to calibration or reference sources that have been manufactured or initially transferred according to a specific license issued to the manufacturer under part 4731.3365 or by the NRC or an agreement state that authorizes manufacture of the sources for distribution to persons generally licensed by an agreement state.

Subp. 5. **Additional requirements.**

A. The general licenses issued under this part are subject to parts 4731.0260; 4731.1000 to 4731.2950; 4731.3025, subpart 4; 4731.3075, subparts 1, 2, 3, 5, and 6; and 4731.3110 to 4731.3135 and Code of Federal Regulations, title 10, part 21.

B. Persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources under the general licenses:

(1) must not possess at any one time, at any one location of storage or use, more than five microcuries (0.185 kilobecquerels) of americium-241 or radium-226 in the sources;

(2) must not receive, possess, use, or transfer the source unless the source or storage container bears a label that includes the following statement or a substantially similar statement that contains the information called for:

"The receipt, possession, use, and transfer of this source, Model....., Serial No. ....., are subject to a general license and the regulations of the Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS AMERICIUM-241 [or RADIUM-226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)";

(3) must not transfer, abandon, or dispose of the source except by transfer to a person authorized by a license from the commissioner, the NRC, or an agreement state to receive the source;

(4) must store the source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 or radium-226 that might otherwise escape during storage; and

(5) must not use the source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

C. Sources generally licensed under this part before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975. Sources containing radium-226 generally licensed under this part and manufactured before November 30, 2007, must be labeled according to the applicable state regulations at the time of manufacture or import.

Subp. 6. **Limitation.** The general licenses under this part do not authorize the manufacture, export, or import of calibration or reference sources containing americium-241 or radium-226.

4731.3245 GENERAL LICENSE; IN VITRO CLINICAL OR LABORATORY TESTING USE.

Subpart 1. **License issued.** A physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital is issued a general license to receive, acquire, possess, transfer, or use, according to this part, 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:

A. iodine-125, in units not exceeding ten microcuries (0.37 MBq) each;

B. iodine-131, in units not exceeding ten microcuries (0.37 MBq) each;

C. carbon-14, in units not exceeding ten microcuries (0.37 MBq) each;

D. hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each;

E. iron-59, in units not exceeding 20 microcuries (0.74 MBq) each;

F. selenium-75, in units not exceeding ten microcuries (0.37 MBq) each;

G. mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (0.185 kBq) of americium-241 each; and

H. cobalt-57, in units not exceeding ten microcuries (0.37 MBq) each.

[For text of subps 2 to 6, see M.R.]

4731.3250 GENERAL LICENSE; CERTAIN ITEMS AND SELF-LUMINOUS PRODUCTS CONTAINING RADIUM-226.

Subpart 1. **General license.** A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, according to the provisions of subparts 2 to 4, radium-226 contained in the following products manufactured prior to November 30, 2007.

A. Antiquities originally intended for use by the general public. For the purposes of this item, "antiquities" means products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

B. Intact timepieces containing greater than one microcurie (0.037 MBq), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

C. Luminous items installed in air, marine, or land vehicles.

D. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

E. Small radium sources containing no more than one microcurie (0.037 MBq) of radium-226. For the purposes of this item, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations, such as cloud chambers and spinthariscopes, electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

Subp. 2. **Exempt provisions.** Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in subpart 1, item A, are exempt from the provisions of parts 4731.1000 to 4731.2950, 4731.3110 and 4731.3115, and Code of Federal Regulations, title 10, part 21, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, that this exemption is not deemed to apply to any person specifically licensed under this chapter.

Subp. 3. **General requirements.** Any person who acquires, receives, possesses, uses, or transfers byproduct material according to the general license in subpart 1:

A. must notify the commissioner if there is any indication that damage to the product may result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished within 30 days to the Radioactive Materials Unit, Minnesota Department of Health, 625 Robert Street N., P.O. Box 64975, St. Paul, MN 55164-0975;

B. must not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to part 4731.2460 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the NRC;

C. must not export products containing radium-226 except according to Code of Federal Regulations, title 10, part 110;

D. must dispose of products containing radium-226:

(1) at a disposal facility authorized to dispose of radioactive material according to any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005;

(2) by transfer to a person authorized to receive radium-226 under a specific license issued by the NRC or an agreement state; or

(3) as otherwise approved by the commissioner; and

E. must respond to written requests from the commissioner to provide information relating to the general license within 30 calendar 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 licensee must, within that same time period, request a longer period to supply the information by providing the commissioner a written justification for the request.

Subp. 4. **Limitation.** The general license in subpart 1 does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

4731.3315 PROHIBITION OF INTRODUCTION.

No person may introduce radioactive material in a product or material knowing or having reason to believe that it will be transferred to a person that is exempt under part 4731.3025 or equivalent regulations of the NRC or an agreement state, except according to a specific license issued under Code of Federal Regulations, title 10, section 32.11.

4731.3365 SPECIFIC LICENSE; CALIBRATION OR REFERENCE SOURCES; MANUFACTURE OR INITIAL TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241 or

radium-226 for distribution to persons generally licensed under part 4731.3230 shall be approved if:

A. the applicant satisfies the general requirements of part 4731.3070;

B. the applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(2) details of construction and design;

(3) details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(4) procedures for and results of prototype testing of sources that are designed to contain more than 0.005 microcurie (185 Bq) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226, respectively, contained in each source will not be released or be removed from the source under normal conditions of use;

(5) details of quality control procedures to be followed in manufacture of the source;

(6) a description of labeling to be affixed to the source or the storage container for the source; and

(7) any additional information, including experimental studies and tests, required by the commissioner to facilitate a determination of the safety of the source;

C. each source will contain no more than five microcuries (185 kBq) of americium-241 or radium-226; and

D. the commissioner determines, with respect to any type of source containing more than 0.005 microcurie (185 Bq) of americium-241 or radium-226, that:

(1) the method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) the source has been subjected to and has satisfactorily passed the prototype tests under part 4731.3410.

Subp. 2. **Labeling requirements.** A person licensed under this part must affix to each source or storage container for the source a label that:

A. contains sufficient information relative to safe use and storage of the source; and

B. includes the following statement or a substantially similar statement that contains the information called for:

"The receipt, possession, use, and transfer of this source, Model ..., Serial No. ..., are subject to a general license and the regulations of the Minnesota commissioner of health, the Nuclear Regulatory Commission, or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS AMERICIUM-241 [or RADIUM-226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)"

Sources licensed under Code of Federal Regulations, title 10, before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

Subp. 3. **Leak testing.**

A. A person licensed under this part must perform a dry wipe test upon each source containing more than 0.1 microcurie (3.7 kBq) of americium-241 or radium-226 before transferring the source to a general licensee under part 4731.3230.

B. The test must be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure.

C. The radioactivity on the paper must be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie (0.185 kBq) of americium-241 or radium-226.

D. If the test discloses more than 0.005 microcurie (0.185kBq) of radioactive material, the source must be deemed to be leaking or losing americium-241 or radium-226 and must not be transferred to a general licensee under part 4731.3230.

4731.3390 SPECIFIC LICENSE; MATERIAL FOR IN VITRO CLINICAL OR LABORATORY TESTING; MANUFACTURE AND DISTRIBUTION.

An application for a specific license to manufacture or distribute radioactive material for use under the general license under part 4731.3245 shall be approved if:

A. the applicant satisfies the general requirements of part 4731.3070;

B. the radioactive material is prepared for distribution in prepackaged units of:

(1) iodine-125 in units not exceeding ten microcuries (370 kBq) each;

(2) iodine-131 in units not exceeding ten microcuries (370 kBq) each;

(3) carbon-14 in units not exceeding ten microcuries (370 kBq) each;

(4) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;

(5) iron-59 in units not exceeding 20 microcuries (740 kBq) each;

(6) selenium-75 in units not exceeding ten microcuries (370 kBq) each;

(7) mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(8) cobalt-57 in units not exceeding ten microcuries (370 kBq) each;

C. each prepackaged unit bears a durable, clearly visible label that:

(1) identifies the radioactive contents as to chemical form and radionuclide; and

(2) indicates that the amount of radioactivity does not exceed:

(a) ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, or selenium-75;

(b) 50 microcuries (1.85 MBq) of hydrogen-3 (tritium);

(c) 20 microcuries (740 kBq) of iron-59;

(d) mock iodine-125 in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or

(e) cobalt-57 in units not exceeding ten microcuries (370 kBq); and

(3) displays the radiation caution symbol described in part 4731.2300, and the words "Caution, Radioactive Material" and "Not for Internal or External Use in Humans or Animals";

D. the following statement, or a substantially similar statement that contains all the information called for, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

"The 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 Minnesota commissioner of health, the Nuclear Regulatory Commission, or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)"; and

E. the label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing the radioactive material. In the case of a mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements under part 4731.2400.

4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE; MANUFACTURE, PREPARATION, OR TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized according to parts 4731.4400 to 4731.4527 shall be approved if the applicant:

A. satisfies the general requirements specified in part 4731.3070;

B. submits evidence that the applicant is at least one of the following:

(1) registered or licensed with the United States Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under Code of Federal Regulations, title 21, section 207.20(a);

(2) registered or licensed with a state agency as a drug manufacturer;

(3) licensed as a pharmacy by a state board of pharmacy;

(4) operating as a nuclear pharmacy within a federal medical institution; or

(5) a positron emission tomography (PET) drug production facility registered with a state agency;

C. submits the following information regarding the radionuclide:

(1) the chemical and physical form;

(2) the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

(3) the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

D. satisfies the following labeling requirements:

(1) a label must be 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 and include the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specific date and time. For a radioactive drug with a half-life greater than 100 days, the time may be omitted; and

(2) a label must be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

Subp. 2. **Pharmacy licensees.**

[For text of items A and B, see M.R.]

C. A licensee described in subpart 1, item B, subitem (3) or (4), may designate a pharmacist as an authorized nuclear pharmacist if the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

D. No later than 30 days after the date that a licensee described in subpart 1, item B, subitem (3) or (4), allows an individual to work as an authorized nuclear pharmacist under item A, subitem (2), unit (a) or (c), the licensee must provide to the commissioner a copy of:

(1) the individual's certification by a specialty board whose certification process has been recognized as specified in part 4731.4413, subpart 1, with the written attestation signed by a preceptor as required by part 4731.4413, subpart 1; or

(2) the NRC or agreement state license, or the permit issued by an NRC master materials licensee, or the permit issued by a licensee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to issue its own authorized nuclear pharmacist; or

(3) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; and

(4) a copy of the individual's state pharmacy licensure or registration.

[For text of subps 3 and 4, see M.R.]

4731.3400 SPECIFIC LICENSE; SOURCES OR DEVICES FOR MEDICAL USE; MANUFACTURE AND DISTRIBUTION.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed according to parts 4731.4400 to 4731.4527 for use as a calibration, transmission, or reference source or for the uses listed under parts 4731.4404, 4731.4450, 4731.4460, and 4731.4463 shall be approved if:

[For text of items A to C, see M.R.]

[For text of subps 2 and 3, see M.R.]

4731.3410 PROTOTYPE TESTS; CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM-226.

An applicant for a license under part 4731.3365 must, for any type of source that is designed to contain more than 0.005 microcurie (0.185 kBq) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of such source that contains more than 0.005 microcurie (0.185 kBq) of americium-241 or radium-226 as follows:

[For text of items A to F, see M.R.]

4731.3450 SERIALIZATION OF NATIONALLY TRACKED SOURCES.

Each licensee who manufactures a nationally tracked source after February 6, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alphanumeric characters.

4731.3580 LIMITS FOR BROAD SCOPE LICENSES.

The following limits apply to specific licenses of broad scope issued under parts 4731.3500 to 4731.3580:

Radioactive Material	Column I curies	Column II curies

56.25	Antimony-122	1	0.01
57.1	Antimony-124	1	0.01
57.2	Antimony-125	1	0.01
57.3	Arsenic-73	10	0.1
57.4	Arsenic-74	1	0.01
57.5	Arsenic-76	1	0.01
57.6	Arsenic-77	10	0.1
57.7	Barium-131	10	0.1
57.8	Barium-140	1	0.01
57.9	Beryllium-7	10	0.1
57.10	Bismuth-210	0.1	0.001
57.11	Bromine-82	10	0.1
57.12	Cadmium-109	1	0.01
57.13	Cadmium-115m	1	0.01
57.14	Cadmium-115	10	0.1
57.15	Calcium-45	1	0.01
57.16	Calcium-47	10	0.1
57.17	Carbon-14	100	1
57.18	Cerium-141	10	0.1
57.19	Cerium-143	10	0.1
57.20	Cerium-144	0.1	0.001
57.21	Cesium-131	100	1
57.22	Cesium-134m	100	1
57.23	Cesium-134	0.1	0.001
57.24	Cesium-135	1	0.01
57.25	Cesium-136	10	0.1
57.26	Cesium-137	0.1	0.001
57.27	Chlorine-36	1	0.01
57.28	Chlorine-38	100	1

57.29	Chromium-51	100	1
58.1	Cobalt-57	10	0.1
58.2	Cobalt-58m	100	1
58.3	Cobalt-58	1	0.01
58.4	Cobalt-60	0.1	0.001
58.5	Copper-64	10	0.1
58.6	Dysprosium-165	100	1
58.7	Dysprosium-166	10	0.1
58.8	Erbium-169	10	0.1
58.9	Erbium-171	10	0.1
58.10	Europium-152 9.2 h	10	0.1
58.11	Europium-152 13 y	0.1	0.001
58.12	Europium-154	0.1	0.001
58.13	Europium-155	1	0.01
58.14	Fluorine-18	100	1
58.15	Gadolinium-153	1	0.01
58.16	Gadolinium-159	10	0.1
58.17	Gallium-72	10	0.1
58.18	Germanium-71	100	1
58.19	Gold-198	10	0.1
58.20	Gold-199	10	0.1
58.21	Hafnium-181	1	0.01
58.22	Holmium-166	10	0.1
58.23	Hydrogen-3	100	1
58.24	Indium-113m	100	1
58.25	Indium-114m	1	0.01
58.26	Indium-115m	100	1
58.27	Indium-115	1	0.01

Iodine-125		0.1	0.001
Iodine-126		0.1	0.001
Iodine-129		0.1	0.01
Iodine-131		0.1	0.001
Iodine-132		10	0.1
Iodine-133		1	0.01
Iodine-134		10	0.1
Iodine-135		1	0.01
Iridium-192		1	0.01
Iridium-194		10	0.1
Iron-55		10	0.1
Iron-59		1	0.01
Krypton-85		100	1
Krypton-87		10	0.1
Lanthanum-140		1	0.01
Lutetium-177		10	0.1
Manganese-52		1	0.01
Manganese-54		1	0.01
Manganese-56		10	0.1
Mercury-197m		10	0.1
Mercury-197		10	0.1
Mercury-203		1	0.01
Molybdenum-99		10	0.1
Neodymium-147		10	0.1
Neodymium-149		10	0.1
Nickel-59		10	0.1
Nickel-63		1	0.01
Nickel-65		10	0.1

Niobium-93m		1	0.01
Niobium-95		1	0.01
Niobium-97		100	1
Osmium-185		1	0.01
Osmium-191m		100	1
Osmium-191		10	0.1
Osmium-193		10	0.1
Palladium-103		10	0.1
Palladium-109		10	0.1
Phosphorus-32		1	0.01
Platinum-191		10	0.1
Platinum-193m		100	1
Platinum-193		10	0.1
Platinum-197m		100	1
Platinum-197		10	0.1
Polonium-210		0.01	0.0001
Potassium-42		1	0.01
Praseodymium-142		10	0.1
Praseodymium-143		10	0.1
Promethium-147		1	0.01
Promethium-149		10	0.1
Radium-226		0.01	0.0001
Rhenium-186		10	0.1
Rhenium-188		10	0.1
Rhodium-103m		1,000	10
Rhodium-105		10	0.1
Rubidium-86		1	0.01
Rubidium-87		1	0.01
Ruthenium-97		100	1

Ruthenium-103		1	0.01
Ruthenium-105		10	0.1
Ruthenium-106		0.1	0.001
Samarium-151		1	0.01
Samarium-153		10	0.1
Scandium-46		1	0.01
Scandium-47		10	0.1
Scandium-48		1	0.01
Selenium-75		1	0.01
Silicon-31		10	0.1
Silver-105		1	0.01
Silver-110m		0.1	0.001
Silver-111		10	0.1
Sodium-22		0.1	0.001
Sodium-24		1	0.01
Strontium-85m		1,000	10
Strontium-85		1	0.01
Strontium-89		1	0.01
Strontium-90		0.01	0.0001
Strontium-91		10	0.1
Strontium-92		10	0.1
Sulfur-35		10	0.1
Tantalum-182		1	0.01
Technetium-96		10	0.1
Technetium-97m		10	0.1
Technetium-97		10	0.1
Technetium-99m		100	1
Technetium-99		1	0.01
Tellurium-125m		1	0.01

Tellurium-127m		1	0.01
Tellurium-127		10	0.1
Tellurium-129m		1	0.01
Tellurium-129		100	1
Tellurium-131m		10	0.1
Tellurium-132		1	0.01
Terbium-160		1	0.01
Thallium-200		10	0.1
Thallium-201		10	0.1
Thallium-202		10	0.1
Thallium-204		1	0.01
Thulium-170		1	0.01
Thulium-171		1	0.01
Tin-113		1	0.01
Tin-125		1	0.01
Tungsten-181		1	0.01
Tungsten-185		1	0.01
Tungsten-187		10	0.1
Vanadium-48		1	0.01
Xenon-131m		1,000	10
Xenon-133		100	1
Xenon-135		100	1
Ytterbium-175		10	0.1
Yttrium-90		1	0.01
Yttrium-91		1	0.01
Yttrium-92		10	0.1
Yttrium-93		1	0.01
Zinc-65		1	0.01

Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than alpha-emitting byproduct material not listed above	0.1	0.001

4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE MATERIALS.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **License amendments.** A licensee must apply for and receive a license amendment:

A. before the licensee receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but not authorized under the licensee's current license issued under parts 4731.4400 to 4731.4527;

B. before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except that the licensee may permit an individual to work as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist for 60 days before being authorized on a license if the individual is an authorized user, authorized nuclear pharmacist, or authorized medical physicist for the same type of use:

(1) on a license issued by the NRC or an agreement state or on an equivalent permit or license recognized by the commissioner, the NRC, or an agreement state that

authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) on a permit issued by an NRC or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(3) on a permit issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

[For text of items C to G, see M.R.]

Subp. 4. **Notifications of changes.**

A. A licensee must notify the commissioner by letter no later than 30 days after:

(1) an authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist has a name change;

(2) the licensee's mailing address changes;

(3) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described under part 4731.3075, subpart 2;

(4) the licensee has added to or changed the areas of use identified in the application or license where radioactive material is used according to part 4731.4432 or 4731.4434; or

(5) the licensee permits an authorized user or an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer as described under part 4731.4405, subpart 1, item C.

B. A licensee must mail required documents to the address under part 4731.0200, subpart 4.

Subp. 5. **Exemptions; broad scope license.** A licensee possessing a Type A specific license of broad scope for medical use, issued under parts 4731.3500 to 4731.3580, is exempt from:

A. subpart 2, item D, regarding the need to file an amendment to the license for medical use of radioactive materials under part 4731.4404;

B. subpart 3, item B;

C. subpart 3, item E, regarding additions to or changes in the areas of use at the addresses identified in the application or license;

D. subpart 4, item A, subitem (1), for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

E. subpart 4, item A, subitem (4), regarding additions to or changes in the areas of use identified in the application or license where radioactive material is used under part 4731.4432 or 4731.4434; and

F. part 4731.4410, item A.

[For text of subps 6 and 7, see M.R.]

4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN DIRECTIVE.

[For text of item A, see M.R.]

B. At a minimum, the procedures required by item A must address the following that are applicable to the licensee's use of radioactive material:

(1) verifying the identity of the patient or human research subject;

(2) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) checking both manual and computer-generated dose calculations; and

(4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized under part 4731.4404 or 4731.4463.

[For text of item C, see M.R.]

4731.4420 MEASURING ACTIVITY OF UNSEALED RADIOACTIVE MATERIAL; INSTRUMENTS REQUIRED.

A. For direct measurements performed according to part 4731.4422, a licensee must possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to a patient or human research subject.

B. A licensee must check and test the instrumentation required under item A according to nationally recognized standards or the manufacturer's instructions and at the following intervals as applicable:

(1) check each instrument for constancy at the beginning of each day of use;

(2) test each instrument for linearity upon installation and at intervals not to exceed three months thereafter;

(3) test each instrument for accuracy upon installation and at intervals not to exceed 12 months thereafter; and

(4) test each instrument for geometry dependence upon installation.

C. A licensee must also perform the required checks and tests in this part following adjustment or repair of the instrument.

D. The licensee must keep a record of geometry dependence for the duration of the use of the instrument and must retain a record of all other instrument checks and tests for three years. The records must include:

(1) the model and serial number of the instrument;

(2) the date of the check or test;

(3) the results of the check or test; and

(4) the name of the individual performing the check or test.

4731.4422 DETERMINATION OF DOSAGES; UNSEALED RADIOACTIVE MATERIAL.

A. A licensee must determine and record the activity of each dosage before medical use.

B. For a unit dosage, the determination under item A must be made by:

(1) direct measurement of radioactivity; or

(2) a decay correction, based on the activity or activity concentration determined by:

(a) a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state;

(b) an NRC or agreement state licensee for use in research according to the radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the Food and Drug Administration; or

(c) a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state.

C. For other than unit dosages, the determination under item A must be made by:

(1) direct measurement of radioactivity;

(2) a combination of measurement of radioactivity and mathematical calculations;

(3) a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state; or

(4) a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state.

D. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

E. A licensee must retain a record of the dosage determination required under this part according to part 4731.4503.

4731.4429 DECAY-IN-STORAGE.

A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity, if the licensee adheres to the requirements of part 4731.2405.

4731.4432 UNSEALED RADIOACTIVE MATERIAL; UPTAKE, DILUTION, AND EXCRETION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.

Except for quantities that require a written directive under part 4731.4408 or 4731.4409, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

A. obtained from a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state or a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state;

B. excluding production of PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements of part 4731.4436 or parts 4731.4436, subpart 1, item C, subitem (1), unit (b), subunit vii, and 4731.4443; or

(3) an individual under the supervision, according to part 4731.4407, of the authorized nuclear pharmacist in subitem (1) or the physician who is an authorized user in subitem (2);

C. obtained from and prepared for a commissioner, NRC, or agreement state licensee for use in research according to a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the Food and Drug Administration; or

D. prepared by the licensee for use in research according to a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the Food and Drug Administration.

4731.4434 UNSEALED RADIOACTIVE MATERIAL; IMAGING AND LOCALIZATION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.

Except for quantities that require a written directive under part 4731.4408, a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

A. obtained from a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state or a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state;

B. excluding production of PET radionuclides, prepared by:

[For text of subitems (1) to (3), see M.R.]

[For text of items C and D, see M.R.]

4731.4435 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATION.

A. A licensee may not administer to humans a radiopharmaceutical that contains:

(1) more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or

(2) more than 0.02 microcuries of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride); or

(3) more than 0.2 microcuries of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kBq of strontium-85 per MBq of rubidium-82).

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with item A.

C. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical must, before the first patient use of the day, measure the concentration of strontium-82 and strontium-85 radionuclides to demonstrate compliance with item A.

D. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee must retain a record of each measurement according to part 4731.4509.

4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED.

A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

A. obtained from a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state or a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state;

B. excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and meets the requirements under part 4731.4436 or 4731.4443, or an individual under the supervision of either, as specified under part 4731.4407;

C. obtained from and prepared by a commissioner, NRC, or agreement state licensee for use in research according to an investigational new drug protocol accepted by the Food and Drug Administration; or

D. prepared by the licensee for use in research according to an investigational new drug protocol accepted by the Food and Drug Administration.

4731.4509 MOLYBDENUM-99, STRONTIUM-82, and STRONTIUM-85 CONCENTRATION RECORDS.

A licensee must maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required under part 4731.4435, item B, for three years. The record must include:

A. for each measured elution of technetium-99m:

(1) the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium-99m, (or kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m);

(2) the time and date of the measurement; and

(3) the name of the individual who made the measurement; and

B. for each measured elution of rubidium-82:

(1) the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (or kBq of strontium-82 per MBq or rubidium-82), and microcuries of strontium-85 per millicurie of rubidium-82 (or kBq of strontium-85 per MBq or rubidium-82);

(2) the time and date of the measurement; and

(3) the name of the individual who made the measurement.

REPEALER. Minnesota Rules, parts 4731.3035; 4731.3230, subparts 2 and 3; 4731.3305; 4731.3320; and 4731.4508, are repealed.