



*Protecting, maintaining and improving the health of all Minnesotans*

July 23, 2008

James Luehman  
Deputy Director of Division on Material Safety and State Agreements  
US Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike, 3<sup>rd</sup> Floor  
Rockville, Maryland 20852

Dear Mr. Luehman:

Subject: Revised Request for Review of Minnesota Department of Health Rule Changes (RATS IDs Included)

The Minnesota Department of Health is requesting a review of the proposed changes to Minnesota Department of Health *Radiation Rules*, Chapter 4731. These changes accomplish the following:

- Incorporate the rules for the National Source Tracking System [RATS ID 2006-2 & 3]
- Amendments, exemptions from licensing, and distribution of byproduct material: Licensing and Reporting Requirements [RATS ID 2007-2]
- Definition of byproduct material [RATS ID 2007-3]
- Occupational dose records, labeling containers, and total effective dose equivalent [RATS ID 2008-1]
- Some of the Medical use of byproduct material – minor corrections and clarifications parts 32 and 35 [RATS ID 2007-1]
- MDH initiated minor clarifications

If you have any questions concerning the rules changes, please contact Sherrie Flaherty at (651) 201-4522, or me at (651) 201-4530.

Sincerely,

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Attachments: (1) Proposed Rule Changes  
(2) Cross Reference and Compatibility Table

General Information: 651-201-5000 • Toll-free: 888-345-0823 • TTY: 651-201-5797 • [www.health.state.mn.us](http://www.health.state.mn.us)

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**CROSS REFERENCE AND COMPATIBILITY TABLE**

<b>MN Rule Part</b>	<b>Title</b>	<b>10 CFR</b>	<b>Compatibility</b>	<b>RATS ID</b>
4731.0100	Definitions			
Subp. 4a	Accelerator-produced radioactive material	30.4	H&S	2007-3
Subp. 32	By-product material	30.4, 40.4, 150.3	A	2007-3
Subp. 43b	Consortium	30.4	C	2007-3
Subp. 51a	Cyclotron	30.4, 35.2	D	2007-3
Subp. 60a	Discrete Source	20.1003, 30.4, 150.3	H&S	2007-3
Subp. 140	Medium dose-rate remote afterloader	35.2	D	2007-1
Subp. 147a	Nationally tracked source	20.1003, 32.2	B	2006-2 & 3
Subp. 163a	Particle accelerator	20.1003, 30.4	H&S	2007-3
Subp. 171a	Positron Emission Tomography (PET) radionuclide production facility	35.2	H&S	2007-3
Subp. 196	Radioactive waste or waste	61.2	B	2007-3
Subp. 243	Total Effective Dose Equivalent	20.1003	B	2008-1
4731.0355	Reciprocity	150.20	C	2007-2
4731.1030	Exposure Notifications and Reports	19.13	C	2008-1
4731.2020	Occupational Dose Limits for Adults			
Subp. 3	Assessing Dose	20.1201	A	2008-1
4731.2200	Surveys and Monitoring	20.1501	DH&S	MDH
4731.2360	Leak Test Requirements	License Cond.		MDH
4731.2400	Waste Disposal	20.2001	C	2007-3
4731.2405	Decay-in-storage	35.92	H&S	2007-1 & MDH
4731.2450	Transfer for disposal; manifests	20.2006	B	2007-3
4731.2460	Disposal of Certain Byproduct material	20.2008	B	2007-3
4731.2510	Records; surveys	20.2103	D	MDH

4731.2520	Determination of Prior Occupational Dose	20.2104	D	2008-1
4731.2640	Reports to Individuals; Dose Limits Exceeded	20.2205	C	2007-3
4731.2705	Reports of transactions involving nationally tracked sources	20.2207	B	2006-3
4731.2750	Annual limits on intake and derived air concentrations; ALIs & DACs	Appendix B	A	2007-3
4731.2820	Nationally tracked source thresholds	Appendix E	B	2006-2 & 3
4731.3025	Exemption; Certain Concentrations	30.14	B	2007-2
4731.3030	Exemption; certain items containing radioactive material	30.15	B	2007-2 & 3
4731.3035	Exemption; resins containing Scandium-46; sand-consolidation in oil wells	30.16	Removed	2007-2
4731.3040	Exempt quantities	30.18	B	2007-2 & 3
4731.3050	Exemption; gas and aerosol detectors containing radioactive material	30.20	B	2007-3
4731.3065	Specific licenses; application	30.32	C	2007-3
4731.3075	Terms and conditions of licenses	30.34	C	2007-3
4731.3145	Exempt Quantities	30.71	B	2007-3
4731.3150	Radioactive materials; Emergency plan quantities	30.72	DH&S	2007-3
4731.3215	General license; detecting, measuring, gauging, controlling, and other devices	31.5	D	2007-2 & 3
4731.3230	General license; calibration or reference sources	31.8	D	2007-3
4731.3245	General license; in vitro clinical or laboratory testing use	31.11	D	2007-3
4731.3250	General license for certain items and self-luminous products containing radium-226	31.12	C	2007-3
4731.3305	Specific License; Introduction of Radioactive Material in Exempt Concentrations; Transfer of Ownership or Possession	32.11, 32.12	Removed NRC only	2007-2
4731.3315	Prohibition of Introduction	32.13	C	2007-2
4731.3320	Specific License; Resins Containing Scandium-46; Manufacture or Initial Transfer	32.17	Removed NRC only	2007-2
4731.3365	Specific license; calibration or reference sources, manufacture or initial transfer			
Subp. 1	Approval criteria	32.57	B	2007-3
Subp. 2	Labeling	32.58	B	2007-3
Subp. 3	Leak testing	32.59	B	2007-3
4731.3390	Specific license; material for in vitro clinical or laboratory testing; manufacture and distribution	32.71	B	2007-3

4731.3395	Specific license; radioactive drugs for medical use; manufacture, preparation, or transfer	32.72	B	2007-1 & 3
4731.3400	Specific License; Sources or Devices for Medical Use; Manufacture or Distribution	32.74	B	2007-1
4731.3410	Prototype tests; calibration or reference sources containing Americium-241, Plutonium, or Radium-226	32.102	B	2007-3
4731.3450	Serialization of nationally tracked sources	32.201	B	2006-2
4731.3580	Limits for broad scope licenses	33.100	D	2007-3
4731.4403	Specific License; Medical Use of Radioactive Materials			
Subp. 3	License Amendments	35.13	D	MDH
Subp. 4	Notification of Changes	35.14	D	MDH
Subp. 5	Exemptions; broad scope license	35.15	D	MDH
4731.4409	Procedures for Administrations Requiring Written Directive	35.41	D	2007-1
4731.4420	Measuring activity of unsealed radioactive material; instruments required	35.60	DH&S	MDH
4731.4422	Determination of dosages; unsealed radioactive material	35.63	DH&S	2007-3
4731.4429	Decay-in-storage	35.92	DH&S	2007-1 & MDH
4731.4432	Unsealed radioactive material; uptake, dilution, and excretion studies; written directive not required	35.100	H&S	2007-3
4731.4434	Unsealed radioactive material; imaging and localization studies; written directive not required	35.200	H&S	2007-3
4731.4435	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	35.204	DH&S	2007-3
4731.4440	Unsealed radioactive material; written directive required	35.300	DH&S	2007-3
4731.4508	Decay-in-storage records	35.2092	D	MDH
4731.4509	Molybdenum-99, strontium-82, and strontium-85 records	35.2204	D	2007-3

1.1 **Department of Health**1.2 **Proposed Permanent Rules Relating to Radiation Control**1.3 **4731.0100 DEFINITIONS.**1.4 [For text of subps 1 to 4, see M.R.]1.5 Subp. 4a. Accelerator-produced radioactive material. "Accelerator-produced  
1.6 radioactive material" means any material made radioactive by a particle accelerator.1.7 [For text of subps 5 to 31, see M.R.]1.8 Subp. 32. ~~By-product~~ Byproduct material. "~~By-product~~ Byproduct material"  
1.9 means:1.10 A. any radioactive material, except special nuclear material, yielded in, or made  
1.11 radioactive by, exposure to the radiation incident to the process of producing or ~~utilizing~~  
1.12 ~~using~~ special nuclear material; ~~or~~1.13 B. the tailings or wastes produced by the extraction or concentration of uranium  
1.14 or thorium from ore processed primarily for its source material content, including discrete  
1.15 surface wastes resulting from uranium solution extraction processes. Underground ore  
1.16 bodies depleted by ~~such these~~ solution extraction operations ~~are not by-product material.~~  
1.17 ~~do not constitute byproduct material within this definition;~~1.18 C. any discrete source of radium-226 that is produced, extracted, or converted  
1.19 after extraction for commercial, medical, or research activity, or any material that:1.20 (1) has been made radioactive by use of a particle accelerator; and1.21 (2) is produced, extracted, or converted after extraction for commercial,  
1.22 medical, or research activity; and1.23 D. any discrete source of naturally occurring radioactive material, other than  
1.24 source material, that:

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

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

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

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

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

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

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

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

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

3.1 Subp. 140. **Medium dose-rate remote afterloader.** "Medium dose-rate remote  
3.2 afterloader" means a brachytherapy device that remotely delivers a dose rate of greater  
3.3 than 200 rads (2 Gy), but less than or equal to 1,200 rads (12 Gy) per hour at the point  
3.4 or surface where the dose is prescribed.

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

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

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

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

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

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

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

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

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

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

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

#### 4.13 **4731.0355 RECIPROCITY.**

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

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

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

4.18 C. The out-of-state licensee must not transfer or dispose of radioactive material  
4.19 possessed or used under the general license under this part except by transfer to a person  
4.20 who is specifically licensed by the NRC or an agreement state to receive the material ~~or~~  
4.21 ~~who is exempt from the requirements for a license for the material under part 4731.3025.~~

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

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

#### 4.24 **4731.1030 EXPOSURE NOTIFICATIONS AND REPORTS.**

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

5.2 Subp. 2. **Frequency of report.** A licensee must annually advise each worker of  
5.3 the worker's dose as shown in records maintained by the licensee according to part  
5.4 4731.2540. Each licensee shall make dose information available to workers as shown in  
5.5 records maintained by the licensee under the provisions of part 4731.2540. The licensee  
5.6 shall provide an annual report to each individual monitored under part 4731.2210 of the  
5.7 dose received in that monitoring year if:

5.8 A. The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or  
5.9 100 mrem (1 mSv) to any individual organ or tissue; or

5.10 B. The individual requests their report.

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

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

5.13 C. When a licensee is required under part 4731.2610, 4731.2620, or 4731.2630;  
5.14 or 4731.2650 to report to the commissioner any exposure of an individual to radiation  
5.15 or radioactive material, the licensee must also provide the individual a report on ~~the~~  
5.16 ~~individual's exposure data contained therein~~ the individual's exposure data included in  
5.17 the report to the commissioner. The report must be transmitted to the individual no later  
5.18 than the transmittal to the commissioner.

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

5.20 **4731.2020 OCCUPATIONAL DOSE LIMITS FOR ADULTS.**

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

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

6.1 must be for the part of the body receiving the highest exposure. The assigned shallow  
6.2 dose equivalent must be the dose averaged over the contiguous ten square centimeters of  
6.3 skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent, and  
6.4 shallow dose equivalent may be assessed from surveys or other radiation measurements to  
6.5 demonstrate compliance with the occupational dose limits if the individual monitoring  
6.6 device was not in the region of highest potential exposure or if the results of individual  
6.7 monitoring are unavailable.

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

6.9 **4731.2200 SURVEYS AND MONITORING.**

6.10 [For text of subpart 1, see M.R.]

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

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

6.16 **4731.2360 LEAK TEST REQUIREMENTS.**

6.17 Subpart 1. Sealed sources. Sealed sources must be tested for leakage at intervals  
6.18 not to exceed the intervals specified in the certificate of registration issued by the NRC or  
6.19 an agreement state.

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

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

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

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

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

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

7.18 Subp. 7. Retention of leak test records. A licensee shall retain leak test records for  
7.19 three years. The records must contain the model number and serial number, if assigned, of  
7.20 each source tested, the identity of each source radionuclide and its estimated activity, the  
7.21 measured activity of each test sample expressed in microcuries (becquerel), a description  
7.22 of the method used to measure each test sample, the date of the test, and the signature of  
7.23 the radiation safety officer.

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

- 8.1 A. sources containing only radioactive material with a half-life of less than  
8.2 30 days;
- 8.3 B. sources containing only radioactive material as a gas;
- 8.4 C. sources containing 100 microcuries (3.7 MBq) or less of beta or  
8.5 photon-emitting material or ten microcuries (0.37 MBq) or less of alpha-emitting material;  
8.6 and
- 8.7 D. seeds of iridium-192 encased in nylon ribbon.

8.8 **4731.2400 WASTE DISPOSAL.**

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

- 8.10 A. by transfer to an authorized recipient as provided under parts 4731.0525 to  
8.11 4731.0840, 4731.2450, and 4731.3000 to 4731.3175 or in Code of Federal Regulations,  
8.12 title 10, parts 60, 63, and 72;
- 8.13 B. by decay in storage;
- 8.14 C. by release in effluents within the limits under part 4731.2090; or
- 8.15 D. as authorized under parts 4731.2410 to 4731.2440 or 4731.2460.

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

8.17 **4731.2405 DECAY-IN-STORAGE.**

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

- 8.21 A. monitors radioactive material at the surface before disposal;

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

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

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

9.9 A. the date of the disposal;

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

9.11 C. the radionuclides disposed;

9.12 D. the manufacturer's name, model number, and serial number of the survey  
9.13 instrument used;

9.14 E. the background radiation level;

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

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

9.17 **4731.2450 TRANSFER FOR DISPOSAL; MANIFESTS.**

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

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

10.1 **4731.2460 DISPOSAL OF CERTAIN BYPRODUCT MATERIAL.**

10.2 Subpart 1. Disposal of licensed material. Licensed material as defined in part  
10.3 4731.0100, subpart 32, items C and D, may be disposed of according to Code of Federal  
10.4 Regulations, title 10, part 61, even though it is not defined as low-level radioactive waste.  
10.5 Therefore, any licensed byproduct material being disposed of at a facility, or transferred  
10.6 for ultimate disposal under Code of Federal Regulations, title 10, part 61, must meet the  
10.7 requirements of part 4731.2450.

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

10.13 **4731.2510 RECORDS; SURVEYS.**

10.14 Subpart 1. Record maintenance; three years. A licensee must maintain records  
10.15 showing the results of surveys and calibrations required under parts 4731.2200 and  
10.16 4731.2350, subpart 2, for three years after the record is made. The record must include:

- 10.17 A. the date of the measurements;  
10.18 B. the manufacturer's name, model number, and serial number for the instrument  
10.19 used to measure radiation levels;  
10.20 C. the radiation level; and  
10.21 D. the signature of the individual who performed the surveys or calibrations.

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

10.23 **4731.2520 DETERMINATION OF PRIOR OCCUPATIONAL DOSE.**

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

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

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

11.4 Subp. 4. **Record keeping.**

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

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

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

11.17 **4731.2640 REPORTS TO INDIVIDUALS; DOSE LIMITS EXCEEDED.**

11.18 When a licensee is required, under part 4731.2620; or 4731.2630; ~~or 4731.2650~~; to  
11.19 report to the commissioner any exposure of an identified occupationally exposed individual  
11.20 or an identified member of the public to radiation or radioactive material, the licensee must  
11.21 also provide ~~a copy of the report submitted to the commissioner~~ to the individual a report  
11.22 on the individual's exposure data included in the report to the commissioner. The report  
11.23 must be transmitted at a time no later than the transmittal to the commissioner.

11.24 **4731.2705 NATIONAL SOURCE TRACKING TRANSACTION REPORTING.**

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

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

- 12.8 A. the name, address, and license number of the reporting licensee;  
12.9 B. the name of the individual preparing the report;  
12.10 C. the manufacturer, model, and serial number of the source;  
12.11 D. the radioactive material in the source;  
12.12 E. the initial source strength in becquerels or curies at the time of manufacture;  
12.13 and  
12.14 F. the manufacture date of the source.

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

- 12.18 A. the name, address, and license number of the reporting licensee;  
12.19 B. the name of the individual preparing the report;  
12.20 C. the name and license number of the recipient facility and the shipping  
12.21 address;  
12.22 D. the manufacturer, model, and serial number of the source or, if not available,  
12.23 other information to uniquely identify the source;  
12.24 E. the radioactive material in the source;

- 13.1 F. the initial or current source strength in becquerels or curies;  
13.2 G. the date for which the source strength is reported;  
13.3 H. the shipping date;  
13.4 I. the estimated arrival date; and  
13.5 J. for nationally tracked sources transferred as waste under a Uniform  
13.6 Low-Level Radioactive Waste Manifest, the waste manifest number and the container  
13.7 identification of the container with the nationally tracked source.

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

- 13.11 A. the name, address, and license number of the reporting licensee;  
13.12 B. the name of the individual preparing the report;  
13.13 C. the name, address, and license number of the person that provided the source;  
13.14 D. the manufacturer, model, and serial number of the source or, if not available,  
13.15 other information to uniquely identify the source;  
13.16 E. the radioactive material in the source;  
13.17 F. the initial or current source strength in becquerels or curies;  
13.18 G. the date for which the source strength is reported;  
13.19 H. the date of receipt; and  
13.20 I. for material received under a Uniform Low-Level Radioactive Waste  
13.21 Manifest, the waste manifest number and the container identification with the nationally  
13.22 tracked source.

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

- 14.4 A. the name, address, and license number of the reporting licensee;  
14.5 B. the name of the individual preparing the report;  
14.6 C. the manufacturer, model, and serial number of the source or, if not available,  
14.7 other information to uniquely identify the source;  
14.8 D. the radioactive material in the source;  
14.9 E. the initial or current source strength in becquerels or curies;  
14.10 F. the date for which the source strength is reported; and  
14.11 G. the disassemble date of the source.

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

- 14.15 A. the name, address, and license number of the reporting licensee;  
14.16 B. the name of the individual preparing the report;  
14.17 C. the waste manifest number;  
14.18 D. the container identification with the nationally tracked source;  
14.19 E. the date of disposal; and  
14.20 F. the method of disposal.

14.21 Subp. 7. Report submission. The reports discussed in subparts 2 to 6 must be  
14.22 submitted by the close of the next business day after the transaction. A single report may

15.1 be submitted for multiple sources and transactions. The reports must be submitted to  
15.2 the National Source Tracking System by:

15.3 A. using the online National Source Tracking System;

15.4 B. electronically using a computer-readable format;

15.5 C. facsimile;

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

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

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

15.21 Subp. 9. Initial inventory. Each licensee that possesses Category 1 nationally  
15.22 tracked sources must report its initial inventory of Category 1 nationally tracked sources to  
15.23 the National Source Tracking System by the date required by Code of Federal Regulations,  
15.24 title 10, section 20.2207(h). Each licensee that possesses Category 2 nationally tracked  
15.25 sources must report its initial inventory of Category 2 nationally tracked sources to the

16.1 National Source Tracking System by the date required under Code of Federal Regulations,  
 16.2 title 10, section 20.2207(h). The information may be submitted by using any of the  
 16.3 methods identified by subpart 7, items A to D. The initial inventory report must include  
 16.4 the following information:

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

16.6 B. the name of the individual preparing the report;

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

16.9 D. the radioactive material in the sealed source;

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

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

16.12 **4731.2750 ANNUAL LIMITS ON INTAKE AND DERIVED AIR**  
 16.13 **CONCENTRATIONS.**

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

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

16.16	Name	Symbol	Atomic Number (AN)
16.17	Actinium	Ac	89
16.18	Aluminum	Al	13
16.19	Americium	Am	95
16.20	Antimony	Sb	51
16.21	Argon	Ar	18
16.22	Arsenic	As	33
16.23	Astatine	At	85
16.24	Barium	Ba	56
16.25	Berkelium	Bk	97

17.1	Beryllium	Be	4
17.2	Bismuth	Bi	83
17.3	Bromine	Br	35
17.4	Cadmium	Cd	48
17.5	Calcium	Ca	20
17.6	Californium	Cf	98
17.7	Carbon	C	6
17.8	Cerium	Ce	58
17.9	Cesium	Cs	55
17.10	Chlorine	Cl	17
17.11	Chromium	Cr	24
17.12	Cobalt	Co	27
17.13	Copper	Cu	29
17.14	Curium	Cm	96
17.15	Dysprosium	Dy	66
17.16	Einsteinium	Es	99
17.17	Erbium	Er	68
17.18	Europium	Eu	63
17.19	Fermium	Fm	100
17.20	Fluorine	F	9
17.21	Francium	Fr	87
17.22	Gadolinium	Gd	64
17.23	Gallium	Ga	31
17.24	Germanium	Ge	32
17.25	Gold	Au	79
17.26	Hafnium	Hf	72

18.1	Holmium	Ho	67
18.2	Hydrogen	H	1
18.3	Indium	In	49
18.4	Iodine	I	53
18.5	Iridium	Ir	77
18.6	Iron	Fe	26
18.7	Krypton	Kr	36
18.8	Lanthanum	La	57
18.9	Lead	Pb	82
18.10	Lutetium	Lu	71
18.11	Magnesium	Mg	12
18.12	Manganese	Mn	25
18.13	Mendelevium	Md	101
18.14	Mercury	Hg	80
18.15	Molybdenum	Mo	42
18.16	Neodymium	Nd	60
18.17	Neptunium	Np	93
18.18	Nickel	Ni	28
18.19	Niobium	Nb	41
18.20	<u>Nitrogen</u>	<u>N</u>	<u>7</u>
18.21	Osmium	Os	76
18.22	<u>Oxygen</u>	<u>O</u>	<u>8</u>
18.23	Palladium	Pd	46
18.24	Phosphorus	P	15
18.25	Platinum	Pt	78

19.1	Plutonium	Pu	94
19.2	Polonium	Po	84
19.3	Potassium	K	19
19.4	Praseodymium	Pr	59
19.5	Promethium	Pm	61
19.6	Protactinium	Pa	91
19.7	Radium	Ra	88
19.8	Radon	Rn	86
19.9	Rhenium	Re	75
19.10	Rhodium	Rh	45
19.11	Rubidium	Rb	37
19.12	Ruthenium	Ru	44
19.13	Samarium	Sm	62
19.14	Scandium	Sc	21
19.15	Selenium	Se	34
19.16	Silicon	Si	14
19.17	Silver	Ag	47
19.18	Sodium	Na	11
19.19	Strontium	Sr	38
19.20	Sulfur	S	16
19.21	Tantalum	Ta	73
19.22	Technetium	Tc	43
19.23	Tellurium	Te	52
19.24	Terbium	Tb	65
19.25	Thallium	Tl	81
19.26	Thorium	Th	90
19.27	Thulium	Tm	69
19.28	Tin	Sn	50

20.1	Titanium	Ti	22
20.2	Tungsten	W	74
20.3	Uranium	U	92
20.4	Vanadium	V	23
20.5	Xenon	Xe	54
20.6	Ytterbium	Yb	70
20.7	Yttrium	Y	39
20.8	Zinc	Zn	30
20.9	Zirconium	Zr	40

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

20.11		Table 1			Table 2		Table 3
20.12	Atomic Number (AN),						
20.13	Radionuclide, and Class	1	2	3	1	2	
20.14	<b>AN 1</b>						
20.15	Hydrogen-3						
20.16	Water, DAC includes skin						
20.17	absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
20.18	Gas (HT or T <sub>2</sub> )						
20.19	submersion <sup>1</sup> : Use above						
20.20	values as HT and T <sub>2</sub> oxidize						
20.21	in air and in the body to						
20.22	HTO.						
20.23	<b>AN 4</b>						
20.24	Beryllium-7						

21.1	W, all compounds except						
21.2	those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
21.3	Y, oxides, halides, and						
21.4	nitrates	—	2E+4	8E-6	3E-8	—	—
21.5	Beryllium-10						
21.6	W, see <sup>7</sup> Be	1E+3	2E+2	6E-8	2E-10	—	—
21.7		LLI					
21.8		(1E+3)	—	—	2E-5	2E-4	—
21.9	Y, see <sup>7</sup> Be	—	1E+1	6E-9	2E-11	—	—
21.10	<b>AN 6</b>						
21.11	Carbon-11 <sup>2</sup>						
21.12	Monoxide	—	1E+6	5E-4	2E-6	—	—
21.13	Dioxide	—	6E+5	3E-4	9E-7	—	—
21.14	Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
21.15	Carbon-14						
21.16	Monoxide	—	2E+6	7E-4	2E-6	—	—
21.17	Dioxide	—	2E+5	9E-5	3E-7	—	—
21.18	Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
21.19	<b><u>AN 7</u></b>						
21.20	<b><u>Nitrogen-13<sup>2</sup></u></b>						
21.21	<b><u>Submersion<sup>1</sup></u></b>	==	==	<u>4E-6</u>	<u>2E-8</u>	==	==
21.22	<b><u>AN 8</u></b>						
21.23	<b><u>Oxygen-15<sup>2</sup></u></b>						
21.24	<b><u>Submersion<sup>1</sup></u></b>	==	==	<u>4E-6</u>	<u>2E-8</u>	==	==

[The remainder of the table is unchanged.]

## 22.1 FOOTNOTES:

22.2 <sup>1</sup> "Submersion" means that values given are for submersion in a hemispherical  
22.3 semi-infinite cloud of airborne material.

22.4 <sup>2</sup> These radionuclides have radiological half-lives of less than two hours. The total  
22.5 effective dose equivalent received during operations with these radionuclides might  
22.6 include a significant contribution from external exposure. The DAC values for all  
22.7 radionuclides, other than those designated Class "Submersion," are based upon the  
22.8 committed effective dose equivalent due to the intake of the radionuclide into the  
22.9 body and do not include potentially significant contributions to dose equivalent from  
22.10 external exposures. The licensee may substitute  $1E-7$   $\mu\text{Ci/ml}$  for the listed DAC to  
22.11 account for the submersion dose prospectively, but must use individual monitoring  
22.12 devices or other radiation measuring instruments that measure external exposure to  
22.13 demonstrate compliance with the limits according to part 4731.2040.

22.14 <sup>3</sup> For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may  
22.15 be the limiting factor according to part 4731.2020, subpart 5. If the percent by  
22.16 weight (enrichment) of U-235 is not greater than five, the concentration value for a  
22.17 40-hour work week is 0.2 milligrams uranium per cubic meter of air average. For any  
22.18 enrichment, the product of the average concentration and time of exposure during a  
22.19 40-hour work week must not exceed  $8E-3$  (SA)  $\mu\text{Ci-hr/ml}$ , where SA is the specific  
22.20 activity of the uranium inhaled. The specific activity for natural uranium is  $6.77E-7$   
22.21 curies per gram U. The specific activity for other mixtures of U-238, U-235, and  
22.22 U-234, if not known, is:

22.23 
$$\text{SA} = 3.6E-7 \text{ curies/gram U U-depleted}$$

22.24 
$$\text{SA} = [0.4 + 0.38 (\text{enrichment}) + 0.0034 (\text{enrichment})^2] E-6, \text{ enrichment} > 0.72$$
  
22.25 where enrichment is the percentage by weight of U-235, expressed as percent.

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

22.27 **4731.2820 NATIONALLY TRACKED SOURCE THRESHOLDS.**

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

22.31 Category 1

Category 2

	<u>(TBq)</u>	<u>(Ci)</u>	<u>(TBq)</u>	<u>(Ci)</u>
23.1	<u>Radioactive material</u>			
23.2	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
23.3	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>
23.4	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>
23.5	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
23.6	<u>30</u>	<u>810</u>	<u>0.3</u>	<u>8.1</u>
23.7	<u>50</u>	<u>1,400</u>	<u>0.5</u>	<u>14</u>
23.8	<u>100</u>	<u>2,700</u>	<u>1</u>	<u>27</u>
23.9	<u>1,000</u>	<u>27,000</u>	<u>10</u>	<u>270</u>
23.10	<u>80</u>	<u>2,200</u>	<u>0.8</u>	<u>22</u>
23.11	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>
23.12	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>
23.13	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>
23.14	<u>40,000</u>	<u>1,100,000</u>	<u>400</u>	<u>11,000</u>
23.15	<u>40</u>	<u>1,100</u>	<u>0.4</u>	<u>11</u>
23.16	<u>200</u>	<u>5,400</u>	<u>2</u>	<u>54</u>
23.17	<u>1,000</u>	<u>27,000</u>	<u>10</u>	<u>270</u>
23.18	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
23.19	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
23.20	<u>20,000</u>	<u>540,000</u>	<u>200</u>	<u>5,400</u>
23.21	<u>300</u>	<u>8,100</u>	<u>3</u>	<u>81</u>

23.22 **4731.3025 EXEMPTION; CERTAIN CONCENTRATIONS.**

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

23.24 Subp. 3. **Introduction by specific licensee.** A manufacturer, processor, or producer  
 23.25 of a product or material in an agreement state is exempt from parts 4731.3000 to  
 23.26 4731.7280 to the extent that:

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

24.4 B. the radioactive material is introduced into the product or material by a  
24.5 licensee holding a specific license issued by ~~the commissioner, the NRC, or an agreement~~  
24.6 ~~state~~ expressly authorizing such introduction.

24.7 The exemption in this subpart does not apply to the transfer of radioactive material in any  
24.8 food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or  
24.9 inhalation by, or application to, a human being.

24.10 Subp. 4. **Transfer limitations.** No person may introduce radioactive material into  
24.11 a product or material knowing or having reason to believe that it will be transferred to  
24.12 persons exempt under this part or equivalent regulations of the NRC or an agreement state,  
24.13 except according to a specific license issued under ~~part 4731.3305 or the general license~~  
24.14 ~~issued under part 4731.0355~~ Code of Federal Regulations, title 10, section 32.11.

24.15 **4731.3030 EXEMPTION; CERTAIN ITEMS CONTAINING RADIOACTIVE**  
24.16 **MATERIAL.**

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

24.22 A. timepieces or hands or dials of timepieces that:

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

24.25 (a) 25 millicuries of tritium per timepiece;

- 25.1 (b) five millicuries of tritium per hand;
- 25.2 (c) 15 millicuries of tritium per dial (bezels, when used, are considered
- 25.3 part of the dial);
- 25.4 (d) 100 microcuries of promethium-147 per watch or 200 microcuries
- 25.5 of promethium-147 per any other timepiece;
- 25.6 (e) 20 microcuries of promethium-147 per watch hand or 40
- 25.7 microcuries of promethium-147 per other timepiece hand; ~~and~~
- 25.8 (f) 60 microcuries of promethium-147 per watch dial or 120
- 25.9 microcuries of promethium-147 per any other timepiece dial (bezels, when used, are
- 25.10 considered as part of the dial); ~~and~~
- 25.11 (g) one microcurie (0.037 MBq) of radium-226 per timepiece in intact
- 25.12 timepieces manufactured prior to November 30, 2007; and

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

25.14 ~~B. lock illuminators containing not more than 15 millicuries of tritium or not~~

25.15 ~~more than two millicuries of promethium-147 installed on automobile locks. The levels~~

25.16 ~~of radiation from each lock illuminator containing promethium-147 must not exceed~~

25.17 ~~one millirad per hour at one centimeter from any surface when measured through 50~~

25.18 ~~milligrams per square centimeter absorber;~~

25.19 ~~E. B.~~ balances of precision containing not more than one millicurie of tritium

25.20 per balance or not more than 0.5 millicurie of tritium per balance part manufactured

25.21 before December 17, 2007;

25.22 ~~D. automobile shift quadrants containing not more than 25 millicuries of tritium;~~

25.23 ~~E. C.~~ marine compasses containing not more than 750 millicuries of tritium

25.24 gas and other marine navigational instruments containing not more than 250 millicuries

25.25 of tritium gas manufactured before December 17, 2007;

26.1 ~~F. thermostat dials and pointers containing not more than 25 millicuries of~~  
26.2 ~~tritium per thermostat;~~

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

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

26.14 (1) 150 millicuries of tritium per microwave receiver protector tube or ten  
26.15 millicuries of tritium per any other electron tube;

26.16 (2) one microcurie of cobalt-60;

26.17 (3) five microcuries of nickel-63;

26.18 (4) 30 microcuries of krypton-85;

26.19 (5) five microcuries of cesium-137; or

26.20 (6) 30 microcuries of promethium-147; or

26.21 ~~H.~~ F. ionizing radiation measuring instruments containing, for purposes of  
26.22 internal calibration or standardization, one or more sources of radioactive material. For  
26.23 purposes of this item, an instrument's source may contain either one type or different  
26.24 types of radionuclides and an individual exempt quantity may be composed of fractional  
26.25 parts of one or more of the exempt quantities in part 4731.3145, provided that the sum

27.1 of the fractions does not exceed unity. For purposes of this item, 0.05 microcurie of  
27.2 americium-241 is an exempt quantity under part 4731.3145. The exemption under this  
27.3 item applies only if:

27.4 (1) each source contains no more than one exempt quantity under part  
27.5 4731.3145; and

27.6 (2) each instrument contains no more than ten exempt quantities; ~~or,~~

27.7 ~~I. spark gap irradiators containing not more than one microcurie of cobalt-60~~  
27.8 ~~per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate~~  
27.9 ~~of at least three gallons (11.4 liters) per hour.~~

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

#### 27.11 **4731.3040 EXEMPT QUANTITIES.**

27.12 Subpart 1. **Exempt quantities.** Except as provided in subparts 3 ~~and 4~~ to 5, a person  
27.13 is exempt from parts 4731.3000 to 4731.7280 to the extent that the person receives,  
27.14 possesses, uses, transfers, owns, or acquires radioactive material in individual quantities,  
27.15 each of which does not exceed the applicable quantity in part 4731.3145.

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

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

27.22 Subp. 5. **Aggregation.** No person may, for purposes of producing an increased  
27.23 radiation level, combine quantities of radioactive material covered by this exemption  
27.24 so that the aggregate quantity exceeds the limits set forth in part 4731.3145, except for

28.1 radioactive material combined within a device placed in use before May 3, 1999, or as  
28.2 otherwise permitted by this part.

28.3 **4731.3050 EXEMPTION; GAS AND AEROSOL DETECTORS CONTAINING**  
28.4 **RADIOACTIVE MATERIAL.**

28.5 Subpart 1. **Specific license exemption.** Except for persons who manufacture,  
28.6 process, produce, or initially transfer for sale or distribution gas and aerosol detectors  
28.7 containing radioactive material, a person is exempt from parts ~~4731.2000~~ 4731.1000 to  
28.8 4731.2090 and 4731.3000 to 4731.7280 to the extent that the person receives, possesses,  
28.9 uses, transfers, owns, or acquires radioactive material in gas or aerosol detectors designed  
28.10 to protect life or property from fires and airborne hazards and manufactured, processed,  
28.11 produced, or initially transferred according to a specific license issued under Code of  
28.12 Federal Regulations, title 10, section 32.26, that authorizes the initial transfer of the  
28.13 product for use under this part. This exemption also covers gas and aerosol detectors  
28.14 manufactured or distributed before November 30, 2007, in accordance with a specific  
28.15 license issued by a state under comparable provisions to Code of Federal Regulations, title  
28.16 10, section 32.26, authorizing distribution to persons exempt from regulatory requirements.

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

28.18 **4731.3065 SPECIFIC LICENSES; APPLICATION.**

28.19 [For text of subpart 1, see M.R.]

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

28.23 A. identify the source or device by manufacturer and model number as  
28.24 registered with the NRC under Code of Federal Regulations, title 10, section 32.210,  
28.25 or with an agreement state, or for a source or a device containing radium-226 or

29.1 accelerator-produced radioactive material with a state under provisions comparable to  
29.2 Code of Federal Regulations, title 10, section 32.210; or

29.3 B. contain the information identified in Code of Federal Regulations, title  
29.4 10, section 32.210(c); or

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

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

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

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

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

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

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

30.7 C. identification of individuals authorized to prepare the PET radioactive  
30.8 drugs if the applicant is a pharmacy, and documentation that each individual meets the  
30.9 requirements of an authorized nuclear pharmacist as specified in part 4731.3395, subpart  
30.10 2; and

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

30.13 **4731.3075 TERMS AND CONDITIONS OF LICENSES.**

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

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

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

30.22 Subp. 9. Authorization to produce PET. Authorization under part 4731.3065,  
30.23 subpart 7, to produce positron emission tomography (PET) radioactive drugs for  
30.24 noncommercial transfer to medical use licensees in its consortium does not relieve the

31.1 licensee from complying with applicable FDA requirements or other federal and state  
31.2 requirements governing radioactive drugs.

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

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

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

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

31.17 (1) an authorized nuclear pharmacist that meets the requirements in part  
31.18 4731.3395, subpart 2; or

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

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

31.25 **4731.3145 EXEMPT QUANTITIES.**

	Radioactive Material	Microcuries
32.1	Radioactive Material	Microcuries
32.2	Antimony 122 (Sb 122)	100
32.3	Antimony 124 (Sb 124)	10
32.4	Antimony 125 (Sb 125)	10
32.5	Arsenic 73 (As 73)	100
32.6	Arsenic 74 (As 74)	10
32.7	Arsenic 76 (As 76)	10
32.8	Arsenic 77 (As 77)	100
32.9	Barium 131 (Ba 131)	10
32.10	Barium 133 (Ba 133)	10
32.11	Barium 140 (Ba 140)	10
32.12	Bismuth 210 (Bi 210)	1
32.13	Bromine 82 (Br 82)	10
32.14	Cadmium 109 (Cd 109)	10
32.15	Cadmium 115m (Cd 115m)	10
32.16	Cadmium 115 (Cd 115)	100
32.17	Calcium 45 (Ca 45)	10
32.18	Calcium 47 (Ca 47)	10
32.19	Carbon 11 (C 11)	1,000
32.20	Carbon 14 (C 14)	100
32.21	Cerium 141 (Ce 141)	100
32.22	Cerium 143 (Ce 143)	100
32.23	Cerium 144 (Ce 144)	1
32.24	<u>Cesium 129 (Cs 129)</u>	<u>100</u>
32.25	Cesium 131 (Cs 131)	1,000
32.26	Cesium 134m (Cs 134m)	100
32.27	Cesium 134 (Cs 134)	1
32.28	Cesium 135 (Cs 135)	10

33.1	Cesium 136 (Cs 136)	10
33.2	Cesium 137 (Cs 137)	10
33.3	Chlorine 36 (Cl 36)	10
33.4	Chlorine 38 (Cl 38)	10
33.5	Chromium 51 (Cr 51)	1,000
33.6	Cobalt 57 (Co 57)	100
33.7	Cobalt 58m (Co 58m)	10
33.8	Cobalt 58 (Co 58)	10
33.9	Cobalt 60 (Co 60)	1
33.10	Copper 64 (Cu 64)	100
33.11	Dysprosium 165 (Dy 165)	10
33.12	Dysprosium 166 (Dy 166)	100
33.13	Erbium 169 (Er 169)	100
33.14	Erbium 171 (Er 171)	100
33.15	Europium 152 9.2 h (Eu 152 9.2 h)	100
33.16	Europium 152 13 yr (Eu 152 13 yr)	1
33.17	Europium 154 (Eu 154)	1
33.18	Europium 155 (Eu 155)	10
33.19	Fluorine 18 (F 18)	1,000
33.20	Gadolinium 153 (Gd 153)	10
33.21	Gadolinium 159 (Gd 159)	100
33.22	Gallium 67 (Ga 67)	100
33.23	Gallium 72 (Ga 72)	10
33.24	Germanium 68 (Ge 68)	10
33.25	Germanium 71 (Ge 71)	100
33.26	Gold 195 (Au 195)	10
33.27	Gold 198 (Au 198)	100
33.28	Gold 199 (Au 199)	100

34.1	Hafnium 181 (Hf 181)	10
34.2	Holmium 166 (Ho 166)	100
34.3	Hydrogen 3 (H 3)	1,000
34.4	Indium 111 (In 111)	100
34.5	Indium 113m (In 113m)	100
34.6	Indium 114m (In 114m)	10
34.7	Indium 115m (In 115m)	100
34.8	Indium 115 (In 115)	10
34.9	Iodine 123 (I 123)	100
34.10	Iodine 125 (I 125)	1
34.11	Iodine 126 (I 126)	1
34.12	Iodine 129 (I 129)	0.1
34.13	Iodine 131 (I 131)	1
34.14	Iodine 132 (I 132)	10
34.15	Iodine 133 (I 133)	1
34.16	Iodine 134 (I 134)	10
34.17	Iodine 135 (I 135)	10
34.18	Iridium 192 (Ir 192)	10
34.19	Iridium 194 (Ir 194)	100
34.20	Iron 52 (Fe 52)	10
34.21	Iron 55 (Fe 55)	100
34.22	Iron 59 (Fe 59)	10
34.23	Krypton 85 (Kr 85)	100
34.24	Krypton 87 (Kr 87)	10
34.25	Lanthanum 140 (La 140)	10
34.26	Lutetium 177 (Lu 177)	100
34.27	Manganese 52 (Mn 52)	10

35.1	Manganese 54 (Mn 54)	10
35.2	Manganese 56 (Mn 56)	10
35.3	Mercury 197m (Hg 197m)	100
35.4	Mercury 197 (Hg 197)	100
35.5	Mercury 203 (Hg 203)	10
35.6	Molybdenum 99 (Mo 99)	100
35.7	Neodymium 147 (Nd 147)	100
35.8	Neodymium 149 (Nd 149)	100
35.9	Nickel 59 (Ni 59)	100
35.10	Nickel 63 (Ni 63)	10
35.11	Nickel 65 (Ni 65)	100
35.12	Niobium 93m (Nb 93m)	10
35.13	Niobium 95 (Nb 95)	10
35.14	Niobium 97 (Nb 97)	10
35.15	Nitrogen 13 (N 13)	1,000
35.16	Osmium 185 (Os 185)	10
35.17	Osmium 191m (Os 191m)	100
35.18	Osmium 191 (Os 191)	100
35.19	Osmium 193 (Os 193)	100
35.20	Oxygen 15 (O 15)	1,000
35.21	Palladium 103 (Pd 103)	100
35.22	Palladium 109 (Pd 109)	100
35.23	Phosphorus 32 (P 32)	10
35.24	Platinum 191 (Pt 191)	100
35.25	Platinum 193m (Pt 193m)	100
35.26	Platinum 193 (Pt 193)	100
35.27	Platinum 197m (Pt 197m)	100
35.28	Platinum 197 (Pt 197)	100

36.1	Polonium 210 (Po 210)	0.1
36.2	Potassium 42 (K 42)	10
36.3	<u>Potassium 43 (K 43)</u>	<u>10</u>
36.4	Praseodymium 142 (Pr 142)	100
36.5	Praseodymium 143 (Pr 143)	100
36.6	Promethium 147 (Pm 147)	10
36.7	Promethium 149 (Pm 149)	10
36.8	Radium 226 (Ra 226)	1
36.9	Rhenium 186 (Re 186)	100
36.10	Rhenium 188 (Re 188)	100
36.11	Rhodium 103m (Rh 103m)	100
36.12	Rhodium 105 (Rh 105)	100
36.13	Rubidium 81 (Rb 81)	10
36.14	Rubidium 86 (Rb 86)	10
36.15	Rubidium 87 (Rb 87)	10
36.16	Ruthenium 97 (Ru 97)	100
36.17	Ruthenium 103 (Ru 103)	10
36.18	Ruthenium 105 (Ru 105)	10
36.19	Ruthenium 106 (Ru 106)	1
36.20	Samarium 151 (Sm 151)	10
36.21	Samarium 153 (Sm 153)	100
36.22	Scandium 46 (Sc 46)	10
36.23	Scandium 47 (Sc 47)	100
36.24	Scandium 48 (Sc 48)	10
36.25	Selenium 75 (Se 75)	10
36.26	Silicon 31 (Si 31)	100
36.27	Silver 105 (Ag 105)	10
36.28	Silver 110m (Ag 110m)	1
36.29	Silver 111 (Ag 111)	100

37.1	Sodium 22 (Na 22)	10
37.2	Sodium 24 (Na 24)	10
37.3	Strontium 85 (Sr 85)	10
37.4	Strontium 89 (Sr 89)	1
37.5	Strontium 90 (Sr 90)	0.1
37.6	Strontium 91 (Sr 91)	10
37.7	Strontium 92 (Sr 92)	10
37.8	Sulfur 35 (S 35)	100
37.9	Tantalum 182 (Ta 182)	10
37.10	Technetium 96 (Tc 96)	10
37.11	Technetium 97m (Tc 97m)	100
37.12	Technetium 97 (Tc 97)	100
37.13	Technetium 99m (Tc 99m)	100
37.14	Technetium 99 (Tc 99)	10
37.15	Tellurium 125m (Te 125m)	10
37.16	Tellurium 127m (Te 127m)	10
37.17	Tellurium 127 (Te 127)	100
37.18	Tellurium 129m (Te 129m)	10
37.19	Tellurium 129 (Te 129)	100
37.20	Tellurium 131m (Te 131m)	10
37.21	Tellurium 132 (Te 132)	10
37.22	Terbium 160 (Tb 160)	10
37.23	Thallium 200 (Tl 200)	100
37.24	Thallium 201 (Tl 201)	100
37.25	Thallium 202 (Tl 202)	100
37.26	Thallium 204 (Tl 204)	10
37.27	Thulium 170 (Tm 170)	10
37.28	Thulium 171 (Tm 171)	10
37.29	Tin 113 (Sn 113)	10
37.30	Tin 125 (Sn 125)	10

38.1	Tungsten 181 (W 181)	10
38.2	Tungsten 185 (W 185)	10
38.3	Tungsten 187 (W 187)	100
38.4	Vanadium 48 (V 48)	10
38.5	Xenon 131m (Xe 131m)	1,000
38.6	Xenon 133 (Xe 133)	100
38.7	Xenon 135 (Xe 135)	100
38.8	Ytterbium 175 (Yb 175)	100
38.9	<u>Yttrium 87 (Y 87)</u>	<u>10</u>
38.10	Yttrium 88 (Y 88)	10
38.11	Yttrium 90 (Y 90)	10
38.12	Yttrium 91 (Y 91)	10
38.13	Yttrium 92 (Y 92)	100
38.14	Yttrium 93 (Y 93)	100
38.15	Zinc 65 (Zn 65)	10
38.16	Zinc 69m (Zn 69m)	100
38.17	Zinc 69 (Zn 69)	1,000
38.18	Zirconium 93 (Zr 93)	10
38.19	Zirconium 95 (Zr 95)	10
38.20	Zirconium 97 (Zr 97)	10
38.21	Any radioactive material not	
38.22	listed above other than alpha-	
38.23	emitting radioactive materials	0.1

38.24 **4731.3150 RADIOACTIVE MATERIALS; EMERGENCY PLAN QUANTITIES.**

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

		Release fraction	Quantity (curies)
39.1			
39.2	Radioactive material <sup>1</sup>		
39.3	Actinium-228	0.001	4,000
39.4	Americium-241	0.001	2
39.5	Americium-242	0.001	2
39.6	Americium-243	0.001	2
39.7	Antimony-124	0.01	4,000
39.8	Antimony-126	0.01	6,000
39.9	Barium-133	0.01	10,000
39.10	Barium-140	0.01	30,000
39.11	Bismuth-207	0.01	5,000
39.12	Bismuth-210	0.01	600
39.13	Cadmium-109	0.01	1,000
39.14	Cadmium-113	0.01	80
39.15	Calcium-45	0.01	20,000
39.16	Californium-252	0.001	9 (20 mg)
39.17	Carbon-14 (noncarbon dioxide)	0.01	50,000
39.18	Cerium-141	0.01	10,000
39.19	Cerium-144	0.01	300
39.20	Cesium-134	0.01	2,000
39.21	Cesium-137	0.01	3,000
39.22	Chlorine-36	0.5	100
39.23	Chromium-51	0.01	300,000
39.24	Cobalt-60	0.001	5,000
39.25	Copper-64	0.01	200,000
39.26	Curium-242	0.001	60
39.27	Curium-243	0.001	3
39.28	Curium-244	0.001	4
39.29	Curium-245	0.001	2

07/10/08

REVISOR

SGS/JK

RD3752

40.1	Europium-152	0.01	500
40.2	Europium-154	0.01	400
40.3	Europium-155	0.01	3,000
40.4	Germanium-68	0.01	2,000
40.5	Gadolinium-153	0.01	5,000
40.6	Gold-198	0.01	30,000
40.7	Hafnium-172	0.01	400
40.8	Hafnium-181	0.01	7,000
40.9	Holmium-166m	0.01	100
40.10	Hydrogen-3	0.5	20,000
40.11	Iodine-125	0.5	1
40.12	Iodine-131	0.5	10
40.13	Indium-114m	0.01	1,000
40.14	Iridium-192	0.001	40,000
40.15	Iron-55	0.01	40,000
40.16	Iron-59	0.01	7,000
40.17	Krypton-85	1.0	6,000,000
40.18	Lead-210	0.01	8
40.19	Manganese-56	0.01	60,000
40.20	Mercury-203	0.01	10,000
40.21	Molybdenum-99	0.01	30,000
40.22	Neptunium-237	0.001	2
40.23	Nickel-63	0.01	20,000
40.24	Niobium-94	0.01	300

41.1	Phosphorus-32	0.5	100
41.2	Phosphorus-33	0.5	1,000
41.3	Polonium-210	0.01	10
41.4	Potassium-42	0.01	9,000
41.5	Promethium-145	0.01	4,000
41.6	Promethium-147	0.01	4,000
41.7	<u>Radium-226</u>	<u>0.001</u>	<u>100</u>
41.8	Ruthenium-106	0.01	200
41.9	Samarium-151	0.01	4,000
41.10	Scandium-46	0.01	3,000
41.11	Selenium-75	0.01	10,000
41.12	Silver-110m	0.01	1,000
41.13	Sodium-22	0.01	9,000
41.14	Sodium-24	0.01	10,000
41.15	Strontium-89	0.01	3,000
41.16	Strontium-90	0.01	90
41.17	Sulfur-35	0.5	900
41.18	Technetium-99	0.01	10,000
41.19	Technetium-99m	0.01	400,000
41.20	Tellurium-127m	0.01	5,000
41.21	Tellurium-129m	0.01	5,000
41.22	Terbium-160	0.01	4,000
41.23	Thulium-170	0.01	4,000
41.24	Tin-113	0.01	10,000
41.25	Tin-123	0.01	3,000
41.26	Tin-126	0.01	1,000
41.27	Titanium-44	0.01	100
41.28	Vanadium-48	0.01	7,000

07/10/08

REVISOR

SGS/JK

RD3752

42.1	Xenon-133	1.0	900,000
42.2	Yttrium-91	0.01	2,000
42.3	Zinc-65	0.01	5,000
42.4	Zirconium-93	0.01	400
42.5	Zirconium-95	0.01	5,000
42.6	Any other beta-gamma emitter	0.01	10,000
42.7	Mixed fission products	0.01	1,000
42.8	Mixed corrosion products	0.01	10,000
42.9	Contaminated equipment,		
42.10	beta-gamma	0.001	10,000
42.11	Irradiated material, any form		
42.12	other than solid noncombustible	0.01	1,000
42.13	Irradiated material, solid		
42.14	noncombustible	0.001	10,000
42.15	Mixed radioactive waste,		
42.16	beta-gamma	0.01	1,000
42.17	Packaged mixed waste,		
42.18	beta-gamma <sup>2</sup>	0.001	10,000
42.19	Any other alpha emitter	0.001	2
42.20	Contaminated equipment, alpha	0.0001	20
42.21	Packaged waste, alpha <sup>2</sup>	0.0001	20

43.1 Combinations of radioactive materials listed above<sup>1</sup>

43.2 <sup>1</sup>For combinations of radioactive materials, consideration of the need for an  
43.3 emergency plan is required if the sum of the ratios of the quantity of each radioactive  
43.4 material authorized to the quantity listed for that material in this part exceeds one.

43.5 <sup>2</sup>Waste packaged in Type B containers does not require an emergency plan.

43.6 **4731.3215 GENERAL LICENSE; DETECTING, MEASURING, GAUGING,**  
43.7 **CONTROLLING, AND OTHER DEVICES.**

43.8 [For text of subpart 1, see M.R.]

43.9 **Subp. 2. Applicability.**

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

43.13 (1) a specific license issued under part 4731.3330; ~~or~~

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

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

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

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

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

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

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

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

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

44.14 (4) reports the transfer under item K;

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

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

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

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

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

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

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



46.1 A. The general licenses issued under this part are subject to parts 4731.0260;  
 46.2 4731.1000 to 4731.2950; 4731.3025, subpart 4; 4731.3075, subparts 1, 2, 3, 5, and 6; and  
 46.3 4731.3110 to 4731.3135 and Code of Federal Regulations, title 10, part 21.

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

46.6 (1) must not possess at any one time, at any one location of storage or  
 46.7 use, more than five microcuries (~~185 kBq~~ 0.185 kilobecquerels) of americium-241, ~~five~~  
 46.8 ~~microcuries (185 kBq) of plutonium, or five microcuries (185 kBq) of~~ or radium-226  
 46.9 in the sources;

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

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

46.18 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS  
 46.19 ~~{AMERICIUM-241 or PLUTONIUM~~ [or RADIUM-226, as appropriate]. DO NOT  
 46.20 TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

46.21 (Name of manufacturer or initial transferor)"; ~~or~~

46.22 (b) ~~"The receipt, possession, use, and transfer of this source, Model~~  
 46.23 ~~....., Serial No. ...., are subject to a general license and the regulations of a licensing~~  
 46.24 ~~state. Do not remove this label.~~

46.25 ~~CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS~~  
 46.26 ~~RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.~~

47.1 ~~(Name of manufacturer or initial transferor)";~~

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

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

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

47.10 C. Sources generally licensed under this part before January 19, 1975, may bear  
47.11 labels authorized by the regulations in effect on January 1, 1975. Sources containing  
47.12 radium-226 generally licensed under this part and manufactured before November  
47.13 30, 2007, must be labeled according to the applicable state regulations at the time of  
47.14 manufacture or import.

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

47.18 **4731.3245 GENERAL LICENSE; IN VITRO CLINICAL OR LABORATORY**  
47.19 **TESTING USE.**

47.20 Subpart 1. **License issued.** A physician, veterinarian in the practice of veterinary  
47.21 medicine, clinical laboratory, or hospital is issued a general license to receive, acquire,  
47.22 possess, transfer, or use, according to this part, the following radioactive materials in  
47.23 prepackaged units for use in in vitro clinical or laboratory tests not involving internal or  
47.24 external administration of radioactive material, or the radiation therefrom, to human  
47.25 beings or animals:

- 48.1 A. iodine-125, in units not exceeding ten microcuries (0.37 MBq) each;
- 48.2 B. iodine-131, in units not exceeding ten microcuries (0.37 MBq) each;
- 48.3 C. carbon-14, in units not exceeding ten microcuries (0.37 MBq) each;
- 48.4 D. hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each;
- 48.5 E. iron-59, in units not exceeding 20 microcuries (0.74 MBq) each;
- 48.6 F. selenium-75, in units not exceeding ten microcuries (0.37 MBq) each;
- 48.7 G. mock iodine-125 reference or calibration sources, in units not exceeding 0.05
- 48.8 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (0.185 kBq) of americium-241
- 48.9 each; and
- 48.10 H. cobalt-57, in units not exceeding ten microcuries (0.37 MBq) each.

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

48.12 **4731.3250 GENERAL LICENSE; CERTAIN ITEMS AND SELF-LUMINOUS**

48.13 **PRODUCTS CONTAINING RADIUM-226.**

48.14 Subpart 1. General license. A general license is hereby issued to any person to

48.15 acquire, receive, possess, use, or transfer, according to the provisions of subparts 2 to 4,

48.16 radium-226 contained in the following products manufactured prior to November 30, 2007.

48.17 A. Antiquities originally intended for use by the general public. For the

48.18 purposes of this item, "antiquities" means products originally intended for use by the

48.19 general public and distributed in the late 19th and early 20th centuries, such as radium

48.20 emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium

48.21 bath salts, and healing pads.

48.22 B. Intact timepieces containing greater than one microcurie (0.037 MBq),

48.23 nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

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

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

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

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

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

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

49.22 B. must not abandon products containing radium-226. The product, and  
49.23 any radioactive material from the product, may only be disposed of according to part  
49.24 4731.2460 or by transfer to a person authorized by a specific license to receive the  
49.25 radium-226 in the product or as otherwise approved by the NRC;

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

50.3 D. must dispose of products containing radium-226:

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

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

50.9 (3) as otherwise approved by the commissioner; and

50.10 E. must respond to written requests from the commissioner to provide  
50.11 information relating to the general license within 30 calendar days of the date of the  
50.12 request, or other time specified in the request. If the general licensee cannot provide the  
50.13 requested information within the allotted time, the licensee must, within that same time  
50.14 period, request a longer period to supply the information by providing the commissioner a  
50.15 written justification for the request.

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

50.19 **4731.3315 PROHIBITION OF INTRODUCTION.**

50.20 No person may introduce radioactive material in a product or material knowing or  
50.21 having reason to believe that it will be transferred to a person that is exempt under part  
50.22 4731.3025 or equivalent regulations of the NRC or an agreement state, except according  
50.23 to a specific license issued under part 4731.3305 or the general license issued under part  
50.24 4731.0355 Code of Federal Regulations, title 10, section 32.11.

51.1 **4731.3365 SPECIFIC LICENSE; CALIBRATION OR REFERENCE SOURCES;**  
51.2 **MANUFACTURE OR INITIAL TRANSFER.**

51.3 Subpart 1. **Approval criteria.** An application for a specific license to manufacture or  
51.4 initially transfer calibration and reference sources containing americium-241, ~~plutonium,~~  
51.5 or radium-226 for distribution to persons generally licensed under part 4731.3230 shall  
51.6 be approved if:

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

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

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

51.12 (2) details of construction and design;

51.13 (3) details of the method of incorporation and binding of the  
51.14 americium-241, ~~plutonium,~~ or radium-226 in the source;

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

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

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

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

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

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

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

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

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

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

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

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

53.1 CAUTION – RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS  
53.2 AMERICIUM-241 ~~OR PLUTONIUM OR RADIUM-226~~ [or RADIUM-226, as  
53.3 appropriate]. DO NOT TOUCH  
53.4 RADIOACTIVE PORTION OF THIS SOURCE.

53.5 (Name of manufacturer or initial transferor)"

53.6 Sources licensed under Code of Federal Regulations, title 10, before January 19,  
53.7 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

53.8 Subp. 3. **Leak testing.**

53.9 A. A person licensed under this part must perform a dry wipe test upon each  
53.10 source containing more than 0.1 microcurie (3.7 kBq) of americium-241, ~~0.1 microcurie~~  
53.11 ~~(3.7 kBq) of plutonium, or 0.1 microcurie (3.7 kBq) of~~ or radium-226 before transferring  
53.12 the source to a general licensee under part 4731.3230.

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

53.15 C. The radioactivity on the paper must be measured by using radiation  
53.16 detection instrumentation capable of detecting 0.005 microcurie ~~(185 Bq~~ 0.185 kBq) of  
53.17 americium-241, ~~plutonium,~~ or radium-226.

53.18 D. If the test discloses more than 0.005 microcurie ~~(185 Bq~~ 0.185kBq) of  
53.19 radioactive material, the source must be deemed to be leaking or losing americium-241;  
53.20 ~~plutonium,~~ or radium-226 and must not be transferred to a general licensee under part  
53.21 4731.3230.

53.22 **4731.3390 SPECIFIC LICENSE; MATERIAL FOR IN VITRO CLINICAL OR**  
53.23 **LABORATORY TESTING; MANUFACTURE AND DISTRIBUTION.**

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

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

- 54.1 B. the radioactive material is prepared for distribution in prepackaged units of:
- 54.2 (1) iodine-125 in units not exceeding ten microcuries (370 kBq) each;
- 54.3 (2) iodine-131 in units not exceeding ten microcuries (370 kBq) each;
- 54.4 (3) carbon-14 in units not exceeding ten microcuries (370 kBq) each;
- 54.5 (4) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq)
- 54.6 each;
- 54.7 (5) iron-59 in units not exceeding 20 microcuries (740 kBq) each;
- 54.8 (6) selenium-75 in units not exceeding ten microcuries (370 kBq) each; ~~and~~
- 54.9 (7) mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of
- 54.10 iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and
- 54.11 (8) cobalt-57 in units not exceeding ten microcuries (370 kBq) each;
- 54.12 C. each prepackaged unit bears a durable, clearly visible label that:
- 54.13 (1) identifies the radioactive contents as to chemical form and radionuclide;
- 54.14 and
- 54.15 (2) indicates that the amount of radioactivity does not exceed:
- 54.16 (a) ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, or
- 54.17 selenium-75;
- 54.18 (b) 50 microcuries (1.85 MBq) of hydrogen-3 (tritium);
- 54.19 (c) 20 microcuries (740 kBq) of iron-59; ~~or~~
- 54.20 (d) mock iodine-125 in units not exceeding 0.05 microcuries (1.85
- 54.21 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; ~~and~~ or
- 54.22 (e) cobalt-57 in units not exceeding ten microcuries (370 kBq); and

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

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

55.7 "The radioactive material may be received, acquired, possessed, and used only by  
55.8 physicians, veterinarians in the practice of veterinary medicine, clinical laboratories,  
55.9 or hospitals and only for in vitro clinical or laboratory tests not involving internal  
55.10 or external administration of the material, or the radiation therefrom, to human  
55.11 beings or animals. Its receipt, acquisition, possession, use, and transfer are subject  
55.12 to the regulations and a general license of the Minnesota commissioner of health,  
55.13 the Nuclear Regulatory Commission, or a state with which the Nuclear Regulatory  
55.14 Commission has entered into an agreement for the exercise of regulatory authority.

55.15 (Name of manufacturer)"; and

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

55.21 **4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE;**  
55.22 **MANUFACTURE, PREPARATION, OR TRANSFER.**

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

- 56.1 A. satisfies the general requirements specified in part 4731.3070;
- 56.2 B. submits evidence that the applicant is at least one of the following:
- 56.3 (1) registered or licensed with the United States Food and Drug  
56.4 Administration as ~~a drug manufacturer~~ the owner or operator of a drug establishment that  
56.5 engages in the manufacture, preparation, propagation, compounding, or processing of a  
56.6 drug under Code of Federal Regulations, title 21, section 207.20(a);
- 56.7 (2) registered or licensed with a state agency as a drug manufacturer;
- 56.8 (3) licensed as a pharmacy by a state board of pharmacy; ~~or~~
- 56.9 (4) operating as a nuclear pharmacy within a federal medical institution; or
- 56.10 (5) a positron emission tomography (PET) drug production facility  
56.11 registered with a state agency;
- 56.12 C. submits the following information regarding the radionuclide:
- 56.13 (1) the chemical and physical form;
- 56.14 (2) the maximum activity per vial, syringe, generator, or other container of  
56.15 the radioactive drug; and
- 56.16 (3) the shielding provided by the packaging to show it is appropriate for  
56.17 safe handling and storage of the radioactive drugs by medical use licensees; and
- 56.18 D. satisfies the following labeling requirements:
- 56.19 (1) a label must be affixed to each transport radiation shield, whether it is  
56.20 constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred  
56.21 for commercial distribution and include the radiation symbol, the words "CAUTION,  
56.22 RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name  
56.23 of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specific

57.1 date and time. For a radioactive drug with a half-life greater than 100 days, the time  
57.2 may be omitted; and

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

57.9 Subp. 2. **Pharmacy licensees.**

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

57.11 C. A licensee described in subpart 1, item B, subitem (3) or (4), may designate  
57.12 a pharmacist as an authorized nuclear pharmacist if the individual ~~is identified as of~~  
57.13 ~~December 2, 1994, as an authorized user on a nuclear pharmacy license issued by the~~  
57.14 ~~NRC or an agreement state.~~ was a nuclear pharmacist preparing only radioactive drugs  
57.15 containing accelerator-produced radioactive material, and the individual practiced at a  
57.16 pharmacy at a government agency or federally recognized Indian tribe before November  
57.17 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by  
57.18 the NRC.

57.19 D. No later than 30 days after the date that a licensee described in subpart  
57.20 1, item B, subitem (3) or (4), allows an individual to work as an authorized nuclear  
57.21 pharmacist under item A, subitem (2), unit (a) or (c), the licensee must provide to the  
57.22 commissioner a copy of:

57.23 (1) ~~the individual's certification by the Board of Pharmaceutical Specialties;~~  
57.24 a specialty board whose certification process has been recognized as specified in part  
57.25 4731.4413, subpart 1, with the written attestation signed by a preceptor as required by part  
57.26 4731.4413, subpart 1; or

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

58.5 (2) (3) documentation that only accelerator-produced radioactive materials  
 58.6 were used in the practice of nuclear pharmacy at a government agency or federally  
 58.7 recognized Indian tribe before November 30, 2007, or at all other pharmacies before  
 58.8 August 8, 2009, or an earlier date as noticed by the NRC; and

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

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

58.11 **4731.3400 SPECIFIC LICENSE; SOURCES OR DEVICES FOR MEDICAL USE;**  
 58.12 **MANUFACTURE AND DISTRIBUTION.**

58.13 Subpart 1. **Approval criteria.** An application for a specific license to manufacture  
 58.14 and distribute sources and devices containing radioactive material to persons licensed  
 58.15 according to parts 4731.4400 to 4731.4527 for use as a calibration, transmission, or  
 58.16 reference source or for the uses listed under parts 4731.4404, 4731.4450, 4731.4460, and  
 58.17 4731.4463 shall be approved if:

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

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

58.20 **4731.3410 PROTOTYPE TESTS; CALIBRATION OR REFERENCE SOURCES**  
 58.21 **CONTAINING AMERICIUM-241, ~~PLUTONIUM,~~ OR RADIUM-226.**

58.22 An applicant for a license under part 4731.3365 must, for any type of source that is  
 58.23 designed to contain more than 0.005 microcurie (~~185 Bq~~ 0.185 kBq) of americium-241;  
 58.24 ~~0.005 microcurie (185 Bq) of plutonium,~~ or ~~0.005 microcurie (185 Bq) of radium-226,~~  
 58.25 conduct prototype tests, in the order listed, on each of five prototypes of such source

59.1 that contains more than 0.005 microcurie (~~185 Bq~~ 0.185 kBq) of americium-241, ~~0.005~~  
 59.2 ~~microcurie (185 Bq) of plutonium, or 0.005 microcurie (185 Bq) of radium-226 as follows:~~

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

59.4 **4731.3450 SERIALIZATION OF NATIONALLY TRACKED SOURCES.**

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

59.8 **4731.3580 LIMITS FOR BROAD SCOPE LICENSES.**

59.9 The following limits apply to specific licenses of broad scope issued under parts  
 59.10 4731.3500 to 4731.3580:

59.11		Column I	Column II
59.12	Radioactive Material	curies	curies
59.13	Antimony-122	1	0.01
59.14	Antimony-124	1	0.01
59.15	Antimony-125	1	0.01
59.16	Arsenic-73	10	0.1
59.17	Arsenic-74	1	0.01
59.18	Arsenic-76	1	0.01
59.19	Arsenic-77	10	0.1
59.20	Barium-131	10	0.1
59.21	Barium-140	1	0.01
59.22	<u>Beryllium-7</u>	<u>10</u>	<u>0.1</u>
59.23	Bismuth-210	0.1	0.001
59.24	Bromine-82	10	0.1
59.25	Cadmium-109	1	0.01
59.26	Cadmium-115m	1	0.01

60.1	Cadmium-115	10	0.1
60.2	Calcium-45	1	0.01
60.3	Calcium-47	10	0.1
60.4	Carbon-14	100	1
60.5	Cerium-141	10	0.1
60.6	Cerium-143	10	0.1
60.7	Cerium-144	0.1	0.001
60.8	Cesium-131	100	1
60.9	Cesium-134m	100	1
60.10	Cesium-134	0.1	0.001
60.11	Cesium-135	1	0.01
60.12	Cesium-136	10	0.1
60.13	Cesium-137	0.1	0.001
60.14	Chlorine-36	1	0.01
60.15	Chlorine-38	100	1
60.16	Chromium-51	100	1
60.17	<u>Cobalt-57</u>	<u>10</u>	<u>0.1</u>
60.18	Cobalt-58m	100	1
60.19	Cobalt-58	1	0.01
60.20	Cobalt-60	0.1	0.001
60.21	Copper-64	10	0.1
60.22	Dysprosium-165	100	1
60.23	Dysprosium-166	10	0.1
60.24	Erbium-169	10	0.1
60.25	Erbium-171	10	0.1
60.26	Europium-152 9.2 h	10	0.1
60.27	Europium-152 13 y	0.1	0.001
60.28	Europium-154	0.1	0.001
60.29	Europium-155	1	0.01

61.1	Fluorine-18	100	1
61.2	Gadolinium-153	1	0.01
61.3	Gadolinium-159	10	0.1
61.4	Gallium-72	10	0.1
61.5	Germanium-71	100	1
61.6	Gold-198	10	0.1
61.7	Gold-199	10	0.1
61.8	Hafnium-181	1	0.01
61.9	Holmium-166	10	0.1
61.10	Hydrogen-3	100	1
61.11	Indium-113m	100	1
61.12	Indium-114m	1	0.01
61.13	Indium-115m	100	1
61.14	Indium-115	1	0.01
61.15	Iodine-125	0.1	0.001
61.16	Iodine-126	0.1	0.001
61.17	Iodine-129	0.1	0.01
61.18	Iodine-131	0.1	0.001
61.19	Iodine-132	10	0.1
61.20	Iodine-133	1	0.01
61.21	Iodine-134	10	0.1
61.22	Iodine-135	1	0.01
61.23	Iridium-192	1	0.01
61.24	Iridium-194	10	0.1
61.25	Iron-55	10	0.1
61.26	Iron-59	1	0.01
61.27	Krypton-85	100	1

62.1	Krypton-87	10	0.1
62.2	Lanthanum-140	1	0.01
62.3	Lutetium-177	10	0.1
62.4	Manganese-52	1	0.01
62.5	Manganese-54	1	0.01
62.6	Manganese-56	10	0.1
62.7	Mercury-197m	10	0.1
62.8	Mercury-197	10	0.1
62.9	Mercury-203	1	0.01
62.10	Molybdenum-99	10	0.1
62.11	Neodymium-147	10	0.1
62.12	Neodymium-149	10	0.1
62.13	Nickel-59	10	0.1
62.14	Nickel-63	1	0.01
62.15	Nickel-65	10	0.1
62.16	Niobium-93m	1	0.01
62.17	Niobium-95	1	0.01
62.18	Niobium-97	100	1
62.19	Osmium-185	1	0.01
62.20	Osmium-191m	100	1
62.21	Osmium-191	10	0.1
62.22	Osmium-193	10	0.1
62.23	Palladium-103	10	0.1
62.24	Palladium-109	10	0.1
62.25	Phosphorus-32	1	0.01
62.26	Platinum-191	10	0.1
62.27	Platinum-193m	100	1

63.1	Platinum-193	10	0.1
63.2	Platinum-197m	100	1
63.3	Platinum-197	10	0.1
63.4	Polonium-210	0.01	0.0001
63.5	Potassium-42	1	0.01
63.6	Praseodymium-142	10	0.1
63.7	Praseodymium-143	10	0.1
63.8	Promethium-147	1	0.01
63.9	Promethium-149	10	0.1
63.10	<u>Radium-226</u>	<u>0.01</u>	<u>0.0001</u>
63.11	Rhenium-186	10	0.1
63.12	Rhenium-188	10	0.1
63.13	Rhodium-103m	1,000	10
63.14	Rhodium-105	10	0.1
63.15	Rubidium-86	1	0.01
63.16	Rubidium-87	1	0.01
63.17	Ruthenium-97	100	1
63.18	Ruthenium-103	1	0.01
63.19	Ruthenium-105	10	0.1
63.20	Ruthenium-106	0.1	0.001
63.21	Samarium-151	1	0.01
63.22	Samarium-153	10	0.1
63.23	Scandium-46	1	0.01
63.24	Scandium-47	10	0.1
63.25	Scandium-48	1	0.01
63.26	Selenium-75	1	0.01
63.27	Silicon-31	10	0.1
63.28	Silver-105	1	0.01
63.29	Silver-110m	0.1	0.001

64.1	Silver-111	10	0.1
64.2	<u>Sodium-22</u>	<u>0.1</u>	<u>0.001</u>
64.3	Sodium-24	1	0.01
64.4	Strontium-85m	1,000	10
64.5	Strontium-85	1	0.01
64.6	Strontium-89	1	0.01
64.7	Strontium-90	0.01	0.0001
64.8	Strontium-91	10	0.1
64.9	Strontium-92	10	0.1
64.10	Sulfur-35	10	0.1
64.11	Tantalum-182	1	0.01
64.12	Technetium-96	10	0.1
64.13	Technetium-97m	10	0.1
64.14	Technetium-97	10	0.1
64.15	Technetium-99m	100	1
64.16	Technetium-99	1	0.01
64.17	Tellurium-125m	1	0.01
64.18	Tellurium-127m	1	0.01
64.19	Tellurium-127	10	0.1
64.20	Tellurium-129m	1	0.01
64.21	Tellurium-129	100	1
64.22	Tellurium-131m	10	0.1
64.23	Tellurium-132	1	0.01
64.24	Terbium-160	1	0.01
64.25	Thallium-200	10	0.1
64.26	Thallium-201	10	0.1
64.27	Thallium-202	10	0.1
64.28	Thallium-204	1	0.01
64.29	Thulium-170	1	0.01
64.30	Thulium-171	1	0.01

65.1	Tin-113	1	0.01
65.2	Tin-125	1	0.01
65.3	Tungsten-181	1	0.01
65.4	Tungsten-185	1	0.01
65.5	Tungsten-187	10	0.1
65.6	Vanadium-48	1	0.01
65.7	Xenon-131m	1,000	10
65.8	Xenon-133	100	1
65.9	Xenon-135	100	1
65.10	Ytterbium-175	10	0.1
65.11	Yttrium-90	1	0.01
65.12	Yttrium-91	1	0.01
65.13	Yttrium-92	10	0.1
65.14	Yttrium-93	1	0.01
65.15	Zinc-65	1	0.01
65.16	Zinc-69m	10	0.1
65.17	Zinc-69	100	1
65.18	Zirconium-93	1	0.01
65.19	Zirconium-95	1	0.01
65.20	Zirconium-97	1	0.01
65.21	Any radioactive material		
65.22	other than alpha-emitting		
65.23	by-product material not		
65.24	listed above	0.1	0.001

65.25 **4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE**  
65.26 **MATERIALS.**

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

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

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

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

66.13 (1) on a license issued by the NRC or an agreement state or on an  
66.14 equivalent permit or license recognized by the commissioner, the NRC, or an agreement  
66.15 state that authorizes the use of radioactive material in medical use or in the practice of  
66.16 nuclear pharmacy;

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

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

66.23 (1) ~~for an authorized user, an individual who meets the requirements~~  
66.24 ~~under parts 4731.4415 and 4731.4433, subpart 1, item A; 4731.4436, subpart 1, item A;~~

67.1 ~~4731.4443, subpart 1, item A; 4731.4444, item A; 4731.4445, item A; 4731.4458, subpart~~  
67.2 ~~1, item A; 4731.4461, item A; or 4731.4479, subpart 1, item A;~~

67.3 ~~(2) for an authorized nuclear pharmacist, an individual who meets the~~  
67.4 ~~requirements under parts 4731.4413, subpart 1, item A, and 4731.4415;~~

67.5 ~~(3) for an authorized medical physicist, an individual who meets the~~  
67.6 ~~requirements under parts 4731.4412, subpart 1, item A, and 4731.4415; or~~

67.7 ~~(4) an individual who is identified as an authorized user, an authorized~~  
67.8 ~~nuclear pharmacist, or authorized medical physicist:~~

67.9 ~~(a) on a license issued by the NRC or an agreement state or on an~~  
67.10 ~~equivalent permit or license recognized by the commissioner, the NRC, or an agreement~~  
67.11 ~~state that authorizes the use of radioactive material in medical use or in the practice of~~  
67.12 ~~nuclear pharmacy; or~~

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

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

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

67.18 ~~A. A licensee must provide the commissioner a copy of the board certification~~  
67.19 ~~and written attestation signed by a preceptor, the license issued by the NRC or an~~  
67.20 ~~agreement state, the permit issued by an NRC or agreement state master material license~~  
67.21 ~~broad scope permittee, or the permit issued by an NRC or agreement state licensee~~  
67.22 ~~of broad scope for each individual no later than 30 days after the date that the licensee~~  
67.23 ~~allows, under subpart 3, item B, the individual to work as:~~

67.24 ~~(1) an authorized user;~~

67.25 ~~(2) an authorized nuclear pharmacist; or~~

68.1 ~~(3) an authorized medical physicist.~~

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

68.4 (1) an authorized user, an authorized nuclear pharmacist, a radiation safety  
68.5 officer, or an authorized medical physicist ~~permanently discontinues performance of duties~~  
68.6 ~~under the license or has a name change;~~

68.7 (2) the licensee's mailing address changes;

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

68.10 (4) the licensee has added to or changed the areas of use identified in the  
68.11 application or license where radioactive material is used according to part 4731.4432 or  
68.12 4731.4434; or

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

68.17 ~~C.~~ B. A licensee must mail required documents to the address under part  
68.18 4731.0200, subpart 4.

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

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

68.24 B. subpart 3, item B;

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

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

69.5 ~~E. subpart 4, item B, subitem (1), for an authorized user, an authorized nuclear~~  
69.6 ~~pharmacist, or an authorized medical physicist;~~

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

69.10 ~~G. F.~~ part 4731.4410, item A.

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

69.12 **4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN**  
69.13 **DIRECTIVE.**

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

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

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

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

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

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

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

70.1 **4731.4420 MEASURING ACTIVITY OF UNSEALED RADIOACTIVE**  
70.2 **MATERIAL; INSTRUMENTS REQUIRED.**

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

70.6 B. A licensee must ~~calibrate~~ check and test the instrumentation required under  
70.7 item A according to nationally recognized standards or the manufacturer's instructions:  
70.8 and at the following intervals:

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

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

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

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

70.15 C. A licensee must ~~retain a record of each instrument calibration required under~~  
70.16 ~~item B according to part 4731.4502, subpart 1~~ also perform the required checks and tests  
70.17 in this part following adjustment or repair of the instrument.

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

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

70.22 (2) the date of the check or test;

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

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

71.1 **4731.4422 DETERMINATION OF DOSAGES; UNSEALED RADIOACTIVE**  
71.2 **MATERIAL.**

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

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

71.6 (1) direct measurement of radioactivity; or

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

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

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

71.14 (c) a PET radioactive drug producer licensed according to part  
71.15 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state.

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

71.17 (1) direct measurement of radioactivity;

71.18 (2) a combination of measurement of radioactivity and mathematical  
71.19 calculations; ~~or~~

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

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

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

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

72.6 **4731.4429 DECAY-IN-STORAGE.**

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

72.10 ~~(1) monitors radioactive material at the surface before disposal;~~

72.11 ~~(2) determines that its radioactivity cannot be distinguished from the~~  
72.12 ~~background radiation level with an appropriate radiation detection survey meter set on its~~  
72.13 ~~most sensitive scale and with no interposed shielding; and~~

72.14 ~~(3) removes or obliterates all radiation labels, except for radiation labels~~  
72.15 ~~on materials that are within containers and that will be managed as biomedical waste~~  
72.16 ~~after they are released from the licensee.~~

72.17 ~~B. A licensee must retain a record of each disposal under item A according~~  
72.18 ~~to part 4731.4508.~~

72.19 **4731.4432 UNSEALED RADIOACTIVE MATERIAL; UPTAKE, DILUTION,**  
72.20 **AND EXCRETION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.**

72.21 Except for quantities that require a written directive under part 4731.4408 or  
72.22 4731.4409, a licensee may use any unsealed radioactive material prepared for medical use  
72.23 for uptake, dilution, or excretion studies that is:

72.24 A. obtained from a manufacturer or preparer licensed under part 4731.3395 or  
72.25 equivalent requirements of the NRC or an agreement state; or a PET radioactive drug

73.1 producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of  
73.2 the NRC or an agreement state;

73.3 B. excluding production of PET radionuclides, prepared by:

73.4 (1) an authorized nuclear pharmacist;

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

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

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

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

73.18 **4731.4434 UNSEALED RADIOACTIVE MATERIAL; IMAGING AND**  
73.19 **LOCALIZATION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.**

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

73.23 A. obtained from a manufacturer or preparer licensed under part 4731.3395 or  
73.24 equivalent requirements of the NRC or an agreement state or a PET radioactive drug

74.1 producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of  
74.2 the NRC or an agreement state;

74.3 B. excluding production of PET radionuclides, prepared by:

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

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

74.6 **4731.4435 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND**  
74.7 **STRONTIUM-85 CONCENTRATION.**

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

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

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

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

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

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

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

75.4 **4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE**  
75.5 **REQUIRED.**

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

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

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

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

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

75.21 **4731.4509 MOLYBDENUM-99, STRONTIUM-82, and STRONTIUM-85**  
75.22 **CONCENTRATION RECORDS.**

75.23 A licensee must maintain a record of the molybdenum-99 concentration or  
75.24 strontium-82 and strontium-85 concentration tests required under part 4731.4435, item B,  
75.25 for three years. The record ~~for each measured elution of technetium-99m~~ must include:

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

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

76.4           ~~B.~~ (2) the time and date of the measurement; and

76.5           ~~C.~~ (3) the name of the individual who made the measurement; and

76.6           B. for each measured elution of rubidium-82:

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

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

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

76.13           **REPEALER.** Minnesota Rules, parts 4731.3035; 4731.3230, subparts 2 and 3;  
76.14 4731.3305; 4731.3320; and 4731.4508, are repealed.