

Office of the Revisor of Statutes

Administrative Rules



TITLE: Adopted Permanent Rules Relating to Radiation Control

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4731



RULE APPROVED
OFFICE OF ADMINISTRATIVE HEARINGS

February 5, 2009
DATE

Eric L. Lipman By BUN
ADMINISTRATIVE LAW JUDGE.

The attached rules are approved for
filing with the Secretary of State

Sandra Glass-Sirany

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Senior Assistant Revisor

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ADMINISTRATIVE
HEARINGS

1.1 **Department of Health**

1.2 **Adopted 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. **Byproduct material.** "Byproduct material" means:

1.9 A. any radioactive material, except special nuclear material, yielded in, or made
1.10 radioactive by, exposure to the radiation incident to the process of producing or using
1.11 special nuclear material;

1.12 B. the tailings or wastes produced by the extraction or concentration of uranium
1.13 or thorium from ore processed primarily for its source material content, including discrete
1.14 surface wastes resulting from uranium solution extraction processes. Underground ore
1.15 bodies depleted by these solution extraction operations do not constitute byproduct
1.16 material within this definition;

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

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

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

1.22 D. any discrete source of naturally occurring radioactive material, other than
1.23 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 byproduct
4.4 material that are acceptable for disposal in a land disposal facility. For the purposes of
4.5 this definition, low-level radioactive waste means radioactive waste not classified as
4.6 high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material
4.7 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 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.

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

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

4.23 **4731.1030 EXPOSURE NOTIFICATIONS AND REPORTS.**

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

5.1 Subp. 2. **Frequency of report.** Each licensee shall make dose information available
5.2 to workers as shown in records maintained by the licensee under the provisions of part
5.3 4731.2540. The licensee shall provide an annual report to each individual monitored under
5.4 part 4731.2210 of the dose received in that monitoring year if:

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

5.7 B. The individual requests their report.

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

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

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

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

5.16 **4731.2020 OCCUPATIONAL DOSE LIMITS FOR ADULTS.**

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

5.18 Subp. 3. **Assessing dose.** When the external exposure is determined by measurement
5.19 with an external personal monitoring device, the deep-dose equivalent must be used in
5.20 place of the effective dose equivalent, unless the effective dose equivalent is determined
5.21 by a dosimetry method approved by the commissioner. The assigned deep dose equivalent
5.22 must be for the part of the body receiving the highest exposure. The assigned shallow
5.23 dose equivalent must be the dose averaged over the contiguous ten square centimeters of
5.24 skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent, and
5.25 shallow dose equivalent may be assessed from surveys or other radiation measurements to

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

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

4731.2200 SURVEYS AND MONITORING.

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

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

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

4731.2360 LEAK TEST REQUIREMENTS.

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

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

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

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

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

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

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

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

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

7.20 A. sources containing only radioactive material with a half-life of less than
7.21 30 days;

7.22 B. sources containing only radioactive material as a gas;

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

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

8.2 **4731.2400 WASTE DISPOSAL.**

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

8.4 A. by transfer to an authorized recipient as provided under parts 4731.0525 to
8.5 4731.0840, 4731.2450, and 4731.3000 to 4731.3175 or in Code of Federal Regulations,
8.6 title 10, parts 60, 63, and 72;

8.7 B. by decay in storage;

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

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

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

8.11 **4731.2405 DECAY-IN-STORAGE.**

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

8.15 A. monitors radioactive material at the surface before disposal;

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

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

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

- 9.1 A. the date of the disposal;
- 9.2 B. the date on which the radioactive material was placed in storage;
- 9.3 C. the radionuclide with the longest half-life;
- 9.4 D. the manufacturer's name, model number, and serial number of the survey
- 9.5 instrument used, or a unique survey meter identification that can be cross-referenced to a
- 9.6 specific manufacturer, model, and serial number;
- 9.7 E. the background radiation level;
- 9.8 F. the radiation level measured at the surface of each waste container; and
- 9.9 G. the name of the individual who performed the disposal.

9.10 **4731.2450 TRANSFER FOR DISPOSAL; MANIFESTS.**

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

9.12 Subp. 4. **Shipping byproduct material.** Any licensee shipping byproduct material,

9.13 as defined in part 4731.0100, subpart 32, items C and D, intended for ultimate disposal at

9.14 a land disposal facility licensed under Code of Federal Regulations, title 10, part 61, must

9.15 document the information on the NRC's Uniform Low-Level Radioactive Waste Manifest

9.16 and transfer this recorded manifest information to the intended consignee according to

9.17 part 4731.2950.

9.18 **4731.2460 DISPOSAL OF CERTAIN BYPRODUCT MATERIAL.**

9.19 Subpart 1. **Disposal of licensed material.** Licensed material as defined in part

9.20 4731.0100, subpart 32, items C and D, may be disposed of according to Code of Federal

9.21 Regulations, title 10, part 61, even though it is not defined as low-level radioactive waste.

9.22 Therefore, any licensed byproduct material being disposed of at a facility, or transferred

9.23 for ultimate disposal under Code of Federal Regulations, title 10, part 61, must meet the

9.24 requirements of part 4731.2450.

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

10.6 **4731.2510 RECORDS; SURVEYS.**

10.7 Subpart 1. **Record maintenance; three years.** A licensee must maintain records
10.8 showing the results of surveys and calibrations required under parts 4731.2200 and
10.9 4731.2350, subpart 2, for three years after the record is made. The record must include:

10.10 A. the date of the measurements;

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

10.13 C. the radiation level; and

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

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

10.17 **4731.2520 DETERMINATION OF PRIOR OCCUPATIONAL DOSE.**

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

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

10.22 Subp. 3. **Compliance methods.** In complying with the requirements of subparts
10.23 1 and 2, a licensee may:

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

11.1 Subp. 4. **Record keeping.**

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

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

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

11.14 **4731.2640 REPORTS TO INDIVIDUALS; DOSE LIMITS EXCEEDED.**

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

11.21 **4731.2705 NATIONAL SOURCE TRACKING TRANSACTION REPORTING.**

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

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

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

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

- 12.14 A. the name, address, and license number of the reporting licensee;
- 12.15 B. the name of the individual preparing the report;
- 12.16 C. the name and license number of the recipient facility and the shipping address;
- 12.17 D. the manufacturer, model, and serial number of the source or, if not available,
12.18 other information to uniquely identify the source;
- 12.19 E. the radioactive material in the source;
- 12.20 F. the initial or current source strength in becquerels or curies;
- 12.21 G. the date for which the source strength is reported;
- 12.22 H. the shipping date;
- 12.23 I. the estimated arrival date; and

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

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

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

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

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

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

13.12 E. the radioactive material in the source;

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

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

13.15 H. the date of receipt; and

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

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

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

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

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

14.3 D. the radioactive material in the source;

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

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

14.6 G. the disassemble date of the source.

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

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

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

14.12 C. the waste manifest number;

14.13 D. the container identification with the nationally tracked source;

14.14 E. the date of disposal; and

14.15 F. the method of disposal.

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

14.20 A. using the online National Source Tracking System;

14.21 B. electronically using a computer-readable format;

14.22 C. facsimile;

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

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

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

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

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

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

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

15.25 D. the radioactive material in the sealed source;

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

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

16.3 **4731.2750 ANNUAL LIMITS ON INTAKE AND DERIVED AIR**
16.4 **CONCENTRATIONS.**

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

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

16.7	Name	Symbol	Atomic Number (AN)
16.8	Actinium	Ac	89
16.9	Aluminum	Al	13
16.10	Americium	Am	95
16.11	Antimony	Sb	51
16.12	Argon	Ar	18
16.13	Arsenic	As	33
16.14	Astatine	At	85
16.15	Barium	Ba	56
16.16	Berkelium	Bk	97
16.17	Beryllium	Be	4
16.18	Bismuth	Bi	83
16.19	Bromine	Br	35
16.20	Cadmium	Cd	48
16.21	Calcium	Ca	20
16.22	Californium	Cf	98
16.23	Carbon	C	6
16.24	Cerium	Ce	58
16.25	Cesium	Cs	55
16.26	Chlorine	Cl	17
16.27	Chromium	Cr	24

17.1	Cobalt	Co	27
17.2	Copper	Cu	29
17.3	Curium	Cm	96
17.4	Dysprosium	Dy	66
17.5	Einsteinium	Es	99
17.6	Erbium	Er	68
17.7	Europium	Eu	63
17.8	Fermium	Fm	100
17.9	Fluorine	F	9
17.10	Francium	Fr	87
17.11	Gadolinium	Gd	64
17.12	Gallium	Ga	31
17.13	Germanium	Ge	32
17.14	Gold	Au	79
17.15	Hafnium	Hf	72
17.16	Holmium	Ho	67
17.17	Hydrogen	H	1
17.18	Indium	In	49
17.19	Iodine	I	53
17.20	Iridium	Ir	77
17.21	Iron	Fe	26
17.22	Krypton	Kr	36
17.23	Lanthanum	La	57
17.24	Lead	Pb	82
17.25	Lutetium	Lu	71
17.26	Magnesium	Mg	12

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18.1	Manganese	Mn	25
18.2	Mendelevium	Md	101
18.3	Mercury	Hg	80
18.4	Molybdenum	Mo	42
18.5	Neodymium	Nd	60
18.6	Neptunium	Np	93
18.7	Nickel	Ni	28
18.8	Niobium	Nb	41
18.9	Nitrogen	N	7
18.10	Osmium	Os	76
18.11	Oxygen	O	8
18.12	Palladium	Pd	46
18.13	Phosphorus	P	15
18.14	Platinum	Pt	78
18.15	Plutonium	Pu	94
18.16	Polonium	Po	84
18.17	Potassium	K	19
18.18	Praseodymium	Pr	59
18.19	Promethium	Pm	61
18.20	Protactinium	Pa	91
18.21	Radium	Ra	88
18.22	Radon	Rn	86
18.23	Rhenium	Re	75
18.24	Rhodium	Rh	45
18.25	Rubidium	Rb	37
18.26	Ruthenium	Ru	44
18.27	Samarium	Sm	62
18.28	Scandium	Sc	21

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19.1	Selenium	Se	34
19.2	Silicon	Si	14
19.3	Silver	Ag	47
19.4	Sodium	Na	11
19.5	Strontium	Sr	38
19.6	Sulfur	S	16
19.7	Tantalum	Ta	73
19.8	Technetium	Tc	43
19.9	Tellurium	Te	52
19.10	Terbium	Tb	65
19.11	Thallium	Tl	81
19.12	Thorium	Th	90
19.13	Thulium	Tm	69
19.14	Tin	Sn	50
19.15	Titanium	Ti	22
19.16	Tungsten	W	74
19.17	Uranium	U	92
19.18	Vanadium	V	23
19.19	Xenon	Xe	54
19.20	Ytterbium	Yb	70
19.21	Yttrium	Y	39
19.22	Zinc	Zn	30
19.23	Zirconium	Zr	40

19.24 Subp. 7. Table of ALIs and DACs.

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

20.1	AN 1						
20.2	Hydrogen-3						
20.3	Water, DAC includes skin						
20.4	absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
20.5	Gas (HT or T ₂) submersion ¹ :						
20.6	Use above values as HT and						
20.7	T ₂ oxidize in air and in the						
20.8	body to HTO.						
20.9	AN 4						
20.10	Beryllium-7						
20.11	W, all compounds except						
20.12	those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
20.13	Y, oxides, halides, and						
20.14	nitrates	—	2E+4	8E-6	3E-8	—	—
20.15	Beryllium-10						
20.16	W, see ⁷ Be	1E+3	2E+2	6E-8	2E-10	—	—
20.17		LLI					
20.18		(1E+3)	—	—	2E-5	2E-4	—
20.19	Y, see ⁷ Be	—	1E+1	6E-9	2E-11	—	—
20.20	AN 6						
20.21	Carbon-11 ²						
20.22	Monoxide	—	1E+6	5E-4	2E-6	—	—
20.23	Dioxide	—	6E+5	3E-4	9E-7	—	—
20.24	Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
20.25	Carbon-14						
20.26	Monoxide	—	2E+6	7E-4	2E-6	—	—
20.27	Dioxide	—	2E+5	9E-5	3E-7	—	—

21.1	Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
21.2	AN 7						
21.3	Nitrogen-13 ²						
21.4	Submersion ¹	—	—	4E-6	2E-8	—	—
21.5	AN 8						
21.6	Oxygen-15 ²						
21.7	Submersion ¹	—	—	4E-6	2E-8	—	—

21.8 [The remainder of the table is unchanged.]

21.9 FOOTNOTES:

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

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

21.22 ³For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may
21.23 be the limiting factor according to part 4731.2020, subpart 5. If the percent by
21.24 weight (enrichment) of U-235 is not greater than five, the concentration value for a
21.25 40-hour work week is 0.2 milligrams uranium per cubic meter of air average. For any
21.26 enrichment, the product of the average concentration and time of exposure during a
21.27 40-hour work week must not exceed 8E-3 (SA) µCi-hr/ml, where SA is the specific
21.28 activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7
21.29 curies per gram U. The specific activity for other mixtures of U-238, U-235, and
21.30 U-234, if not known, is:

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

21.32 SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)²] E-6, enrichment > 0.72

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

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

22.3 **4731.2820 NATIONALLY TRACKED SOURCE THRESHOLDS.**

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

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

23.1 **4731.3025 EXEMPTION; CERTAIN CONCENTRATIONS.**

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

23.3 Subp. 3. **Introduction by specific licensee.** A manufacturer, processor, or producer
23.4 of a product or material in an agreement state is exempt from parts 4731.3000 to
23.5 4731.7280 to the extent that:

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

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

23.14 Subp. 4. **Transfer limitations.** No person may introduce radioactive material into
23.15 a product or material knowing or having reason to believe that it will be transferred to
23.16 persons exempt under this part or equivalent regulations of the NRC or an agreement
23.17 state, except according to a specific license issued under Code of Federal Regulations, title
23.18 10, section 32.11.

23.19 **4731.3030 EXEMPTION; CERTAIN ITEMS CONTAINING RADIOACTIVE**
23.20 **MATERIAL.**

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

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

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

24.4 (a) 25 millicuries of tritium per timepiece;

24.5 (b) five millicuries of tritium per hand;

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

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

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

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

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

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

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

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

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

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

25.12 (1) 150 millicuries of tritium per microwave receiver protector tube or ten
25.13 millicuries of tritium per any other electron tube;

25.14 (2) one microcurie of cobalt-60;

25.15 (3) five microcuries of nickel-63;

25.16 (4) 30 microcuries of krypton-85;

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

25.18 (6) 30 microcuries of promethium-147; or

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

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

26.3 (1) each source contains no more than one exempt quantity under part
26.4 4731.3145; and

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

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

26.7 **4731.3040 EXEMPT QUANTITIES.**

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

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

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

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

26.23 **4731.3050 EXEMPTION; GAS AND AEROSOL DETECTORS CONTAINING**
26.24 **RADIOACTIVE MATERIAL.**

27.1 Subpart 1. **Specific license exemption.** Except for persons who manufacture,
27.2 process, produce, or initially transfer for sale or distribution gas and aerosol detectors
27.3 containing radioactive material, a person is exempt from parts 4731.1000 to 4731.2090 and
27.4 4731.3000 to 4731.7280 to the extent that the person receives, possesses, uses, transfers,
27.5 owns, or acquires radioactive material in gas or aerosol detectors designed to protect life
27.6 or property from fires and airborne hazards and manufactured, processed, produced,
27.7 or initially transferred according to a specific license issued under Code of Federal
27.8 Regulations, title 10, section 32.26, that authorizes the initial transfer of the product for
27.9 use under this part. This exemption also covers gas and aerosol detectors manufactured or
27.10 distributed before November 30, 2007, in accordance with a specific license issued by a
27.11 state under comparable provisions to Code of Federal Regulations, title 10, section 32.26,
27.12 authorizing distribution to persons exempt from regulatory requirements.

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

27.14 **4731.3065 SPECIFIC LICENSES; APPLICATION.**

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

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

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

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

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

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

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

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

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

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

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

29.1 C. identification of individuals authorized to prepare the PET radioactive
29.2 drugs if the applicant is a pharmacy, and documentation that each individual meets the
29.3 requirements of an authorized nuclear pharmacist as specified in part 4731.3395, subpart
29.4 2; and

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

29.7 **4731.3075 TERMS AND CONDITIONS OF LICENSES.**

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

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

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

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

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

29.24 (1) satisfy the labeling requirements in part 4731.3395, subpart 1, for each
29.25 PET radioactive drug transport radiation shield and each syringe, vial, or other container

30.1 used to hold a PET radioactive drug intended for noncommercial distribution to members
30.2 of its consortium; and

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

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

30.10 (1) an authorized nuclear pharmacist that meets the requirements in part
30.11 4731.3395, subpart 2; or

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

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

30.18 **4731.3145 EXEMPT QUANTITIES.**

30.19	Radioactive Material	Microcuries
30.20	Antimony 122 (Sb 122)	100
30.21	Antimony 124 (Sb 124)	10
30.22	Antimony 125 (Sb 125)	10
30.23	Arsenic 73 (As 73)	100
30.24	Arsenic 74 (As 74)	10
30.25	Arsenic 76 (As 76)	10
30.26	Arsenic 77 (As 77)	100

31.1	Barium 131 (Ba 131)	10
31.2	Barium 133 (Ba 133)	10
31.3	Barium 140 (Ba 140)	10
31.4	Bismuth 210 (Bi 210)	1
31.5	Bromine 82 (Br 82)	10
31.6	Cadmium 109 (Cd 109)	10
31.7	Cadmium 115m (Cd 115m)	10
31.8	Cadmium 115 (Cd 115)	100
31.9	Calcium 45 (Ca 45)	10
31.10	Calcium 47 (Ca 47)	10
31.11	Carbon 11 (C 11)	1,000
31.12	Carbon 14 (C 14)	100
31.13	Cerium 141 (Ce 141)	100
31.14	Cerium 143 (Ce 143)	100
31.15	Cerium 144 (Ce 144)	1
31.16	Cesium 129 (Cs 129)	100
31.17	Cesium 131 (Cs 131)	1,000
31.18	Cesium 134m (Cs 134m)	100
31.19	Cesium 134 (Cs 134)	1
31.20	Cesium 135 (Cs 135)	10
31.21	Cesium 136 (Cs 136)	10
31.22	Cesium 137 (Cs 137)	10
31.23	Chlorine 36 (Cl 36)	10
31.24	Chlorine 38 (Cl 38)	10
31.25	Chromium 51 (Cr 51)	1,000
31.26	Cobalt 57 (Co 57)	100
31.27	Cobalt 58m (Co 58m)	10
31.28	Cobalt 58 (Co 58)	10
31.29	Cobalt 60 (Co 60)	1

32.1	Copper 64 (Cu 64)	100
32.2	Dysprosium 165 (Dy 165)	10
32.3	Dysprosium 166 (Dy 166)	100
32.4	Erbium 169 (Er 169)	100
32.5	Erbium 171 (Er 171)	100
32.6	Europium 152 9.2 h (Eu 152 9.2 h)	100
32.7	Europium 152 13 yr (Eu 152 13 yr)	1
32.8	Europium 154 (Eu 154)	1
32.9	Europium 155 (Eu 155)	10
32.10	Fluorine 18 (F 18)	1,000
32.11	Gadolinium 153 (Gd 153)	10
32.12	Gadolinium 159 (Gd 159)	100
32.13	Gallium 67 (Ga 67)	100
32.14	Gallium 72 (Ga 72)	10
32.15	Germanium 68 (Ge 68)	10
32.16	Germanium 71 (Ge 71)	100
32.17	Gold 195 (Au 195)	10
32.18	Gold 198 (Au 198)	100
32.19	Gold 199 (Au 199)	100
32.20	Hafnium 181 (Hf 181)	10
32.21	Holmium 166 (Ho 166)	100
32.22	Hydrogen 3 (H 3)	1,000
32.23	Indium 111 (In 111)	100
32.24	Indium 113m (In 113m)	100
32.25	Indium 114m (In 114m)	10
32.26	Indium 115m (In 115m)	100
32.27	Indium 115 (In 115)	10
32.28	Iodine 123 (I 123)	100

33.1	Iodine 125 (I 125)	1
33.2	Iodine 126 (I 126)	1
33.3	Iodine 129 (I 129)	0.1
33.4	Iodine 131 (I 131)	1
33.5	Iodine 132 (I 132)	10
33.6	Iodine 133 (I 133)	1
33.7	Iodine 134 (I 134)	10
33.8	Iodine 135 (I 135)	10
33.9	Iridium 192 (Ir 192)	10
33.10	Iridium 194 (Ir 194)	100
33.11	Iron 52 (Fe 52)	10
33.12	Iron 55 (Fe 55)	100
33.13	Iron 59 (Fe 59)	10
33.14	Krypton 85 (Kr 85)	100
33.15	Krypton 87 (Kr 87)	10
33.16	Lanthanum 140 (La 140)	10
33.17	Lutetium 177 (Lu 177)	100
33.18	Manganese 52 (Mn 52)	10
33.19	Manganese 54 (Mn 54)	10
33.20	Manganese 56 (Mn 56)	10
33.21	Mercury 197m (Hg 197m)	100
33.22	Mercury 197 (Hg 197)	100
33.23	Mercury 203 (Hg 203)	10
33.24	Molybdenum 99 (Mo 99)	100
33.25	Neodymium 147 (Nd 147)	100
33.26	Neodymium 149 (Nd 149)	100
33.27	Nickel 59 (Ni 59)	100
33.28	Nickel 63 (Ni 63)	10

34.1	Nickel 65 (Ni 65)	100
34.2	Niobium 93m (Nb 93m)	10
34.3	Niobium 95 (Nb 95)	10
34.4	Niobium 97 (Nb 97)	10
34.5	Nitrogen 13 (N 13)	1,000
34.6	Osmium 185 (Os 185)	10
34.7	Osmium 191m (Os 191m)	100
34.8	Osmium 191 (Os 191)	100
34.9	Osmium 193 (Os 193)	100
34.10	Oxygen 15 (O 15)	1,000
34.11	Palladium 103 (Pd 103)	100
34.12	Palladium 109 (Pd 109)	100
34.13	Phosphorus 32 (P 32)	10
34.14	Platinum 191 (Pt 191)	100
34.15	Platinum 193m (Pt 193m)	100
34.16	Platinum 193 (Pt 193)	100
34.17	Platinum 197m (Pt 197m)	100
34.18	Platinum 197 (Pt 197)	100
34.19	Polonium 210 (Po 210)	0.1
34.20	Potassium 42 (K 42)	10
34.21	Potassium 43 (K 43)	10
34.22	Praseodymium 142 (Pr 142)	100
34.23	Praseodymium 143 (Pr 143)	100
34.24	Promethium 147 (Pm 147)	10
34.25	Promethium 149 (Pm 149)	10
34.26	Radium 226 (Ra 226)	1
34.27	Rhenium 186 (Re 186)	100
34.28	Rhenium 188 (Re 188)	100
34.29	Rhodium 103m (Rh 103m)	100

35.1	Rhodium 105 (Rh 105)	100
35.2	Rubidium 81 (Rb 81)	10
35.3	Rubidium 86 (Rb 86)	10
35.4	Rubidium 87 (Rb 87)	10
35.5	Ruthenium 97 (Ru 97)	100
35.6	Ruthenium 103 (Ru 103)	10
35.7	Ruthenium 105 (Ru 105)	10
35.8	Ruthenium 106 (Ru 106)	1
35.9	Samarium 151 (Sm 151)	10
35.10	Samarium 153 (Sm 153)	100
35.11	Scandium 46 (Sc 46)	10
35.12	Scandium 47 (Sc 47)	100
35.13	Scandium 48 (Sc 48)	10
35.14	Selenium 75 (Se 75)	10
35.15	Silicon 31 (Si 31)	100
35.16	Silver 105 (Ag 105)	10
35.17	Silver 110m (Ag 110m)	1
35.18	Silver 111 (Ag 111)	100
35.19	Sodium 22 (Na 22)	10
35.20	Sodium 24 (Na 24)	10
35.21	Strontium 85 (Sr 85)	10
35.22	Strontium 89 (Sr 89)	1
35.23	Strontium 90 (Sr 90)	0.1
35.24	Strontium 91 (Sr 91)	10
35.25	Strontium 92 (Sr 92)	10
35.26	Sulfur 35 (S 35)	100
35.27	Tantalum 182 (Ta 182)	10
35.28	Technetium 96 (Tc 96)	10
35.29	Technetium 97m (Tc 97m)	100

36.1	Technetium 97 (Tc 97)	100
36.2	Technetium 99m (Tc 99m)	100
36.3	Technetium 99 (Tc 99)	10
36.4	Tellurium 125m (Te 125m)	10
36.5	Tellurium 127m (Te 127m)	10
36.6	Tellurium 127 (Te 127)	100
36.7	Tellurium 129m (Te 129m)	10
36.8	Tellurium 129 (Te 129)	100
36.9	Tellurium 131m (Te 131m)	10
36.10	Tellurium 132 (Te 132)	10
36.11	Terbium 160 (Tb 160)	10
36.12	Thallium 200 (Tl 200)	100
36.13	Thallium 201 (Tl 201)	100
36.14	Thallium 202 (Tl 202)	100
36.15	Thallium 204 (Tl 204)	10
36.16	Thulium 170 (Tm 170)	10
36.17	Thulium 171 (Tm 171)	10
36.18	Tin 113 (Sn 113)	10
36.19	Tin 125 (Sn 125)	10
36.20	Tungsten 181 (W 181)	10
36.21	Tungsten 185 (W 185)	10
36.22	Tungsten 187 (W 187)	100
36.23	Vanadium 48 (V 48)	10
36.24	Xenon 131m (Xe 131m)	1,000
36.25	Xenon 133 (Xe 133)	100
36.26	Xenon 135 (Xe 135)	100
36.27	Ytterbium 175 (Yb 175)	100
36.28	Yttrium 87 (Y 87)	10
36.29	Yttrium 88 (Y 88)	10

37.1	Yttrium 90 (Y 90)	10
37.2	Yttrium 91 (Y 91)	10
37.3	Yttrium 92 (Y 92)	100
37.4	Yttrium 93 (Y 93)	100
37.5	Zinc 65 (Zn 65)	10
37.6	Zinc 69m (Zn 69m)	100
37.7	Zinc 69 (Zn 69)	1,000
37.8	Zirconium 93 (Zr 93)	10
37.9	Zirconium 95 (Zr 95)	10
37.10	Zirconium 97 (Zr 97)	10
37.11	Any radioactive material not listed above other than alpha- emitting radioactive materials	0.1
37.12		
37.13		

37.14 **4731.3150 RADIOACTIVE MATERIALS; EMERGENCY PLAN QUANTITIES.**

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

37.17		Release	Quantity
37.18	Radioactive material ¹	fraction	(curies)
37.19	Actinium-228	0.001	4,000
37.20	Americium-241	0.001	2
37.21	Americium-242	0.001	2
37.22	Americium-243	0.001	2
37.23	Antimony-124	0.01	4,000
37.24	Antimony-126	0.01	6,000
37.25	Barium-133	0.01	10,000
37.26	Barium-140	0.01	30,000
37.27	Bismuth-207	0.01	5,000
37.28	Bismuth-210	0.01	600

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38.1	Cadmium-109	0.01	1,000
38.2	Cadmium-113	0.01	80
38.3	Calcium-45	0.01	20,000
38.4	Californium-252	0.001	9 (20 mg)
38.5	Carbon-14 (noncarbon dioxide)	0.01	50,000
38.6	Cerium-141	0.01	10,000
38.7	Cerium-144	0.01	300
38.8	Cesium-134	0.01	2,000
38.9	Cesium-137	0.01	3,000
38.10	Chlorine-36	0.5	100
38.11	Chromium-51	0.01	300,000
38.12	Cobalt-60	0.001	5,000
38.13	Copper-64	0.01	200,000
38.14	Curium-242	0.001	60
38.15	Curium-243	0.001	3
38.16	Curium-244	0.001	4
38.17	Curium-245	0.001	2
38.18	Europium-152	0.01	500
38.19	Europium-154	0.01	400
38.20	Europium-155	0.01	3,000
38.21	Germanium-68	0.01	2,000
38.22	Gadolinium-153	0.01	5,000
38.23	Gold-198	0.01	30,000
38.24	Hafnium-172	0.01	400
38.25	Hafnium-181	0.01	7,000
38.26	Holmium-166m	0.01	100
38.27	Hydrogen-3	0.5	20,000
38.28	Iodine-125	0.5	1

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39.1	Iodine-131	0.5	10
39.2	Indium-114m	0.01	1,000
39.3	Iridium-192	0.001	40,000
39.4	Iron-55	0.01	40,000
39.5	Iron-59	0.01	7,000
39.6	Krypton-85	1.0	6,000,000
39.7	Lead-210	0.01	8
39.8	Manganese-56	0.01	60,000
39.9	Mercury-203	0.01	10,000
39.10	Molybdenum-99	0.01	30,000
39.11	Neptunium-237	0.001	2
39.12	Nickel-63	0.01	20,000
39.13	Niobium-94	0.01	300
39.14	Phosphorus-32	0.5	100
39.15	Phosphorus-33	0.5	1,000
39.16	Polonium-210	0.01	10
39.17	Potassium-42	0.01	9,000
39.18	Promethium-145	0.01	4,000
39.19	Promethium-147	0.01	4,000
39.20	Radium-226	0.001	100
39.21	Ruthenium-106	0.01	200
39.22	Samarium-151	0.01	4,000
39.23	Scandium-46	0.01	3,000
39.24	Selenium-75	0.01	10,000
39.25	Silver-110m	0.01	1,000
39.26	Sodium-22	0.01	9,000
39.27	Sodium-24	0.01	10,000

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40.1	Strontium-89	0.01	3,000
40.2	Strontium-90	0.01	90
40.3	Sulfur-35	0.5	900
40.4	Technetium-99	0.01	10,000
40.5	Technetium-99m	0.01	400,000
40.6	Tellurium-127m	0.01	5,000
40.7	Tellurium-129m	0.01	5,000
40.8	Terbium-160	0.01	4,000
40.9	Thulium-170	0.01	4,000
40.10	Tin-113	0.01	10,000
40.11	Tin-123	0.01	3,000
40.12	Tin-126	0.01	1,000
40.13	Titanium-44	0.01	100
40.14	Vanadium-48	0.01	7,000
40.15	Xenon-133	1.0	900,000
40.16	Yttrium-91	0.01	2,000
40.17	Zinc-65	0.01	5,000
40.18	Zirconium-93	0.01	400
40.19	Zirconium-95	0.01	5,000
40.20	Any other beta-gamma emitter	0.01	10,000
40.21	Mixed fission products	0.01	1,000
40.22	Mixed corrosion products	0.01	10,000
40.23	Contaminated equipment,	0.001	10,000
40.24	beta-gamma		
40.25	Irradiated material, any form	0.01	1,000
40.26	other than solid noncombustible		

41.1	Irradiated material, solid		
41.2	noncombustible	0.001	10,000
41.3	Mixed radioactive waste,		
41.4	beta-gamma	0.01	1,000
41.5	Packaged mixed waste,		
41.6	beta-gamma ²	0.001	10,000
41.7	Any other alpha emitter	0.001	2
41.8	Contaminated equipment, alpha	0.0001	20
41.9	Packaged waste, alpha ²	0.0001	20
41.10	Combinations of radioactive materials listed above ¹		

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

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

41.15 **4731.3215 GENERAL LICENSE; DETECTING, MEASURING, GAUGING,**
 41.16 **CONTROLLING, AND OTHER DEVICES.**

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

41.18 **Subp. 2. Applicability.**

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

41.22 (1) a specific license issued under part 4731.3330;

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

41.24 or

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

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

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

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

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

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

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

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

42.22 (4) reports the transfer under item K;

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

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

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

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

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

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

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

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

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

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

43.12 **4731.3230 GENERAL LICENSE; AMERICIUM-241 AND RADIUM-226**
43.13 **CALIBRATION OR REFERENCE SOURCES.**

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

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

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

43.22 Subp. 2. [See repealer.]

43.23 Subp. 3. [See repealer.]

44.1 Subp. 4. **Calibration or reference source requirements.** The general licenses in
44.2 subpart 1 apply only to calibration or reference sources that have been manufactured or
44.3 initially transferred according to a specific license issued to the manufacturer under part
44.4 4731.3365 or by the NRC or an agreement state that authorizes manufacture of the sources
44.5 for distribution to persons generally licensed by an agreement state.

44.6 Subp. 5. **Additional requirements.**

44.7 A. The general licenses issued under this part are subject to parts 4731.0260;
44.8 4731.1000 to 4731.2950; 4731.3025, subpart 4; 4731.3075, subparts 1, 2, 3, 5, and 6; and
44.9 4731.3110 to 4731.3135 and Code of Federal Regulations, title 10, part 21.

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

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

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

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

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

44.25 (Name of manufacturer or initial transferor)";

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

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

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

45.9 C. Sources generally licensed under this part before January 19, 1975, may bear
45.10 labels authorized by the regulations in effect on January 1, 1975. Sources containing
45.11 radium-226 generally licensed under this part and manufactured before November
45.12 30, 2007, must be labeled according to the applicable state regulations at the time of
45.13 manufacture or import.

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

45.17 **4731.3245 GENERAL LICENSE; IN VITRO CLINICAL OR LABORATORY**
45.18 **TESTING USE.**

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

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

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

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

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

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

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

G. mock iodine-125 reference or calibration sources, in units not exceeding 0.05

microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (0.185 kBq) of americium-241

each; and

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

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

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

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

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

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

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

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

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

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

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

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

47.21 B. must not abandon products containing radium-226. The product, and
47.22 any radioactive material from the product, may only be disposed of according to part
47.23 4731.2460 or by transfer to a person authorized by a specific license to receive the
47.24 radium-226 in the product or as otherwise approved by the NRC;

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

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

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

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

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

48.8 E. must respond to written requests from the commissioner to provide
48.9 information relating to the general license within 30 calendar days of the date of the
48.10 request, or other time specified in the request. If the general licensee cannot provide the
48.11 requested information within the allotted time, the licensee must, within that same time
48.12 period, request a longer period to supply the information by providing the commissioner a
48.13 written justification for the request.

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

48.17 **4731.3315 PROHIBITION OF INTRODUCTION.**

48.18 No person may introduce radioactive material in a product or material knowing or
48.19 having reason to believe that it will be transferred to a person that is exempt under part
48.20 4731.3025 or equivalent regulations of the NRC or an agreement state, except according
48.21 to a specific license issued under Code of Federal Regulations, title 10, section 32.11.

48.22 **4731.3365 SPECIFIC LICENSE; CALIBRATION OR REFERENCE SOURCES;**
48.23 **MANUFACTURE OR INITIAL TRANSFER.**

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

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

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

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

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

49.8 (2) details of construction and design;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

50.21 (Name of manufacturer or initial transferor)"

50.22 Sources licensed under Code of Federal Regulations, title 10, before January 19,
50.23 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

50.24 Subp. 3. **Leak testing.**

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

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

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

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

51.12 **4731.3390 SPECIFIC LICENSE; MATERIAL FOR IN VITRO CLINICAL OR**
51.13 **LABORATORY TESTING; MANUFACTURE AND DISTRIBUTION.**

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

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

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

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

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

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

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

51.22 each;

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

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

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

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

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

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

52.6 and

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

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

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

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

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

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

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

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

52.21 "The radioactive material may be received, acquired, possessed, and used only by
52.22 physicians, veterinarians in the practice of veterinary medicine, clinical laboratories,
52.23 or hospitals and only for in vitro clinical or laboratory tests not involving internal
52.24 or external administration of the material, or the radiation therefrom, to human

53.1 beings or animals. Its receipt, acquisition, possession, use, and transfer are subject
53.2 to the regulations and a general license of the Minnesota commissioner of health,
53.3 the Nuclear Regulatory Commission, or a state with which the Nuclear Regulatory
53.4 Commission has entered into an agreement for the exercise of regulatory authority.
53.5 (Name of manufacturer)"; and

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

53.11 **4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE;**
53.12 **MANUFACTURE, PREPARATION, OR TRANSFER.**

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

53.17 A. satisfies the general requirements specified in part 4731.3070;

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

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

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

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

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

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

54.3 C. submits the following information regarding the radionuclide:

54.4 (1) the chemical and physical form;

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

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

54.9 D. satisfies the following labeling requirements:

54.10 (1) a label must be affixed to each transport radiation shield, whether it is
54.11 constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred
54.12 for commercial distribution and include the radiation symbol, the words "CAUTION,
54.13 RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name
54.14 of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specific
54.15 date and time. For a radioactive drug with a half-life greater than 100 days, the time
54.16 may be omitted; and

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

54.23 Subp. 2. **Pharmacy licensees.**

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

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

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

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

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

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

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

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

55.24 **4731.3400 SPECIFIC LICENSE; SOURCES OR DEVICES FOR MEDICAL USE;**
55.25 **MANUFACTURE AND DISTRIBUTION.**

56.1 Subpart 1. **Approval criteria.** An application for a specific license to manufacture
56.2 and distribute sources and devices containing radioactive material to persons licensed
56.3 according to parts 4731.4400 to 4731.4527 for use as a calibration, transmission, or
56.4 reference source or for the uses listed under parts 4731.4404, 4731.4450, 4731.4460, and
56.5 4731.4463 shall be approved if:

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

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

56.8 **4731.3410 PROTOTYPE TESTS; CALIBRATION OR REFERENCE SOURCES**
56.9 **CONTAINING AMERICIUM-241 OR RADIUM-226.**

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

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

56.16 **4731.3450 SERIALIZATION OF NATIONALLY TRACKED SOURCES.**

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

56.20 **4731.3580 LIMITS FOR BROAD SCOPE LICENSES.**

56.21 The following limits apply to specific licenses of broad scope issued under parts
56.22 4731.3500 to 4731.3580:

56.23		Column I	Column II
56.24	Radioactive Material	curies	curies
56.25	Antimony-122	1	0.01

57.1	Antimony-124	1	0.01
57.2	Antimony-125	1	0.01
57.3	Arsenic-73	10	0.1
57.4	Arsenic-74	1	0.01
57.5	Arsenic-76	1	0.01
57.6	Arsenic-77	10	0.1
57.7	Barium-131	10	0.1
57.8	Barium-140	1	0.01
57.9	Beryllium-7	10	0.1
57.10	Bismuth-210	0.1	0.001
57.11	Bromine-82	10	0.1
57.12	Cadmium-109	1	0.01
57.13	Cadmium-115m	1	0.01
57.14	Cadmium-115	10	0.1
57.15	Calcium-45	1	0.01
57.16	Calcium-47	10	0.1
57.17	Carbon-14	100	1
57.18	Cerium-141	10	0.1
57.19	Cerium-143	10	0.1
57.20	Cerium-144	0.1	0.001
57.21	Cesium-131	100	1
57.22	Cesium-134m	100	1
57.23	Cesium-134	0.1	0.001
57.24	Cesium-135	1	0.01
57.25	Cesium-136	10	0.1
57.26	Cesium-137	0.1	0.001
57.27	Chlorine-36	1	0.01
57.28	Chlorine-38	100	1
57.29	Chromium-51	100	1

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58.1	Cobalt-57	10	0.1
58.2	Cobalt-58m	100	1
58.3	Cobalt-58	1	0.01
58.4	Cobalt-60	0.1	0.001
58.5	Copper-64	10	0.1
58.6	Dysprosium-165	100	1
58.7	Dysprosium-166	10	0.1
58.8	Erbium-169	10	0.1
58.9	Erbium-171	10	0.1
58.10	Europium-152 9.2 h	10	0.1
58.11	Europium-152 13 y	0.1	0.001
58.12	Europium-154	0.1	0.001
58.13	Europium-155	1	0.01
58.14	Fluorine-18	100	1
58.15	Gadolinium-153	1	0.01
58.16	Gadolinium-159	10	0.1
58.17	Gallium-72	10	0.1
58.18	Germanium-71	100	1
58.19	Gold-198	10	0.1
58.20	Gold-199	10	0.1
58.21	Hafnium-181	1	0.01
58.22	Holmium-166	10	0.1
58.23	Hydrogen-3	100	1
58.24	Indium-113m	100	1
58.25	Indium-114m	1	0.01
58.26	Indium-115m	100	1
58.27	Indium-115	1	0.01
58.28	Iodine-125	0.1	0.001

59.1	Iodine-126	0.1	0.001
59.2	Iodine-129	0.1	0.01
59.3	Iodine-131	0.1	0.001
59.4	Iodine-132	10	0.1
59.5	Iodine-133	1	0.01
59.6	Iodine-134	10	0.1
59.7	Iodine-135	1	0.01
59.8	Iridium-192	1	0.01
59.9	Iridium-194	10	0.1
59.10	Iron-55	10	0.1
59.11	Iron-59	1	0.01
59.12	Krypton-85	100	1
59.13	Krypton-87	10	0.1
59.14	Lanthanum-140	1	0.01
59.15	Lutetium-177	10	0.1
59.16	Manganese-52	1	0.01
59.17	Manganese-54	1	0.01
59.18	Manganese-56	10	0.1
59.19	Mercury-197m	10	0.1
59.20	Mercury-197	10	0.1
59.21	Mercury-203	1	0.01
59.22	Molybdenum-99	10	0.1
59.23	Neodymium-147	10	0.1
59.24	Neodymium-149	10	0.1
59.25	Nickel-59	10	0.1
59.26	Nickel-63	1	0.01
59.27	Nickel-65	10	0.1
59.28	Niobium-93m	1	0.01

60.1	Niobium-95	1	0.01
60.2	Niobium-97	100	1
60.3	Osmium-185	1	0.01
60.4	Osmium-191m	100	1
60.5	Osmium-191	10	0.1
60.6	Osmium-193	10	0.1
60.7	Palladium-103	10	0.1
60.8	Palladium-109	10	0.1
60.9	Phosphorus-32	1	0.01
60.10	Platinum-191	10	0.1
60.11	Platinum-193m	100	1
60.12	Platinum-193	10	0.1
60.13	Platinum-197m	100	1
60.14	Platinum-197	10	0.1
60.15	Polonium-210	0.01	0.0001
60.16	Potassium-42	1	0.01
60.17	Praseodymium-142	10	0.1
60.18	Praseodymium-143	10	0.1
60.19	Promethium-147	1	0.01
60.20	Promethium-149	10	0.1
60.21	Radium-226	0.01	0.0001
60.22	Rhenium-186	10	0.1
60.23	Rhenium-188	10	0.1
60.24	Rhodium-103m	1,000	10
60.25	Rhodium-105	10	0.1
60.26	Rubidium-86	1	0.01
60.27	Rubidium-87	1	0.01
60.28	Ruthenium-97	100	1
60.29	Ruthenium-103	1	0.01

61.1	Ruthenium-105	10	0.1
61.2	Ruthenium-106	0.1	0.001
61.3	Samarium-151	1	0.01
61.4	Samarium-153	10	0.1
61.5	Scandium-46	1	0.01
61.6	Scandium-47	10	0.1
61.7	Scandium-48	1	0.01
61.8	Selenium-75	1	0.01
61.9	Silicon-31	10	0.1
61.10	Silver-105	1	0.01
61.11	Silver-110m	0.1	0.001
61.12	Silver-111	10	0.1
61.13	Sodium-22	0.1	0.001
61.14	Sodium-24	1	0.01
61.15	Strontium-85m	1,000	10
61.16	Strontium-85	1	0.01
61.17	Strontium-89	1	0.01
61.18	Strontium-90	0.01	0.0001
61.19	Strontium-91	10	0.1
61.20	Strontium-92	10	0.1
61.21	Sulfur-35	10	0.1
61.22	Tantalum-182	1	0.01
61.23	Technetium-96	10	0.1
61.24	Technetium-97m	10	0.1
61.25	Technetium-97	10	0.1
61.26	Technetium-99m	100	1
61.27	Technetium-99	1	0.01
61.28	Tellurium-125m	1	0.01
61.29	Tellurium-127m	1	0.01

62.1	Tellurium-127	10	0.1
62.2	Tellurium-129m	1	0.01
62.3	Tellurium-129	100	1
62.4	Tellurium-131m	10	0.1
62.5	Tellurium-132	1	0.01
62.6	Terbium-160	1	0.01
62.7	Thallium-200	10	0.1
62.8	Thallium-201	10	0.1
62.9	Thallium-202	10	0.1
62.10	Thallium-204	1	0.01
62.11	Thulium-170	1	0.01
62.12	Thulium-171	1	0.01
62.13	Tin-113	1	0.01
62.14	Tin-125	1	0.01
62.15	Tungsten-181	1	0.01
62.16	Tungsten-185	1	0.01
62.17	Tungsten-187	10	0.1
62.18	Vanadium-48	1	0.01
62.19	Xenon-131m	1,000	10
62.20	Xenon-133	100	1
62.21	Xenon-135	100	1
62.22	Ytterbium-175	10	0.1
62.23	Yttrium-90	1	0.01
62.24	Yttrium-91	1	0.01
62.25	Yttrium-92	10	0.1
62.26	Yttrium-93	1	0.01
62.27	Zinc-65	1	0.01
62.28	Zinc-69m	10	0.1

63.1	Zinc-69	100	1
63.2	Zirconium-93	1	0.01
63.3	Zirconium-95	1	0.01
63.4	Zirconium-97	1	0.01
63.5	Any radioactive material		
63.6	other than alpha-emitting		
63.7	byproduct material not		
63.8	listed above	0.1	0.001

63.9 **4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE**
 63.10 **MATERIALS.**

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

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

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

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

63.23 (1) on a license issued by the NRC or an agreement state or on an equivalent
 63.24 permit or license recognized by the commissioner, the NRC, or an agreement state that
 63.25 authorizes the use of radioactive material in medical use or in the practice of nuclear
 63.26 pharmacy;

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

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

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

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

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

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

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

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

64.15 (4) the licensee has added to or changed the areas of use identified in the
64.16 application or license where radioactive material is used according to part 4731.4432 or
64.17 4731.4434; or

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

64.22 B. A licensee must mail required documents to the address under part
64.23 4731.0200, subpart 4.

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

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

65.6 B. subpart 3, item B;

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

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

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

65.14 F. part 4731.4410, item A.

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

65.16 **4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN**
65.17 **DIRECTIVE.**

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

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

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

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

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

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

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

66.5 **4731.4420 MEASURING ACTIVITY OF UNSEALED RADIOACTIVE**
66.6 **MATERIAL; INSTRUMENTS REQUIRED.**

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

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

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

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

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

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

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

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

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

- 67.1 (2) the date of the check or test;
- 67.2 (3) the results of the check or test; and
- 67.3 (4) the name of the individual performing the check or test.

67.4 **4731.4422 DETERMINATION OF DOSAGES; UNSEALED RADIOACTIVE**
67.5 **MATERIAL.**

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

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

- 67.9 (1) direct measurement of radioactivity; or
- 67.10 (2) a decay correction, based on the activity or activity concentration
67.11 determined by:

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

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

67.17 (c) a PET radioactive drug producer licensed according to part
67.18 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state.

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

- 67.20 (1) direct measurement of radioactivity;
- 67.21 (2) a combination of measurement of radioactivity and mathematical
67.22 calculations;

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

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

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

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

68.11 **4731.4429 DECAY-IN-STORAGE.**

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

68.15 **4731.4432 UNSEALED RADIOACTIVE MATERIAL; UPTAKE, DILUTION,**
68.16 **AND EXCRETION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.**

68.17 Except for quantities that require a written directive under part 4731.4408 or
68.18 4731.4409, a licensee may use any unsealed radioactive material prepared for medical use
68.19 for uptake, dilution, or excretion studies that is:

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

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

68.25 (1) an authorized nuclear pharmacist;

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

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

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

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

69.14 **4731.4434 UNSEALED RADIOACTIVE MATERIAL; IMAGING AND**
69.15 **LOCALIZATION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.**

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

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

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

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

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

70.1 **4731.4435 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND**
70.2 **STRONTIUM-85 CONCENTRATION.**

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

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

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

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

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

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

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

70.23 **4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE**
70.24 **REQUIRED.**

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

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

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

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

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

71.14 **4731.4509 MOLYBDENUM-99, STRONTIUM-82, and STRONTIUM-85**
71.15 **CONCENTRATION RECORDS.**

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

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

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

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

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

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

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

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

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

72.7 **REPEALER.** Minnesota Rules, parts 4731.3035; 4731.3230, subparts 2 and 3;
72.8 4731.3305; 4731.3320; and 4731.4508, are repealed.