

1.1 **Department of Health**

1.2 **Proposed Permanent Rules Governing Radiation Safety**

1.3 **4731.0590 LICENSE CONDITIONS.**

1.4 Subpart 1. **Required conditions.** A specific license issued under parts 4731.0525 to  
1.5 4731.0630 must contain and be subject to the following conditions:

1.6 A. no right to the special nuclear material shall be conferred by the license except  
1.7 as defined by the license;

1.8 B. neither the license nor any right under the license shall be assigned or otherwise  
1.9 transferred in violation of this chapter; and

1.10 C. the license is subject to and the licensee must observe, all applicable rules and  
1.11 orders of the commissioner.

1.12 Subp. 2. **Bankruptcy.**

1.13 A. A licensee under parts 4731.0525 to 4731.0630 must notify the commissioner,  
1.14 in writing, immediately following the filing of a voluntary or involuntary petition for  
1.15 bankruptcy under any chapter of United States Code, title 11, by or against:

1.16 (1) the licensee;

1.17 (2) an entity, ~~which includes a person, estate, trust, governmental unit, or~~  
1.18 ~~United States trustee~~ as defined under United States Code, title 11, section 101(15), that  
1.19 controls the licensee or lists the license or licensee as property of the estate; or

1.20 (3) an affiliate of the licensee, as defined under United States Code, chapter  
1.21 11, section 101, clause (2).

1.22 B. The bankruptcy notification must indicate the bankruptcy court in which the  
1.23 petition for bankruptcy was filed and the date of the filing of the petition.

2.1 Subp. 3. **Additional conditions.** The commissioner may incorporate in any license  
2.2 such additional conditions and requirements with respect to the licensee's ownership, receipt,  
2.3 possession, use, and transfer of special nuclear material as the commissioner deems  
2.4 appropriate or necessary to protect health or to minimize danger to life or property.

2.5 Subp. 4. **Additional requirements.** The commissioner may require reports, record  
2.6 keeping, and inspections of activities under the license as may be necessary or appropriate  
2.7 to effectuate the purposes of this chapter.

2.8 **4731.4413 AUTHORIZED NUCLEAR PHARMACIST TRAINING.**

2.9 Subpart 1. **Training and education requirements.** Except as provided in part  
2.10 4731.4414, a licensee must require an authorized nuclear pharmacist to be a pharmacist  
2.11 who:

2.12 A. is certified by a specialty board whose certification process has been recognized  
2.13 by the NRC or an agreement state. The names of board certifications that have been  
2.14 recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee  
2.15 Toolkit web page; or

2.16 B. (1) has completed 700 hours in a structured educational program consisting  
2.17 of both:

2.18 (a) 200 hours of classroom and laboratory training in the following areas:

2.19 i. radiation physics and instrumentation;

2.20 ii. radiation protection;

2.21 iii. mathematics pertaining to the use and measurement of  
2.22 radioactivity;

2.23 iv. chemistry of radioactive material for medical use; and

2.24 v. radiation biology; and

- 3.1 (b) supervised practical experience in a nuclear pharmacy involving:
- 3.2 i. shipping, receiving, and performing related radiation surveys;
- 3.3 ii. using and performing checks for proper operation of instruments
- 3.4 used to determine the activity of dosages, survey meters, and, if appropriate, instruments
- 3.5 used to measure alpha- or beta-emitting radionuclides;
- 3.6 iii. calculating, assaying, and safely preparing dosages for patients
- 3.7 or human research subjects;
- 3.8 iv. using administrative controls to avoid medical events in the
- 3.9 administration of radioactive material; and
- 3.10 v. using procedures to prevent or minimize radioactive contamination
- 3.11 and using proper decontamination procedures; and

3.12 (2) has obtained written attestation signed by a preceptor authorized nuclear

3.13 pharmacist, that the individual has satisfactorily completed the requirements in this item

3.14 and is able to independently fulfill the radiation safety-related duties as an authorized nuclear

3.15 pharmacist.

3.16 Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A,

3.17 shall require all candidates for certification to:

3.18 A. have graduated from a pharmacy program accredited by the Accreditation

3.19 Council for Pharmacy Education (ACPE), previously named the American Council on

3.20 Pharmaceutical Education (ACPE), or have passed the Foreign Pharmacy Graduate

3.21 Examination Committee (FPGEC) examination;

3.22 B. hold a current, active license to practice pharmacy;

4.1 C. provide evidence of having acquired at least 4,000 hours of training or  
4.2 experience in nuclear pharmacy practice. Academic training may be substituted for no more  
4.3 than 2,000 hours of the required training and experience; and

4.4 D. pass an examination in nuclear pharmacy, administered by diplomates of the  
4.5 specialty board, that assesses knowledge and competency in procurement, compounding,  
4.6 quality assurance, dispensing, distribution, health and safety, radiation safety, provision of  
4.7 information and consultation, monitoring patient outcomes, research, and development.

4.8 **4731.4414 TRAINING; EXPERIENCED RADIATION SAFETY OFFICER,**  
4.9 **TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND**  
4.10 **NUCLEAR PHARMACIST.**

4.11 A. An individual identified as a radiation safety officer, a teletherapy or medical  
4.12 physicist, or a nuclear pharmacist on a license issued by the NRC or an agreement state; a  
4.13 permit issued by an NRC or agreement state broad scope licensee; a master material license  
4.14 permit; or a permit issued by a master material license permittee of broad scope before  
4.15 January 14, 2019, need not comply with the training requirements under parts 4731.4411,  
4.16 4731.4412, or 4731.4413, respectively, except a radiation safety officer or authorized medical  
4.17 physicist identified in this item must meet the training requirements in part 4731.4411,  
4.18 subpart 1, item A, subitem (2), or 4731.4412, subpart 1, item A, subitem (2), as appropriate,  
4.19 for any material or uses for which they were not authorized prior to this date.

4.20 B. An individual certified by the American Board of Health Physics in  
4.21 Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear  
4.22 Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical  
4.23 Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology  
4.24 physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American  
4.25 Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine  
4.26 before October 24, 2005, need not comply with the training requirements of part 4731.4411  
4.27 to be identified as a radiation safety officer or as an associate radiation safety officer on a

5.1 commission or an agreement state license or commission master material license permit for  
5.2 those materials and uses that these individuals performed before October 24, 2005.

5.3 C. An individual certified by the American Board of Radiology in therapeutic  
5.4 radiological physics, roentgen ray and gamma ray physics, x-ray and radium physics, or  
5.5 radiological physics, or certified by the American Board of Medical Physics in radiation  
5.6 oncology physics before October 24, 2005, need not comply with the training requirements  
5.7 for an authorized medical physicist in part 4731.4412 for those materials and uses that these  
5.8 individuals performed before October 24, 2005.

5.9 D. Physicians, dentists, or podiatrists identified as authorized users for the medical  
5.10 use of radioactive material on a license issued by the NRC or an agreement state; a permit  
5.11 issued by an NRC master material licensee; a permit issued by an NRC or agreement state  
5.12 broad scope licensee; or a permit issued by an NRC master material license broad scope  
5.13 permittee before January 14, 2019, who perform only those medical uses for which they  
5.14 were authorized on that date, need not comply with the training requirements of parts  
5.15 4731.4432 to 4731.4479.

5.16 E. Physicians, dentists, or podiatrists not identified as authorized users for the  
5.17 medical use of radioactive material on a license issued by the NRC or an agreement state,  
5.18 a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement  
5.19 state broad scope licensee, or a permit issued by in accordance with an NRC master material  
5.20 ~~license~~ broad scope permittee license before October 24, 2005, need not comply with the  
5.21 training requirements of parts 4731.4432 to 4731.4479 for those materials and uses that  
5.22 these individuals performed before October 24, 2005, as follows:

5.23 (1) for uses authorized under part 4731.4432 or 4731.4434, or oral  
5.24 administration of sodium iodide I-131 requiring a written directive for imaging and  
5.25 localization purposes, a physician who was certified before October 24, 2005, in nuclear  
5.26 medicine by the American Board of Nuclear Medicine, diagnostic radiology by the American

6.1 Board of Radiology, diagnostic radiology or radiology by the American Osteopathic Board  
6.2 of Radiology, nuclear medicine by the Royal College of Physicians and Surgeons of Canada,  
6.3 or the American Osteopathic Board of Nuclear Medicine in nuclear medicine;

6.4 (2) for uses authorized under part 4731.4440, a physician who was certified  
6.5 before October 24, 2005, by the American Board of Nuclear Medicine; the American Board  
6.6 of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine  
6.7 by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic  
6.8 Board of Radiology after 1984;

6.9 (3) for uses authorized under part 4731.4450 or 4731.4463, a physician who  
6.10 was certified before October 24, 2005, in radiology, therapeutic radiology, or radiation  
6.11 oncology by the American Board of Radiology; radiation oncology by the American  
6.12 Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British  
6.13 "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or  
6.14 therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

6.15 (4) for uses authorized under part 4731.4460, a physician who was certified  
6.16 before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or  
6.17 radiation oncology by the American Board of Radiology; nuclear medicine by the American  
6.18 Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic  
6.19 Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons  
6.20 of Canada.

6.21 F. Individuals who need not comply with training requirements described in this  
6.22 part may serve as preceptors for, and supervisors of, applicants seeking authorization on  
6.23 licenses issued under this chapter for the same uses for which these individuals are authorized.

7.1 **4731.8025 REQUIREMENTS FOR CRIMINAL HISTORY RECORDS CHECKS**  
7.2 **OF INDIVIDUALS GRANTED UNESCORTED ACCESS TO CATEGORY 1 OR**  
7.3 **CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL.**

7.4 Subpart 1. **General performance objective and requirements.**

7.5 A. Except for those individuals listed in part 4731.8030 and those individuals  
7.6 grandfathered under part 4731.8020, subpart 2, each licensee subject to the provisions of  
7.7 parts 4731.8010 to 4731.8040 must fingerprint each individual who is to be permitted  
7.8 unescorted access to category 1 or category 2 quantities of radioactive material. Licensees  
7.9 must transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee  
7.10 must use the information received from the FBI as part of the required background  
7.11 investigation to determine whether to grant or deny further unescorted access to category  
7.12 1 or category 2 quantities of radioactive materials for that individual.

7.13 B. The licensee must notify each affected individual that fingerprints are used to  
7.14 secure a review of the individual's criminal history record, and must inform the individual  
7.15 of the procedures for revising the record or adding explanations to the record.

7.16 C. Fingerprinting is not required if a licensee is reinstating an individual's  
7.17 unescorted access authorization to category 1 or category 2 quantities of radioactive materials  
7.18 if:

7.19 (1) the individual returns to the same facility that granted unescorted access  
7.20 authorization within 365 days of the termination of the individual's unescorted access  
7.21 authorization; and

7.22 (2) the previous access was terminated under favorable conditions.

7.23 D. Fingerprints do not need to be taken if an individual who is an employee of a  
7.24 licensee, contractor, manufacturer, or supplier has been granted unescorted access to category  
7.25 1 or category 2 quantities of radioactive material, access to safeguards information, or  
7.26 safeguards information-modified handling by another licensee, based upon a background

8.1 investigation conducted under parts 4731.8010 to 4731.8040, the Fingerprint Orders, or  
8.2 Code of Federal Regulations, title 10, part 73. An existing criminal history records check  
8.3 file may be transferred to the licensee asked to grant unescorted access in accordance with  
8.4 the provisions of part 4731.8035, item C.

8.5 E. Licensees must use the information obtained as part of a criminal history records  
8.6 check solely for the purpose of determining an individual's suitability for unescorted access  
8.7 authorization to category 1 or category 2 quantities of radioactive materials, access to  
8.8 safeguards information, or safeguards information-modified handling.

8.9 **Subp. 2. Prohibitions.**

8.10 A. Licensees shall not base a final determination to deny an individual unescorted  
8.11 access authorization to category 1 or category 2 quantities of radioactive material solely on  
8.12 the basis of information received from the FBI involving:

8.13 (1) an arrest more than one year old for which there is no information of the  
8.14 disposition of the case; or

8.15 (2) an arrest that resulted in dismissal of the charge or an acquittal.

8.16 B. Licensees shall not use information received from a criminal history records  
8.17 check obtained under parts 4731.8010 to 4731.8040 in a manner that would infringe upon  
8.18 the rights of any individual under the First Amendment to the Constitution of the United  
8.19 States, nor shall licensees use the information in any way that would discriminate among  
8.20 individuals on the basis of race, religion, national origin, gender, or age.

8.21 **Subp. 3. Procedures for processing of fingerprint checks.**

8.22 A. For the purpose of complying with parts 4731.8010 to 4731.8040, licensees  
8.23 must submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical  
8.24 and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail  
8.25 Stop T-8B20 T-07D04M, Rockville, MD 20852, one completed, legible standard fingerprint



9.1 card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable,  
 9.2 other fingerprint record for each individual requiring unescorted access to category 1 or  
 9.3 category 2 quantities of radioactive material. Copies of these forms may be obtained by  
 9.4 emailing [MAILSVS.Resource@nrc.gov](mailto:MAILSVS.Resource@nrc.gov). Guidance on submitting electronic fingerprints  
 9.5 can be found at <https://www.nrc.gov/security/chp.html>.

9.6 B. Fees for the processing of fingerprint checks are due upon application. Licensees  
 9.7 must submit payment with the application for the processing of fingerprints through corporate  
 9.8 check, certified check, cashier's check, money order, or electronic payment, made payable  
 9.9 to "U.S. NRC." For guidance on making electronic payments, contact the, Division of  
 9.10 Physical and Cyber Security Policy by emailing [crimhist.resource@nrc.gov](mailto:crimhist.resource@nrc.gov). Combined  
 9.11 payment for multiple applications is acceptable. The NRC publishes the amount of the  
 9.12 fingerprint check application fee on the NRC public website. To find the current fee amount,  
 9.13 go to the Licensee Criminal History Records Checks & Firearms Background Check  
 9.14 information page at <https://www.nrc.gov/security/chp.html> and see the link for "How do I  
 9.15 determine how much to pay for the request?".

9.16 C. The commission must forward to the submitting licensee all data received from  
 9.17 the FBI as a result of the licensee's applications for criminal history records checks.

9.18 **4731.8140 CATEGORY 1 AND CATEGORY 2 RADIOACTIVE MATERIALS.**

9.19 Subpart 1. **Table 1 - category 1 and category 2 threshold.** The Terabecquerel (TBq)  
 9.20 values are the regulatory standard. The curie (Ci) values specified are obtained by converting  
 9.21 from the TBq value. The Ci values are provided for practical usefulness only.

9.22 <b>Radioactive</b>	9.23 <b>Category 1</b>	9.23 <b>Category 1</b>	9.23 <b>Category 2</b>	9.23 <b>Category 2</b>
9.23 <b>material</b>	9.23 <b>(TBq)</b>	9.23 <b>(Ci)</b>	9.23 <b>(TBq)</b>	9.23 <b>(Ci)</b>
9.24 Americium-241	60	1,620	0.6	16.2
9.25 Americium-241/Be	60	1,620	0.6	16.2
9.26 Californium-252	20	540	0.2	5.40

10.1	Cobalt-60	30	810	0.3	8.10
10.2	Curium-244	50	1,350	0.5	13.5
10.3	Cesium-137	100	2,700	1	27.0
10.4	Gadolinium-153	1,000	27,000	10	270
10.5	Iridium-192	80	2,160	0.8	21.6
10.6	Plutonium-238	60	1,620	0.6	16.2
10.7	Plutonium-239/Be	60	1,620	0.6	16.2
10.8	Promethium-147	40,000	1,080,000	400	10,800
10.9	Radium-226	40	1,080	0.4	10.8
10.10	Selenium-75	200	5,400	2	54.0
10.11	Strontium-90	1,000	27,000	10	270
10.12	Thulium-170	20,000	540,000	200	5,400
10.13	Ytterbium-169	300	8,100	3	81.0

10.14           **Subp. 2. Calculations concerning multiple sources or multiple radionuclides.** The  
10.15 "sum of fractions" methodology for evaluating combinations of multiple sources or multiple  
10.16 radionuclides, described in items A and B, is to be used in determining whether a location  
10.17 meets or exceeds the threshold and is thus subject to the requirements of parts 4731.8000 to  
10.18 4731.8140.

10.19           A. If multiple sources of the same radionuclide and/or multiple radionuclides are  
10.20 aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides  
10.21 must be determined to verify whether the activity at the location is less than the category 1  
10.22 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using  
10.23 the equation below, is greater than or equal to 1.0, then the applicable requirements of parts  
10.24 4731.8000 to 4731.8140 apply.

10.25           B. First determine the total activity for each radionuclide from Table 1. This is  
10.26 done by adding the activity of each individual source, material in any device, and any loose  
10.27 or bulk material that contains the radionuclide. Then use the equation in this item to calculate

- 11.1 the sum of the ratios by inserting the total activity of the applicable radionuclides from  
11.2 Table 1 in the numerator of the equation and the corresponding threshold activity from  
11.3 Table 1 in the denominator of the equation. Calculations must be performed in metric values  
11.4 (i.e., TBq) and the numerator and denominator values must be in the same units.

$$\sum_{1}^{n} \left[ \frac{R1}{AR1} + \frac{R2}{AR2} + \frac{Rn}{ARn} \right] \geq 1.0$$

11.5 Where,

11.6 R1 = total activity for radionuclide 1

11.7 R2 = total activity for radionuclide 2

11.8 Rn = total activity for radionuclide n

11.9 AR1 = activity threshold for radionuclide 1

11.10 AR2 = activity threshold for radionuclide 2

11.11 ARn = activity threshold for radionuclide n

11.12 **REPEALER.** Minnesota Rules, part 4731.2705, subpart 9, is repealed.