

Office of the Revisor of Statutes

Administrative Rules



TITLE: Adopted Permanent Rules Governing Radiation Safety

AGENCY: Department of Health

REVISOR ID: R-4793

MINNESOTA RULES: Chapter 4731

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

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1.1 **Department of Health**

1.2 **Adopted Permanent Rules Governing Radiation Safety**

1.3 **4731.0590 LICENSE CONDITIONS.**

1.4 *[For text of subpart 1, see Minnesota Rules]*

1.5 **Subp. 2. Bankruptcy.**

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

1.9 (1) the licensee;

1.10 (2) an entity, as defined under United States Code, title 11, section 101, clause
1.11 (15), that controls the licensee or lists the license or licensee as property of the estate; or

1.12 (3) an affiliate, as defined under United States Code, title 11, section 101,
1.13 clause (2), of the licensee.

1.14 *[For text of item B, see Minnesota Rules]*

1.15 *[For text of subparts 3 and 4, see Minnesota Rules]*

1.16 **4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE;**
1.17 **MANUFACTURE, PREPARATION, OR TRANSFER.**

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

1.22 *[For text of item A, see Minnesota Rules]*

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

(1) registered or licensed with the United States Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under Code of Federal Regulations, title 21, section 207.17(a);

[For text of subitems (2) to (5), see Minnesota Rules]

[For text of items C and D, see Minnesota Rules]

[For text of subparts 2 to 4, see Minnesota Rules]

4731.4413 AUTHORIZED NUCLEAR PHARMACIST TRAINING.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

A. have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE), previously named the American Council on Pharmaceutical Education, or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

[For text of items B to D, see Minnesota Rules]

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

A. An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a license issued by the NRC or an agreement state; a permit issued by an NRC or agreement state broad scope licensee; a master material license permit; or a permit issued by a master material license permittee of broad scope on or before January 14, 2019, need not comply with the training requirements under parts 4731.4411, 4731.4412, or 4731.4413, respectively, except a radiation safety officer or authorized medical

physicist identified in this item must meet the training requirements in part 4731.4411, subpart 1, item A, subitem (2), or 4731.4412, subpart 1, item A, subitem (2), as appropriate, for any material or uses for which they were not authorized prior to this date.

B. An individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of part 4731.4411 to be identified as a radiation safety officer or as an associate radiation safety officer on a commission or an agreement state license or commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

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

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

4.1 E. Physicians, dentists, or podiatrists not identified as authorized users for the
4.2 medical use of radioactive material on a license issued by the NRC or an agreement state,
4.3 a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement
4.4 state broad scope licensee, or a permit issued in accordance with an NRC master material
4.5 broad scope license on or before October 24, 2005, need not comply with the training
4.6 requirements of parts 4731.4432 to 4731.4479 for those materials and uses that these
4.7 individuals performed on or before October 24, 2005, as follows:

4.8 (1) for uses authorized under part 4731.4432 or 4731.4434, or oral
4.9 administration of sodium iodide I-131 requiring a written directive for imaging and
4.10 localization purposes, a physician who was certified on or before October 24, 2005, in
4.11 nuclear medicine by the American Board of Nuclear Medicine, diagnostic radiology by the
4.12 American Board of Radiology, diagnostic radiology or radiology by the American
4.13 Osteopathic Board of Radiology, nuclear medicine by the Royal College of Physicians and
4.14 Surgeons of Canada, or the American Osteopathic Board of Nuclear Medicine in nuclear
4.15 medicine;

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

4.21 (3) for uses authorized under part 4731.4450 or 4731.4463, a physician who
4.22 was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation
4.23 oncology by the American Board of Radiology; radiation oncology by the American
4.24 Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British
4.25 "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
4.26 therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

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

[For text of item F, see Minnesota Rules]

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

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. Procedures for processing of fingerprint checks.

A. For the purpose of complying with parts 4731.8010 to 4731.8040, licensees must submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-07D04M, Rockville, MD 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <https://www.nrc.gov/security/chp.html>.

[For text of items B and C, see Minnesota Rules]

4731.8140 CATEGORY 1 AND CATEGORY 2 RADIOACTIVE MATERIALS.

[For text of subpart 1, see Minnesota Rules]

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

[For text of item A, see Minnesota Rules]

B. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation in this item to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

$$\frac{R1}{AR1} + \frac{R2}{AR2} + \cdots + \frac{Rn}{ARn} \geq 1.0$$

Where,

R1 = total activity for radionuclide 1

R2 = total activity for radionuclide 2

Rn = total activity for radionuclide n

AR1 = activity threshold for radionuclide 1

AR2 = activity threshold for radionuclide 2

ARn = activity threshold for radionuclide n

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