4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of unsealed radioactive material for the uses authorized under part 4731.4440 to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and meets the requirements in item B, subitem (1), unit (b), subunit vi. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. has:

(1) completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(a) classroom and laboratory training in:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. chemistry of radioactive material for medical use; and

v. radiation biology; and

(b) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state. A supervising authorized user who meets the requirements in this item must also have experience in administering dosages in the same dosage category or categories under subunit vi as the individual requesting authorized user status. The work experience must involve:

i. ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

iii. calculating, measuring, and safely preparing patient or human research subject dosages;

iv. using administrative controls to prevent a medical event involving the use of radioactive material;

v. using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and

vi. administering dosages of radioactive drugs to patients or human research subjects from the three categories in this subunit. Radioactive drugs containing radionuclides in categories not included in this subunit are regulated under part 4731.4404. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status: oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required; oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) (experience with at least three cases also satisfies the requirement of oral administration of less than or equal to 33 millicuries of I-131); parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon energy of less than 150 kilo electron volts for which a written directive is required; and

(2) obtained written attestation that the individual has satisfactorily completed the requirements in this item and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under part 4731.4440 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state; has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitem (1).

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

A. successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subpart 1, item B, subitem (1), units (a) and (b), subunits i to v. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

B. pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 32 SR 831; 36 SR 74; 46 SR 791*

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