

4731.4436 IMAGING AND LOCALIZATION STUDIES; 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 4731.4434 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. The names of board certification that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page;

B. is an authorized user under part 4731.4443 and meets the requirements in item C, subitem (1), unit (b), subunit vii, or equivalent requirements of the NRC or an agreement state; or

C. has:

(1) completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

(a) classroom and laboratory training in the following areas:

- 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 in subunit vii and part 4731.4443, or equivalent requirements of the NRC or an agreement state. An authorized nuclear pharmacist who meets the requirements in part 4731.4413 or 4731.4414 may provide the supervised work experience for subunit vii. 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 unsealed radioactive material;

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

vi. administering dosages of radioactive drugs to patients or human research subjects; and

vii. eluting generator systems, appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) obtained written attestation that the individual physician 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 parts 4731.4432 and 4731.4434. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements in this part, part 4731.4414, or in subitem (1), unit (b), subunit vii, and part 4731.4443, or equivalent requirements of the NRC or an agreement state; 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 in this part, part 4731.4414, or in subitem (1), unit (b), subunit vii, and part 4731.4443, or equivalent requirements of the NRC or an agreement state, 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 this item.

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

A. complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that include the topics listed in subpart 1, item C, subitem (1), units (a) and (b); and

B. pass an examination administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

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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