

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 is qualified as follows under item A, B, or C:

A. The physician must:

(1) be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state; and

(2) must also have obtained written attestation that the individual physician has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434. The attestation must be signed by a preceptor authorized user who meets:

(a) the requirements in this part;

(b) the requirements in item C, subitem (1), unit (b), subunit vii, and part 4731.4443;

(c) the requirements in part 4731.4414; or

(d) equivalent requirements of the NRC or an agreement state.

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

C. The physician must have:

(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, involving:

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 has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434. The attestation must be signed by a preceptor authorized user who meets:

(a) the requirements in this part;

(b) the requirements in subitem (1), unit (b), subunit vii, and part 4731.4443;

(c) the requirements in part 4731.4414; or

(d) equivalent requirements of the NRC or an agreement state.

Subp. 2. **Certification requirements.** A specialty board 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*

Published Electronically: *October 3, 2013*