4731.4446 PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

A. Except as provided in part 4731.4414, the licensee must require an authorized user for the parenteral administration requiring a written directive to be a physician who is:

(1) an authorized user under part 4731.4443 for the 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, or equivalent requirements of the NRC or an agreement state;

(2) an authorized user under part 4731.4458 or 4731.4479 or equivalent requirements of the NRC or an agreement state and meets the requirements in item B; or

(3) certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under part 4731.4458 or 4731.4479 and meets the requirements in item B.

B. The physician under item A, subitems (2) and (3), must have:

(1) successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations 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. The training must include:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radioactivity;

(d) chemistry of radioactive material for medical use; and

(e) radiation biology;

(2) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or agreement state, in the 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. A supervising authorized user who meets the requirements in this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

(a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(c) calculating, measuring, and safely preparing patient or human research subject dosages;

(d) using administrative controls to prevent a medical event involving the use of unsealed radioactive materials;

(e) using procedures to contain spilled radioactive materials safely and using proper decontamination procedures; and

(f) administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, 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; and

(3) obtained written attestation that the individual has satisfactorily completed the requirements in this item and item A, subitem (2) or (3), and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements in this part, part 4731.4414, or 4731.4443, or equivalent requirements of the NRC or agreement state. A preceptor authorized user who meets the requirements in this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in administering dosages in the same 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 in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or 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 subitems (1) and (2).

Statutory Authority: *MS s 144.1202; 144.1203*

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

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