4731.4445 ORAL ADMINISTRATION OF SODIUM IODIDE; QUANTITIES GREATER THAN 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE REQUIRED; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 millicuries (1.22 GBq) 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 includes all the requirements in item C, subitems (1) and (2). 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;

B. is an authorized user for the oral administration of I-131 in quantities greater than 33 millicuries under part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi; or equivalent requirements of the NRC or an agreement state; or

C. has:

(1) successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of I-131 for procedures requiring a written directive. 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 materials for medical use; and

(e) radiation biology;

(2) work experience under the supervision of an authorized user who meets the requirements of this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state. A supervising authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must also have experience in the oral administration of I-131 in quantities greater than 33 millicuries under part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi. 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 radioactive material;

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

(f) administering dosages to patients or human research subjects, including at least three cases involving the oral administration of greater than 33 millicuries (1.22 GBq) of I-131; and

(3) obtained written attestation that the individual has satisfactorily completed the requirements of this item and is able to independently fulfill the radiation-related duties as an authorized user for oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide I-131 for medical uses authorized under part 4731.4440. 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 an agreement state, and has experience in the oral administration of I-131 in quantities greater than 33 millicuries (1.22 GBq) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi; 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 an agreement state; has experience in the oral administration of I-131 in quantities greater than 33 millicuries (1.22 GBq) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi; 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: *29 SR 755; 32 SR 831; 36 SR 74; 46 SR 791*

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