4731.4408 WRITTEN DIRECTIVES.

Subpart 1. **Written directive required.**

A. A written directive must be dated and signed by an authorized user before administration of:

(1) I-131 sodium iodide greater than 30 microcuries (1.11 MBq);

(2) any therapeutic dosage of unsealed radioactive material; or

(3) any therapeutic dose of radiation from radioactive material.

B. If, because of the emergent nature of a patient's condition, a delay to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

Subp. 2. **Content requirements.** The written directive under subpart 1 must contain the patient or human research subject's name and:

A. for an administration of quantities greater than 30 microcuries (1.11 MBq) of sodium iodide I-131, the dosage;

B. for an administration of a therapeutic dosage of an unsealed radioactive material other than sodium iodide I-131, the radioactive drug, dosage, and route of administration;

C. for gamma stereotactic radiosurgery, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

D. for teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

E. for high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

F. for permanent implant brachytherapy:

(1) before implantation: the treatment site, radionuclide, and total source strength; and

(2) after implantation but before the patient leaves the post-treatment recovery area: the treatment site, number of sources implanted, total source strength implanted, and date; or

G. for all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders:

(1) before implantation: the treatment site, radionuclide, and dose; and

(2) after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time or the total dose, and date.

Subp. 3. **Revisions.**

A. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

B. If, because of a patient's condition, a delay to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

Subp. 4. **Retention.** A licensee must retain a copy of the written directive according to part 4731.4501, subpart 1.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 46 SR 791*

Published Electronically: *May 26, 2022*