

Written directives.

- (A) A written directive must be dated and signed by an authorized user before the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (-thirty microcuries), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order 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 forty-eight hours of the oral directive.
- (B) The written directive must contain the patient or human research subject's name and the following information:
- (1) For any administration of quantities greater than 1.11 megabecquerels (-thirty microcuries) of sodium iodide iodine-131: the dosage;
 - (2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide iodine-131: the radioactive drug, dosage, and route of administration;
 - (3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
 - (4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
 - (5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
 - (6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
 - (a) Before implantation: treatment site, the radionuclide, and dose; and
 - (b) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).
- (C) 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. If, because of the patient's condition, a delay in order 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 forty-eight hours of the oral revision.

(D) The licensee shall retain a copy of the written directive in accordance with rule 3701:1-58-75 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020

CERTIFIED ELECTRONICALLY

Certification

06/12/2015

Date

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