10A NCAC 15 .0356 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide that:

(1) The patient or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) The procedures required by Paragraph (a) of this Rule must address the following items that are applicable to the licensee's use of radioactive material:

(1) Verify the identity of the patient or human research subject;

(2) Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Check both manual and computer-generated dose calculations; and

(4) Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

(c) A licensee shall retain a copy of the procedures required under Paragraph (a) until the agency terminates the pertinent license.

(d) 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 shall 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.

(e) A revision to an existing written directive may be made:

(1) 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, or

(2) 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 48 hours of the oral revision.

(f) The licensee shall retain a record of the written directive and any revisions to the written directive for three years.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
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