15A NCAC 11 .0322 is amended with changes as published in NCR 27:22, pp. 2031-2073, as follows:

15A NCAC 11 .0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES

(a) In addition to the requirements set forth in Rule .0318, .0319, or .0320 of this Section, a specific license for human use of sealed sources shall be issued only if the applicant, or if the application is made by an institution, the individual user:

(1) ~~has~~ Has training and experience as required by 10 CFR 35.490 or 10 CFR 35.690; and ~~Rule .0117(a)(2) of this Chapter, and~~

(2) ~~is~~ Is a physician.

(b) The licensee shall comply with the provisions of Section .0700 of this Chapter and the requirements of Subpart H of 10 CFR Part 35.

(c) For medical use, a licensee may only use:

(1) Sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State;

(2) Sealed sources or devices noncommercially transferred from a licensee licensed pursuant to Section .0300 of this Chapter, 10 CFR Part 35, or ~~equivalent regulations of~~ an Agreement State medical use licensee;

(3) Teletherapy sources manufactured and distributed in accordance with 10 CFR Part 30 or the equivalent requirements of an Agreement State; or

(4) Brachytherapy sources, photon emitting remote ~~afterlaoder~~ afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses; ~~use as approved in:~~

(A) As approved in the Sealed ~~Sources~~ Source and Device Registry; or

(B) ~~Research~~ In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the ~~FDA.~~ FDA provided the requirements of 10 CFR 35.49(a) are met.

(d) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety ~~instruction,~~ ~~initially~~ instruction prior to assignment and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released in accordance with Rule .0358 of this Section. To satisfy this ~~requirement,~~ requirement the instruction must be commensurate with the duties of the personnel and include:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; ~~and~~

(B) Visitation authorized by Rule .1611(e) of this ~~Chapter.~~ {~~Chapter and~~} Chapter; and

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(e) The licensee shall retain records of the radiation safety instruction required in Paragraph (d) of this Rule for three years. The record must include:

(1) ~~List~~ A list of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007.