15A NCAC 11 .0321 is amended with changes as published in NCR 27:22, pp. 2031-2073, as follows:

15A NCAC 11 .0321 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE OF UNSEALED RADIOACTIVE MATERIALS

(a) An application for a specific license pursuant to Rule .0318 of this Section for any diagnostic or therapeutic use of unsealed radioactive material shall be approved if:

(1) the applicant satisfies the requirements in Rule .0319 or Rule .0320 of this Section;

(2) the applicant's proposed radiation detection instrumentation is adequate for conducting the diagnostic or therapeutic procedure(s) requested;

(3) the physicians designated in the application as individual ~~users,~~ users have clinical experience as required by Rule .0117(a)(2) of this Chapter;

(4) the physicians and all other personnel who will be involved in the preparation and use of radioactive material have training and experience in the handling of unsealed radioactive material appropriate to their use of radioactive material and as required by Rule .0117(a)(2) of this Chapter;

(5) the applicant has radiation safety operating procedures for handling and disposal of the radioactive material that provide protection to the workers, the public and the environment from radiation exposure and radioactive ~~contamination.~~ contamination; and

(6) the applicant has a clinical procedures{~~manual, as~~} manual appropriate for the licensed activities.

(b) Any person authorized by Rules .0318, .0319, .0320, .0322, or .0324 of this Section for medical use of radioactive material may receive, possess and use any of the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources ~~net~~ not exceeding 30 millicuries (mCi)(1.11 Gigabecquerel (GBq)) each, manufactured and distributed by a person licensed under 10 CFR 32.74 or equivalent Agreement State regulations;

(2) Sealed sources, not exceeding 30 mCi (1.11 GBq) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 10 CFR 32.74, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(4) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of 200 microcuries (µCi) (7.4 Megabecquerel (MBq)) or 1000 times the quantities in Appendix C of 10 CFR Part 20; and

(5) Technetium-99m in amounts as needed.

(c) Any licensee who possesses sealed sources as calibration and reference sources pursuant to Paragraph (b) of this Rule shall test each source for leakage and contamination prior to initial use and at intervals not to exceed six months or at ~~other~~ longer intervals as approved by the U.S. Nuclear Regulatory Commission or an Agreement State

in the source specific Sealed Source and Device Registry sheet. ~~Registry.~~ If there is reason for the licensee to suspect that a sealed source may have been damaged, or might be leaking, it shall be tested for leakage before further use.

(d) Leak test results shall be recorded in units of microcuries and maintained for inspection by the agency.

(e) Any licensee who possesses and uses calibration and reference sources pursuant to Paragraph (b) of this Rule shall:

(1) follow the radiation safety and handling instructions that are required by the licensing agency to be furnished by the manufacturer on the label attached to the source or permanent container thereof or in the leaflet or brochure that accompanies the source;

(2) maintain such instructions in a legible and conveniently available form; and

(3 conduct a quarterly physical inventory to account for all sources received an possessed under the license. Records of the inventories shall be maintained for inspection by the agency and shall include the quantities and kinds of radioactive material, location of the sources and the date of the inventory.

(f) Any licensee who is licensed pursuant to Rules .0318, .0319, .0320, or .0324 of this Section for medical use of unsealed radioactive material also is authorized to use radioactive material under the general license in Rule .0314 of this Chapter for the specified ~~IN VITRO~~ *in vitro* uses without filing agency forms as required by Rule .0314(b) of the Chapter, provided that the licensee is subject to the other provisions of ~~Rule .0314 of this Chapter.~~ that Rule.

(g) For each individual receiving radiopharmaceutical therapy and hospitalized because the individual cannot be released in accordance with Rule .0358 of this Section, a licensee shall:

(1) provide a private room with a private sanitary facility;

(2) post on the individual's door ~~with~~ a "Radioactive Materials" sign and note on the door or the individual's chart, where and how long visitors may stay in the individual's room;

(3) either monitor material or items removed from the individual's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste; and

(4) ~~Notify~~ notify the Radiation Safety Officer and authorized user as soon as feasible if the individual has a medical emergency and immediately ~~if the patient dies.~~ after the determination that the patient died.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; May 1, 1993.