

10A NCAC 15 .0324 SPECIFIC LICENSES: BROAD SCOPE

(a) In addition to the requirements set forth in Rule .0317 of this Section, a specific license of broad scope for radioactive material will be issued if:

- (1) the applicant has engaged in a wide variety of activities involving the use of many different types of radioactive material in a variety of physical and chemical forms; and
- (2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - (A) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
 - (B) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety measures; and
 - (C) the establishment of appropriate administrative procedures to assure:
 - (i) control of procurement and use of radioactive material;
 - (ii) completion of safety evaluations of proposed uses of radioactive material which takes into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
 - (iii) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Part (a)(2)(C) of this Rule prior to use of the radioactive material.
- (3) Unless specifically authorized pursuant to other rules of this Section, persons licensed under this Rule shall not:
 - (A) conduct tracer studies in the environment involving direct release of radioactive material;
 - (B) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of byproduct material in sealed sources used for irradiation of materials;
 - (C) conduct activities for which a specific license issued by the agency under the rules of this Section is required; or
 - (D) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.
- (4) Each specific license of broad scope issued under this Rule shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(b) In addition to the requirements set forth in Rule .0319 of this Section, a specific license of broad scope for radioactive material, human use, will be issued only if:

- (1) the applicant has appointed a radiation safety committee as required in Part (a)(2)(A) of this Rule, except that this committee shall evaluate all proposals for research, diagnostic and therapeutic use of radioactive material within the medical facility;
- (2) membership of the committee consists of physicians specializing in nuclear medicine, diagnostic radiology, clinical pathology, and a pharmacist specializing in radiopharmacy, someone competent in radiation safety and a representative of the hospital management; and
- (3) the applicant for a medical radioactive materials license of broad scope has an ongoing teaching program with interns and residents associated with a four-year medical school.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0324 Eff. February 1, 2015.*