15A NCAC 11 .0333 is amended with changes as published in NCR 27:22, pp. 2031-2073, as follows:

15A NCAC 11 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rules ~~Rule~~ .0318, .0319, or .0320 of this Section for ~~the radiopharmaceuticals and associated uses in Groups I, II or IV~~ medical use shall be approved if the applicant meets the ~~subject to the~~ following conditions:

(1) the applicant satisfies the requirements of Rule .0317 of this Section; and

(2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR ~~Part 32.~~ Part 32, and Section 30.32(j) of 10 CFR Part 30.

(b) Authorization under this Rule to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(c) Each licensee authorized under this Rule to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(1) satisfy the labeling requirements in Rule .1626 of this Chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(2) possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in this Rule.

(d) A licensee that is a pharmacy authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs be:

(1) an authorized nuclear pharmacist that meets the requirements in Rule .0318 of this Section; or

(2) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule .0318 of this Section.

(e) A pharmacy authorized under this Rule to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist shall meet the requirements of Rule .0318 of this Section.

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