15A NCAC 11 .0361 is proposed for amendment as follows:

15A NCAC 11 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

(a) A licensee may use any unsealed radioactive material prepared for use for uptake, dilution, or excretion studies, imaging and localization ~~studies and radiopharmaceutical therapy that is:~~ studies, and use requiring a written directive in accordance with Rule .0104 of this chapter that is:

(1) Obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State ~~requirements;~~ requirements;

(2) ~~Prepared by:~~ Obtained from a positron emission tomography (PET) radioactive drug producer licensed under 10 CFR 30.32(j), 15A NCAC 11 .0333, or equivalent Agreement State requirements;

~~(A) An authorized nuclear pharmacist;~~

~~(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2);~~

~~(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;~~

(3) Excluding production of PET radionuclides, prepared by:

(A) An authorized nuclear pharmacist;

(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2); or

(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;

~~(3)~~ (4) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or

~~(4)~~ (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.

(b) A licensee shall not administer to humans a radiopharmaceutical ~~containing~~ that contains; ~~more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m.~~

(1) more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m; or

(2) more than 0.02 microcurie (0.02 kilobecquerel) of strontium-82 per millicurie (megabecquerel) of rubidium-82 chloride, or 0.2 microcurie (0.2 kilobecquerel) of strontium-85 per millicurie (megabecquerel) of rubidium-82 chloride.

~~(c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.~~

(c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99 radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.

(d) A licensee that uses strontium-82/rubidium-82 generators for preparing a rubidium-82 radiopharmaceutical shall measure the concentrations of strontium-82 and strontium-85 before the first patient use of the day to demonstrate compliance with Paragraph (b) of this Rule.

~~(d)~~(e) A licensee that must measure ~~molybdenum~~ molybdenum-99, or strontium-82 and strontium-85, concentration shall retain a record of each measurement for three years. The record shall ~~include for each measured elution of technetium-99m:~~ include:

(1) for each measured elution of technetium-99m: the ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (or kilobecquerels of molybdenum-99 per megabecquerel of technetium-99m);

(2) for each measured elution of rubidium-82: the ratio of the measures expressed as microcuries of strontium-82 and strontium-85 per millicurie of rubidium-82 (or kilobecquerel strontium-82 and strontium-85 per megabecquerel rubidium-82); and

~~(2)~~(3) the time and date of the measurement; and

~~(3)~~(4) the initials of the individual who made the measurement.

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;*
Eff. April 1, 1999;
Amended Eff. October 1, 2013; November 1, 2007.