15A NCAC 11 .0338 is amended with changes as published in NCR 27:22, pp. 2031-2073, as follows:

15A NCAC 11 .0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES

~~(a) Each license issued pursuant to the rules in this Section shall be subject to all the provisions of the Act, now or hereafter in effect, to all rules adopted pursuant to provisions of the Act and to orders of the agency.~~

~~(b) No license issued or granted pursuant to this Section and no right to possess or utilize radioactive material granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency, after securing full information, finds that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.~~

~~(c)~~(a) Each person licensed by the agency pursuant to this Section shall confine ~~his~~ his or her use and possession of the radioactive material licensed to the locations and purposes authorized in the license.

~~(d)~~(b) Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) the licensee;

(2) an entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

~~(e)~~(c) The notification in Paragraph ~~(d)~~ (b) of this Rule shall indicate:

(1) the bankruptcy court in which the petition for bankruptcy was filed; and

(2) the date of the filing of the petition.

~~(f)~~(d) Licensees required to submit emergency plans pursuant to Rule .0352 of this Section shall follow the emergency plan approved by the agency. The licensees may change the approved plan without prior agency approval only if the licensee believes the changes do not decrease the effectiveness of the plan and are submitted to the agency no later than 20 calendar days after the changes are made. The licensee shall furnish the change to affected off-site response organizations within six months after the change is made. Proposed changes that the licensee believes are likely to decrease, or may potentially decrease, the effectiveness of the approved emergency plan shall not be implemented without prior application to and ~~prior~~ approval by the agency.

(e) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule .0361 of this Section. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(f) Each portable nuclear gauge licensee shall use {~~a minimum of~~} at least two independent physical controls that form tangible barriers to secure portable gauges from unauthorized {~~removal,~~} removal whenever portable gauges are not under the control and constant surveillance of the licensee.

{~~(g) Authorization under Rule .0333 of this Section 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.~~

~~(h) Each licensee authorized under Rule .0333 of this Section 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 Rule .0333 of this Section.~~

~~(i) 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.~~

~~(j) A pharmacy, authorized under Rule .0333 of this Section 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; May 1, 1993; May 1, 1992; June 1, 1989.