**21 NCAC 46 .2702 DEFINITIONS**

For purposes of these Rules, the following terms are defined as follows:

(1) Authentication of Product History. Identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other radioactive drug.

(2) Nuclear Pharmacy. A pharmacy holding a permit issued by the North Carolina Board of Pharmacy and licenses issued by the Nuclear Regulatory Commission (NRC) and other state regulatory agencies, where prescriptions for radiopharmaceutical products are filled, compounded, or dispensed.

(3) Nuclear Pharmacy Practice. A patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals.

(4) Nuclear Pharmacy Technician. Any person involved in the dispensing of a radiopharmaceutical, not satisfying the definition of Qualified Licensed Professional; any such person must be registered as a Pharmacy Technician with the State Board of Pharmacy.

(5) Qualified Licensed Professional. A non-pharmacist possessing a valid license issued by the North Carolina Medical Board, the North Carolina Board of Nursing, the North Carolina Dental Board or the North Carolina Board of Veterinary Medicine, and who has sufficient training and experience to safely handle and dispense radiopharmaceuticals as defined by the respective requirements of the regulations of the NRC or the state nuclear regulatory agencies.

(6) Qualified Nuclear Pharmacist. A pharmacist currently licensed by the Board who meets the following standards:

(a) Certification as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or

(b) Meets minimum standards of training for "authorized user status" of radioactive material in accordance with the licensure guide of the United States Nuclear Regulatory Commission or the appropriate state nuclear regulatory agencies as follows:

(i) Has received a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an approved college of pharmacy, including instruction in the following areas: radiation physics and instrumentation; radiation protection; mathematics of radioactivity; radiation biology; and radiopharmaceutical chemistry; and

(ii) Has a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

(7) Radiopharmaceutical Quality Assurance. The performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

(8) Radiopharmaceuticals. Radioactive drugs shall include any article that exhibits spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator that is intended for use in the preparation of any such article.

(9) Radiopharmaceutical Service. The procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record-keeping and disposal of radiopharmaceuticals and other radioactive materials.

(10) Test Assessment. Conducting quality assurance evaluation necessary to ensure the integrity of the test.

*History Note:* *Authority G.S. 90-85.6; 90-85.34;*
*Eff. October 1, 1990;*
*Amended Eff. February 1, 2005;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.*