SECTION .2700 - NUCLEAR PHARMACY

21 NCAC 46 .2701 REQUIREMENTS

No pharmacist shall receive, possess or dispense radioactive drugs, except in accordance with the applicable federal statutes and regulations and these Rules. The requirements of these Rules are in addition to, and not in substitution for, other applicable provisions of the regulations of any federal or state agency with authority for regulating the use and distribution of radioactive materials.

History Note: *Authority G.S. 90-85.6;*
Eff. October 1, 1990.

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.

21 NCAC 46 .2703 OBTAINING A NUCLEAR PHARMACY PERMIT

In order to obtain a nuclear pharmacy permit, the person seeking such a permit shall submit an application to the Board certifying that he or she is a pharmacist currently licensed by the Board and that he or she is a qualified nuclear pharmacist as defined in Rule .2702 of this Section. The application shall describe the location, time and manner by which the contact hours required by Rule .2702(6) of this Section were obtained by the applicant and shall be submitted under oath.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. October 1, 1990;
Amended Eff. February 1, 2005.

21 NCAC 46 .2704 REQ FOR PHARMACIES PROVIDING RADIOPHARMACEUTICAL SERVICES

(a) The permit to operate a pharmacy providing radiopharmaceutical services shall be issued by the Board only to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy related to radiopharmaceutical services and shall be in personal attendance at all times that the pharmacy renders radiopharmaceutical services.

(b) In emergency situations, and in the absence of a qualified nuclear pharmacist, designated qualified licensed professionals as identified by the pharmacist-manager in established written policies and procedures may have access to the area designated as the nuclear pharmacy area, and these individuals may prepare single doses of radiopharmaceuticals for the immediate emergency only and must document such activities.

(c) The nuclear pharmacy area shall be secured from entry by unauthorized personnel as identified by the pharmacist-manager in established written policies and procedures.

(d) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radiopharmaceuticals in accordance with Section .2300 of this Chapter and the applicable regulations of the North Carolina Division of Radiation Protection.

(e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area that provides sufficient protection from radioactivity of all areas surrounding the nuclear pharmacy area. Floor plans shall be submitted and approved by the Board staff before a nuclear pharmacy permit is issued.

(f) Radiopharmaceuticals are to be dispensed only upon a prescription or medication order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

(g) The library of a nuclear pharmacy shall contain, in addition to the volumes required by Rule .1601(a)(3) of this Chapter, copies of current state and federal regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

(h) All pharmacies performing Radiopharmaceutical Services shall have in effect a procedures manual setting forth the procedures and policies of the pharmacy regarding Radiopharmaceutical Quality Assurance. This manual shall at all times be readily available for review by Board personnel.

(i) Permit holders must obtain licensure from the North Carolina Division of Radiation Protection and the number of that license. Copies of the Division's inspection report shall be made available upon request for inspection by Board personnel.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. October 1, 1990;
Amended Eff. February 1, 2005.

21 NCAC 46 .2705 LABELING REQUIREMENTS OF RADIOPHARMACEUTICALS

(a) In addition to other labeling requirements of the Board for non-radioactive drugs described in this Chapter, the container of a radiopharmaceutical shall also be labeled with:

(1) The standard radiation symbol;
(2) The words "CAUTION - RADIOACTIVE MATERIALS";
(3) The radionuclide of the radiopharmaceutical contained therein;
(4) The chemical form of the radiopharmaceutical contained therein;
(5) The amount of radioactivity of the radiopharmaceutical contained therein and the date and time of the calibration of that radioactivity;
(6) The date and time of the expiration of the radiopharmaceutical contained therein;
(7) If the radiopharmaceutical is a liquid, the volume;
(8) If the radiopharmaceutical is a solid, the number of capsules or weight contained therein;
(9) If the radiopharmaceutical is a gas, the number of ampules, vials, or syringes contained therein;
(10) The name, address and telephone number of the nuclear pharmacy dispensing the radiopharmaceutical;
(11) The prescription or lot number; and
(12) The name of the pharmaceutical.

(b) No radiopharmaceutical may be dispensed unless a tamper-evident seal is applied and a label is affixed to the delivery container of each dose bearing the following information:

(1) The standard radiation symbol.
(2) The words "Caution - Radioactive Material."
(3) The radionuclide and chemical form.
(4) The volume if in liquid form.
(5) The requested activity and the calibration date and time.
(6) The prescription number.
(7) Labels for radiolabeled blood components and therapeutic dosages must always contain the patient's name at the time of dispensing.
Where the patient's name is not available at the time of dispensing for diagnostic dosing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after dispensing the radiopharmaceutical, the patient's name must be associated with the prescription in a readily retrievable manner and must be retained for a period of three years.
(8) The name and address of the nuclear pharmacy.
(9) The name of the end authorized user, must also be a prescriber.
(10) The lot number of the preparation.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. January 1, 2005.

21 NCAC 46 .2706 PROHIBITIONS

(a) No person shall utilize unit-dose transport containers for radioactive dosages without an effective mechanism to avoid contamination of the transport container with blood or other biohazardous substances.
(b) No person shall re-use a unit-dose transport container that has been contaminated with blood or other biohazardous

substances. Any unit-dose transport container that is returned with the tamper-evident seal broken and the unit-dose syringe
included must be considered to be contaminated.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. January 1, 2005.