MODEL NUCLEAR PHARMACY REGULATIONS

Purpose and Scope

The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by state boards of pharmacy. As such, the following model rules are intended to address select areas specific or unique to this specialty practice and are intended to supplement regulations of other state agencies.

Definitions

A. “Board” means the [insert state name here] State Board of Pharmacy

B. “Component” means any active or non-active ingredient of a drug product.

C. A “Nuclear Pharmacist” or “Authorized Nuclear Pharmacist” means a pharmacist who holds a current pharmacist license issued by the Board, and who meets the following standards:
   (1) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or
   (2) Is identified as an authorized nuclear pharmacist on a [US NRC or State Agency] license that authorized the use of radioactive material in the practice of nuclear pharmacy; or
   (3) Has completed 700 hours of training and experience consisting of:
      (i) A minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Board, with emphasis in the following areas:
         (a) Radiation physics and instrumentation;
         (b) Radiation protection;
         (c) Mathematics of radioactivity;
         (d) Radiation biology; and
         (e) Radiopharmaceutical chemistry, and
      (ii) A minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a nuclear pharmacist in, but not limited to, the following areas as described in the Nuclear Pharmacy Practice Guidelines and Syllabus for Nuclear Pharmacy Education and training (available from the Section on Nuclear Pharmacy practice, Academy of Pharmacy Practice and management of the American pharmaceutical Association):
         a. Procuring radioactive materials;
         b. Compounding radiopharmaceuticals;
         c. Performing routine quality control/assurance procedures;
         d. Dispensing radiopharmaceuticals;
         e. Distributing radiopharmaceuticals;
         f. Implementation and adherence to basic radiation protection principles and practices
         g. Provision of information and professional consulting services to the medical [nuclear] community, patients, pharmacists, other health care professionals, the general public, and regulatory/governmental agencies relative to nuclear pharmacy practice;
         h. Implementation of pharmaceutical care principles relative to nuclear pharmacy practice and monitoring patient outcomes; and
         i. Product research and development
      (iii) Has submitted an affidavit of training and experience to the Board; or
D. “Nuclear Pharmacy” means a pharmacy which provides radiopharmaceutical services, and shall be licensed by the Board or other appropriate state agency.

E. The “Practice of Nuclear Pharmacy” means a patient-oriented service that embodies the scientific knowledge and professional judgement required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

F. “Quality Assurance Procedures” means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of the product history, internal test assessment, and maintenance of all records as required by the Board or other appropriate state agency.

G. “Quality Control Testing” means the performance of appropriate chemical, biological and physical tests on compounded and prepared radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

H. “Radiopharmaceutical” means any drug which exhibits spontaneous disintegration of unstable nuclide with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in preparation of any such substance. The term “radiopharmaceutical” includes, but is not limited to, positron-emission tomography agents, any biological (i.e., blood formed element, antibody or peptide, etc.) product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide. The term does not include drugs such as carbon-containing compounds or potassium-containing salts that contain trace quantities of naturally occurring radionuclides.

I. “Radiopharmaceutical Compounding” means the preparation, mixing, assembling, packaging, or labeling of a radiopharmaceutical (1) as the result of a practitioner’s drug prescription order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs (including reagent kits and radiopharmaceuticals) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. Radiopharmaceutical compounding does not include: (1) acts performed in accordance with the preparation instructions contained in the approved drug product labeling or other preparation directions as provided by the manufacturer; (2) acts performed, in consideration of patient safety and efficacy, with validated procedures which deviate from the preparation instructions specified in the approved drug product labeling or (3) minor modifications of non-active ingredients of a radiopharmaceutical in order to accommodate patient specific needs. Nuclear pharmacists should utilize professional judgment, scientific knowledge, literature evidence and other reference materials as the basis for employing any deviations from the labeled preparation instructions or modifications to a radiopharmaceutical. The final drug product, created as a result of any such deviations or modifications, should be subjected to quality control testing necessary to confirm the presence of the desired pharmaceutical qualities.

J. “Radiopharmaceutical Services” means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping, and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.
K. “Reagent Kit” means a sterile and pyrogen-free reaction vial containing the nonradioactive chemicals [e.g., complexing agent (ligand), reducing agent, stabilizer, or dispersing agent] that are required to produce a specific radiopharmaceutical after reaction with a radiochemical.

GENERAL REQUIREMENTS FOR PHARMACIES PROVIDING RADIOPHARMACEUTICAL SERVICES

A. A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the nuclear pharmacy, shall supervise the operation of only one nuclear pharmacy during all times when radiopharmaceutical services are being performed, and at all times that the nuclear pharmacy is open for business. Each nuclear pharmacy shall designate a nuclear pharmacist as the Pharmacist-in-Charge who shall be responsible for compliance will all laws and regulations, both state and federal, pertaining to radiopharmaceuticals and radiopharmaceutical services.

B. The license to operate a nuclear pharmacy is effective only so long as the pharmacy also holds an appropriate federal and/or state licenses and permits to possess and distribute radioactive materials. Copies of all associated inspection reports shall be made available upon request for Board inspection.

C. Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided. All nuclear pharmacies are required to include, but not limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping/receiving area; radioactive material storage area; radioactive waste decay area.

D. The nuclear pharmacy professional service area shall be secured from entry by unauthorized personnel.

E. Nuclear pharmacies shall maintain records including, but not limited to, the acquisition, inventory and disposition of all radiopharmaceuticals.

F. Nuclear pharmacies shall compound and dispense radiopharmaceuticals that meet or exceed accepted standards of radiopharmaceutical quality. The Board recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted compendial standards.

G. Radiopharmaceuticals are to be dispensed only upon receipt of an order from a licensed practitioner authorized by the U.S. Nuclear Regulatory Commission (or Agreement State Agency) to possess such drug or radioactive material. A radiopharmaceutical shall be dispensed for medical use only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise a radiopharmaceutical or radioactive material may be transferred to a person who is authorized to possess and use such drug or material for non-medical applications.

H. A nuclear pharmacy upon receiving an order for a radiopharmaceutical shall immediately have the prescription or medication order reduced to writing, or recorded in an automated data processing system, which writing or record shall contain at least the following:
(1) the name of the institution and prescriber, or prescriber’s agent;
(2) the date of dispensing and the calibration time of the radiopharmaceutical;
(3) the name of the procedure;
(4) the name of the radiopharmaceutical;
(5) the dose or quantity of the radiopharmaceutical;
(6) the serial number assigned to the order for the radiopharmaceutical
(7) any specific instructions;
(8) the identity of the person who dispenses the prescription or medication order; and
(9) when the prescription or medication order is for a therapeutic or blood-product
radiopharmaceutical, the patient’s name.

I. The immediate outer container shield of a radiopharmaceutical to be dispensed shall be
labeled with:
(1) the name and address of the pharmacy;
(2) the name of the prescriber;
(3) the date of dispensing;
(4) the serial number assigned to the prescription or medication order for the
radiopharmaceutical;
(5) if radioactive, the standard radiation symbol;
(6) if radioactive, the words “Caution: Radioactive Material”;
(7) the name of the procedure
(8) the radionuclide and chemical form;
(9) the amount of radioactivity and the calibration date and time
(10) expiration time;
(11) if a liquid, the volume;
(12) if a solid, the number of items or weight;
(13) if a gas, the number of ampoules or vials;
(14) when the prescription or medication order is for a therapeutic or blood-product
radiopharmaceutical, the patient’s name; and
(15) the name of the patient or the words “Physician’s Use Only” in the absence of a patient
name.

J. The immediate inner container label of a radiopharmaceutical to be dispensed shall be
labeled with:
(1) the name of the radiopharmaceutical;
(2) the serial number assigned to the prescription or medication order of the
radiopharmaceutical; and
(3) if radioactive, the standard radiation symbol; and
(4) if radioactive, the words “Caution: Radioactive Material”.

K. Each nuclear pharmacy shall have access to, or maintain on the premises, a copy of:
(1) The United States Pharmacopeia/National Formulary (USP/NF), or Remington: The
Science and Practice of Pharmacy; and
(2) Current copy of applicable rules and regulations of the State Radiation Control Branch or
Nuclear Regulatory Commission;
(3) Current copy or the State Board of Pharmacy rules and regulations.

MINIMUM EQUIPMENT

A nuclear pharmacy shall have at least the following equipment and supplies:
A. Radiation detection and measuring instruments capable of accurately measuring quantities of
radioactivity and radiation;
B. Radiation shielding;
C. Appropriate supplies and equipment for performing quality assurance testing;
D. Refrigerator;
E. Materials for decontamination of accidental spills of radioactive materials;
F. Appropriate supplies and equipment necessary for compounding and dispensing sterile parenteral radiopharmaceuticals.