

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 13.00: REGISTRATION REQUIREMENTS AND MINIMAL PROFESSIONAL STANDARDS FOR NUCLEAR PHARMACIES

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13.01: Authority and Purpose

247 CMR 13.00 is promulgated under the authority granted the Board by M.G.L. c. 112, § 39B to register an establishment for transacting business as a nuclear pharmacy as defined in M.G.L. c. 94C. The purpose of 247 CMR 13.00 is to establish minimum professional standards for the operation of a nuclear pharmacy in order to safeguard the public health and welfare.

13.02: Definitions

Authentication of product history means the identification of the purchasing source, or of any intermediate handler, or of the ultimate fate of any radiopharmaceutical or component thereof.

Authorized practitioner means a practitioner who is legally authorized to receive and administer radiopharmaceutical drugs.

Compounding of radiopharmaceuticals means the addition of a radioactive substance, or the use of a radioactive substance in preparation of a single-dose or multiple-dose medication, pursuant to the prescription of an authorized practitioner for a patient who is being treated by the that practitioner. Such compounding of radiopharmaceuticals includes, but is not limited to, loading and eluting of radionuclide generators, using manufactured reagent kits to prepare radio-pharmaceuticals, preparing reagent kits, aliquoting reagents, and formulating and conducting quality assurance tests of radiochemicals which are to be used as radiopharmaceuticals.

Internal test assessment means such testing or quality assurance which is necessary to insure the integrity of a particular test.

Nuclear pharmacy means a facility under the direction or supervision of a registered pharmacist which is registered by the Board to dispense radiopharmaceutical drugs pursuant to M.G.L. c. 112, § 39 and 247 CMR 13.00.

NRC means the Nuclear Regulatory Commission.

Qualified nuclear pharmacist means, for the purposes of 247 CMR 13.00, a pharmacist who is registered as a pharmacist by the Board pursuant to the provisions of M.G.L. c. 112, § 24, who is employed in a nuclear pharmacy, and who has submitted evidence satisfactory to the Board that he or she meets the requirements of 247 CMR 13.00 in regard to education, training and experience, and who has received from the Board an official letter stating that, on the basis of the evidence submitted, he or she has been found qualified to deal with radiopharmaceutical drugs and to handle radiopharmaceutical services.

Radioactive biological product means a biological product which is labeled with a radionuclide or intended to be labeled solely with a radionuclide.

Radiolabeling means the process of adding a radioisotope to a suitable nonradioactive substance.

Radiopharmaceutical means a radioactive drug or other radioactive pharmaceutical products.

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Radiopharmaceutical drug means any substance defined as a drug in section 201(g)(1) of 21 USCA § 321 *et seq.* (Federal Food, Drug and Cosmetic Act) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons, and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

Radiopharmaceutical quality assurance means the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals, and the interpretation of the resulting data to determine the suitability of the radiopharmaceutical for use in humans or animals. The term includes internal test assessment, authentication of product history, and the maintenance of proper records.

Radiopharmaceutical service means the counting, dispensing, labeling, and delivery of radiopharmaceuticals; participating in radiopharmaceutical selection and radiopharmaceutical utilization reviews; properly and safely storing and distributing radiopharmaceuticals; maintaining radiopharmaceutical quality assurance; advising on therapeutic values, hazards, and use of radiopharmaceuticals; and offering or performing those acts, services, operations or transactions necessary in the conduct, operation, management and control of radio-pharmaceutical services within a nuclear pharmacy.

13.03: Requirements for the Issuance of Nuclear Pharmacy Permit

- (1) An applicant for an initial permit to establish a nuclear pharmacy shall be made by submitting to the Board a fully and properly completed application form provided by the Board.
- (2) An application for a nuclear pharmacy permit shall be accompanied by a check or money order in the required amount payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy".
- (3) No permit shall be issued to a proposed nuclear pharmacy unless there are maintained on the pharmacy premises the following publications:
 - (a) The most recent edition of the United States Pharmacopoeia, including the latest supplement thereto;
 - (b) the most recent edition of Remington's Pharmaceutical Sciences; and
 - (c) current texts on the practice of nuclear pharmacy and radiation safety.
- (4) No permit shall be issued to a proposed nuclear pharmacy by the Board unless said proposed nuclear pharmacy maintains on the premises the following equipment:
 - (a) A dose preparation station;
 - (b) a dose calibrator;
 - (c) an exhaust hood and filter system for handling radioactive gases or volatile radioactive materials;
 - (d) a refrigerator for exclusive storage of radioactive materials or reagent kits which require refrigeration;
 - (e) chromatographic apparatus as required for radiopharmaceutical quality assurance;
 - (f) a portable radiation survey meter capable of detecting 0.005 microcuries of radio-nuclides;
 - (g) area radiation detection room monitors;
 - (h) personnel dosimeters;
 - (i) a single-channel or multichannel scintillation analyzer; and
 - (j) supplies necessary for dispensing including, but not limited to, sterile multi-dose vials, syringes, disposable alcohol swabs, and adequate shielding for each dosage dispensed.
- (5) No permit shall be issued to a proposed nuclear pharmacy by the Board unless said proposed pharmacy conforms to the following conditions:
 - (a) The premises are clean and sanitary; and
 - (b) no entrances or exits shall connect directly with other places of business.

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- (6) Prior to acting upon any application for the issuance of a permit for a nuclear pharmacy, the Board may require the applicant to appear before the Board to discuss the merits of the application.
- (7) The Board shall issue a nuclear pharmacy permit to such person as it deems qualified to conduct such a pharmacy; provided, however, that the Board may deny the issuance of a permit if, in its discretion, it determines that such pharmacy would be inconsistent with, or opposed to, the best interest of the public health, welfare, and safety.
- (8) The Board shall, within 150 days after the filing of an application for an initial nuclear pharmacy permit, render a final decision denying or allowing the issuance of such permit. Failure to render such decision; except when failure to act is caused by the delay of the applicant, shall constitute the approval of the application and the permit shall be issued.
- (9) The Board shall not issue a nuclear pharmacy permit to a corporation unless it appears to the satisfaction of the Board that such nuclear pharmacy is managed and operated by a registered pharmacist in good standing with the Board.
- (10) When the Board is satisfied that a proposed nuclear pharmacy has complied with the requirements of 247 CMR 13.00 and shall be operated in compliance with applicable federal, state and local statutes, ordinances, and/or regulations, it shall issue a permit to the applicant nuclear pharmacy.

13.04: Renewal of a Nuclear Pharmacy Permit

- (1) Each nuclear pharmacy permit issued by the Board shall expire on December 31st of each uneven numbered year following the date of its issuance.
- (2) Application for renewal of a nuclear pharmacy permit shall be made on a renewal application form provided by the Board. Such renewal form shall be fully and properly completed and submitted to the Board in a timely manner.
- (3) Each renewal application form submitted to the Board shall be accompanied by a check or money order in the required amount made payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy".

13.05: General Requirements for Nuclear Pharmacies

- (1) A nuclear pharmacy registered pursuant to 247 CMR 13.00 shall comply with all applicable laws, regulations, and guidelines of the United States Nuclear Regulatory Commission, the United States Food and Drug Administration, and other appropriate federal and state agencies.
- (2) No person other than a qualified nuclear pharmacist shall be employed by a nuclear pharmacy to direct and manage the pharmacy.
- (3) Only designated qualified nuclear pharmacists shall conduct the radiopharmaceutical activities of a nuclear pharmacy, and at least one qualified nuclear pharmacist shall be in personal attendance at the pharmacy at all times.
- (4) A nuclear pharmacy shall not dispense those radiopharmaceuticals which do not comply with acceptable professional standards of radiopharmaceutical quality assurance.
- (5) A nuclear pharmacy shall maintain in readily retrievable form for at least three years detailed records of the acquisition and disposition of all radiopharmaceuticals. These records shall be available to the Board or its agents for inspection upon request.
- (6) A nuclear pharmacy shall not prepare, compound, or dispense radiopharmaceutical drugs except upon a valid prescription from an authorized practitioner. In order to be valid, a prescription for radiopharmaceutical drugs shall contain the following information:

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- (a) the name, address, registration number and, in the case of a written prescription, the signature of the practitioner;
 - (b) the date of the prescription;
 - (c) the name, dosage unit, and strength per dosage unit of the radiopharmaceutical drug;
 - (d) the name and address of the patient; if the name of the patient is unknown at the time the prescription is received, the nuclear pharmacy shall obtain the name and address of the patient within 72 hours after dispensing the radiopharmaceutical drug; the address of the facility where the patient is being treated will be sufficient if his or her residential address is unavailable; and
 - (e) any specific instructions required.
- (7) A nuclear pharmacy shall assign a serial number to each radiopharmaceutical drug it dispenses.
- (8) A nuclear pharmacist shall, upon receiving an oral prescription for a radiopharmaceutical drug from a practitioner or his or her expressly authorized representative, immediately reduce such prescription to writing on a prescription form, record on it the same information required under 247 CMR 13.05(6), and assign a serial number to such prescription.
- (9) In the event a prescribed radiopharmaceutical drug is not administered, it shall be returned to the nuclear pharmacy to be disposed of in accordance with the requirements established by the Nuclear Regulatory Commission and the nuclear pharmacy shall note on the prescription form, or shall record on a readily retrievable record form, that the radiopharmaceutical drug has been returned and shall state the amount of the radiopharmaceutical drug that has been returned. The nuclear pharmacy shall comply with all NRC regulations regarding the return and disposal of radioactive materials.
- (10) A nuclear pharmacy may, with proper record-keeping, transfer to authorized persons radioactive materials or side-products which are not intended for medicinal use.
- (11)(a) Radiopharmaceuticals may be dispensed in bulk amounts necessary to activate the single unit doses. The bulk radioactivity shall be supplied no more than once in a 12-hour period. If an emergency radiopharmaceutical is used, the nuclear pharmacy shall, within 72 hours, obtain a written or oral prescription for the radiopharmaceutical which shall contain all the information included in 247 CMR 13.04(5). If the bulk radioactivity is not used, the nuclear pharmacy shall obtain and record a written or oral verification to that effect from the authorized practitioner to whom it was dispensed.
- (b) A nuclear pharmacy shall maintain records on all emergency supplies it dispenses as set out in 247 CMR 13.04(11)(a). The records shall include the names of the authorized practitioner and the institution within which he is or she is practicing, the amounts of non-radioactive material and radioactive material supplied, the dates supplied, the dates the radiopharmaceutical was administered, and the prescription serial number for each dose that was administered. The nuclear pharmacist's records shall also contain the authorized practitioner's written or oral verification when the bulk radioactivity is not used. These records shall be made available for inspection by the Board or its agents upon request.
- (12) In addition to any other labeling required by federal, state, or local laws or regulations, a registered nuclear pharmacy which dispenses radiopharmaceuticals shall place each such pharmaceutical in an outer container and affix to said container a label bearing the following information:
- (a) the standard radiation symbol;
 - (b) the words "Caution - Radioactive Material";
 - (c) the name of the radionuclide;
 - (d) the chemical form or common name;
 - (e) the amount of radioactive material, stated in millicuries or microcuries, or in SI units (becquerels) at the time of calibration;
 - (f) if a liquid, the volume in cubic centimeters or milliliters;
 - (g) auxiliary warning labels, if any, as needed; and
 - (h) the expiration date or time.

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- (13) In the case of investigational radioactive drugs, the nuclear pharmacy's records shall include an investigator's protocol for the preparation of radioactive drugs, a copy of the Human Use Committee Approval, a copy of the approved patient consent form, and a letter from the manufacturer - "sponsor" indicating that the physician requesting the radioactive drug is a qualified investigator.
- (14) The premises of a nuclear pharmacy shall at all times be kept in a clean and sanitary manner.
- (15) A nuclear pharmacy shall, in legible letters not less than one inch high, conspicuously display the name of the director of pharmacy services on the premises.
- (16) A nuclear pharmacy shall have a qualified nuclear pharmacist on the premises during the entire time when said pharmacy is open for business.
- (17) A nuclear pharmacy shall keep posted and displayed in a conspicuous place its permit and the certificate of personal registration to practice pharmacy of each registered pharmacist who is employed on a full-time basis by the pharmacy.
- (18) A nuclear pharmacy shall in advance of any move to a new location submit to the Board an application for a new permit and payment of the appropriate fees.
- (19) Any nuclear pharmacy which is being established, remodeled, or relocated must first submit to the Board for review and approval copies of its structural plans.
- (20) A nuclear pharmacy which has moved to a new location shall not operate in said location until said nuclear pharmacy has been approved by the Board and until it has received from the Board a new permit to manage and operate a nuclear pharmacy and a new controlled substances registration.
- (21) Each nuclear pharmacy shall, within ten days of the commencement of employment of any pharmacist, or within ten days of the termination of employment of any pharmacist, report to the Board such employment or termination of employment. Such reports may be made upon forms available from the Board.
- (22) A nuclear pharmacy shall maintain adequate security measures which are consistent with federal regulations and with the requirements of the Board.
- (23) A nuclear pharmacy shall not perform any pharmacy functions other than the dispensing of radiopharmaceutical drug products; it shall not perform the functions of, or operate as, a retail pharmacy or institutional pharmacy.
- (24) Only a nuclear pharmacy shall keep in stock or handle radiopharmaceuticals.
- (25) No nuclear pharmacy shall require or permit the same nuclear pharmacist to remain on duty for more than 12 hours per day.
- (26) A nuclear pharmacy shall be exempt from the following regulations of the Board:
 - (a) 247 CMR 6.01;
 - (b) 247 CMR 6.02;
 - (c) 247 CMR 6.08;
 - (d) 247 CMR 9.01(12), (15) and (16); and
 - (e) 247 CMR 9.04(4) and (6).

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(22) A nuclear pharmacy shall maintain adequate security measures which are consistent with federal regulations and with the requirements of the Board.

(23) A nuclear pharmacy shall be separate from, and independent of, any other business or store.

(24) A nuclear pharmacy shall not perform any pharmacy functions other than the dispensing of radiopharmaceutical drug products; it shall not perform the functions of, or operate as, a retail pharmacy or institutional pharmacy.

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- (d) 247 CMR 9.01(12), (15) and (16); and
- (e) 247 CMR 9.04(4) and (6).

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13.06: Education and Experience Requirements of a Qualified Nuclear Pharmacist

A qualified nuclear pharmacist shall:

- (1) Be currently registered under M.G.L. c. 112, § 24;
- (2) have received 200 contact hours of formal academic training in the area of radio-pharmaceutical preparation and handling, with no more than 60 of said hours being acquired through laboratory training;
- (3) have received, in addition to formal academic training, a minimum of three months of full-time, or 500 hours of actual on the job practical experience in the field of radioactive drugs and radiopharmaceutical services under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured nuclear pharmacy training program of a Board-approved college/school of pharmacy; and
- (4) submit a detailed affidavit of experience and training to the Board.

REGULATORY AUTHORITY

247 CMR 13.00: M.G.L. 112, §§ 24, 39B and 42A.