Nuclear Pharmacy

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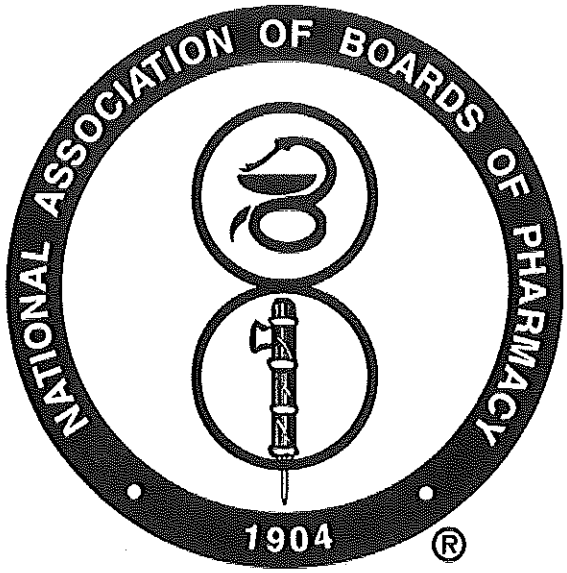

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

August 2012

Model Rules for Nuclear/Radiologic Pharmacy

Section 1. Purpose and Scope.

The Practice of Nuclear/Radiologic Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by State Boards of Pharmacy. As such, the following model rules are included to address those areas specific or unique to this specialty practice. Nuclear/Radiologic Pharmacy Practice refers to 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 and other Drugs.

Section 2. Definitions.

(a) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any Component of a radiopharmaceutical.

(b) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(c) "Nuclear Pharmacy" means a Pharmacy providing radiopharmaceutical services or, as provided in Section 3 of these Rules, an appropriate area of any Institutional Facility.

(d) "Qualified Licensed Professional" means a non-Pharmacist individual (such as a physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and Dispense radiopharmaceuticals as defined by the respective requirements of [cite appropriate Nuclear Regulatory Commission (NRC) or Agreement State and State Board of Pharmacy law(s)].

(e) "Qualified Nuclear Pharmacist" means a currently licensed Pharmacist in the State of practice, who is certified as a Nuclear Pharmacist by the State Board of Pharmacy or by a certification Board recognized by the State Board of Pharmacy, or who meets the following standards:

(1) Minimum standards of training for "authorized user status" of radioactive material [cite State Radiation Control Agency or NRC licensure guide].

(2) Completed 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 State Board of Pharmacy, with emphasis in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics of radioactivity;

(iv) radiation biology; and

(v) radiopharmaceutical chemistry.

(3) Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist.

(f) "Radiopharmaceutical Quality Assurance" means, but is not limited to, 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.

(g) "Radiopharmaceutical Service" means, but shall not be limited to, the procurement, storage, handling, preparation, Labeling, quality assurance testing, Dispensing, Delivery, record keeping, and disposal of radiopharmaceuticals and other Drugs.

(h) "Radiopharmaceuticals" are radioactive Drugs as defined by Food and Drug Administration and the _____ State Board of Pharmacy [cite appropriate law(s)].

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) Nuclear Pharmacy License. A license to operate a Pharmacy providing radiopharmaceutical services shall only be issued to a Qualified Nuclear Pharmacist. All personnel performing tasks in the preparation and Distribution of radioactive Drugs shall be under the direct supervision of a Qualified Nuclear Pharmacist. A Qualified Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business. In emergency situations when a Qualified Nuclear Pharmacist is not present, designated Qualified Licensed Professionals may have access to the licensed area. These individuals may prepare single doses of radiopharmaceuticals for the immediate emergency, and must document such activities.

(b) Nuclear Pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the State or as otherwise defined by the _____ State Board of Pharmacy.

(c) The Nuclear Pharmacy area shall be secured from unauthorized personnel.

(d) Nuclear Pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive Drugs and other radioactive materials in accordance with [cite appropriate Pharmacy and radiological control agency or NRC Statute(s)].

(e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Radiation Control Agency or NRC before approval of the license.

(f) Radiopharmaceuticals are to be Dispensed only upon a Prescription Drug Order from a Practitioner authorized to possess, use, and Administer radiopharmaceuticals.

(g) The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Radiation Control Agency (RCA) or NRC license. Copies of the RCA or NRC inspection reports shall be made available upon request for Board inspection.

Section 4. Other Requirements.

All Nuclear/Radiologic Pharmacies shall also adhere to the principles outlined in the Rules for Pharmacist Care as these pertain to the practice of Nuclear Pharmacy. (See Appendix A for Model Inspection Form for Nuclear Pharmacies.)

Alabama

RULES OF ALABAMA STATE BOARD OF PHARMACY
CHAPTER 680-X-2
PRACTICE OF PHARMACY
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680-X-2-.01. STATE-WIDE CIRCULATION for RULES and REGULATIONS. (Repealed)

Author: James W. McLane
Statutory Authority: Code of Alabama 1975, §34-23-92.
History: Filed June 1, 1982. Repealed: Filed August 23, 1994; effective September 27, 1994.

Alabama

680-X-2-.20. NUCLEAR PHARMACY.

(1) Purpose and Scope: It is unlawful to receive, possess or transfer radioactive drugs, except in accordance with appropriate pharmacy statute(s) and rule(s). It is also unlawful for any person to provide radiopharmaceutical services unless he/she is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with appropriate pharmacy statute(s) and the State Board of Pharmacy rule(s) and rules of the State Board of Health relating to radiation control. No person may receive, acquire, possess, use, transfer or dispose of any radioactive materials except in accordance with the conditions of a radioactive materials license issued by the State Board of Health. The requirements of these Nuclear Pharmacy Regulations are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Board of Health.

(2) Definitions: For the purpose of this rule, the following words and phrases pertaining to the practice of nuclear pharmacy shall have the respective meanings ascribed by this action:

(a) Nuclear Pharmacy - A pharmacy which provides a radiopharmaceutical service.

(b) Nuclear Pharmacist - An actively licensed pharmacist who has met the training qualifications as described in the rule.

(c) Radiopharmaceutical Service - Shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping or disposal of radiopharmaceuticals.

(d) Radiopharmaceutical - Any substance defined as a drug in Code of Alabama 1975, §34-23-1(11) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are 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.

(e) Radiopharmaceutical Quality Assurance - Includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on 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.

(f) Authentication of Product History - Includes, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical or other drug.

(3) Registration and Certification of Pharmacies: The application for a certificate to operate a nuclear pharmacy shall only be issued to a pharmacy registered by the Alabama State Board of Pharmacy and to a licensed, certified nuclear pharmacist. Re-certification shall be ~~annually~~ biennially which shall

expire on December 31 of even-numbered years ~~no later than January 31 of each year~~ on forms provided by the Board. Each nuclear pharmacy shall designate a licensed, certified nuclear pharmacist as the Supervising Pharmacist.

(4) Registration and Certification of Pharmacists: All pharmacists engaged in the practice of nuclear pharmacy shall have training or shall have demonstrated previous training in the safe handling of radioactive pharmaceuticals. They must be registered with and certified by the Alabama State Board of Pharmacy. Applications and re-certification with the Board is required biennially which shall expire on December 31 of even-numbered years ~~no later than January 31 of each year~~ on forms provided by the Board. Satisfactory completion of no less than ~~1~~ two (2) hours of continuing education prior to re-certification earned in the previous calendar year related to nuclear pharmacy shall be required.

(5) General requirements: A licensed, certified nuclear pharmacist shall personally supervise the operation of only one nuclear pharmacy during all times the radiopharmaceutical services are being performed.

(a) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(b) Each nuclear pharmacist shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(c) All nuclear pharmacies shall provide a secure radioactive storage and decay area.

(d) All nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

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

(f) A nuclear pharmacist may transfer radioactive materials to an *authorized user in accordance with all applicable laws and regulations.

(g) A nuclear pharmacy, upon receiving an oral order for a radiopharmaceutical, shall immediately have the order reduced to writing or recorded in a data processing system which writing or records shall contain at least the following:

1. The name of the authorized user or his/her agent.

2. The date of distribution and the time of calibration of the radiopharmaceutical.

3. The name of the procedure.

(*) "Authorized user" means a practitioner of the healing arts who is identified as an authorized user on a license issued by the State Board of Health that authorizes the medical use of radioactive material, hazards, and the applicable regulations of the U.S. Nuclear Regulatory Commission.

4. The name of the radiopharmaceutical.
5. The dose or quantity of the radiopharmaceutical.
6. The prescription number assigned to the order for the radiopharmaceutical.
7. Any specific instructions.
8. The initials of the person dispensing the radiopharmaceutical.
9. Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded.

(h) In addition to other labeling requirements of the state laws and rules of the Board of Pharmacy for nonradioactive pharmaceuticals, the immediate outer shield of a radiopharmaceutical to be distributed shall also be labeled with:
1. The standard radiation symbol.
2. The words, "Caution Radioactive Material".
3. The name of the procedure.
4. The prescription number of the radiopharmaceutical and a suitable lot number for traceability.
5. The radionuclide and chemical form.
6. The amount of radioactivity and the calibration date and time.
7. The expiration date and time.
8. The volume dispensed if liquid chemical form.
9. The number of items or weight if solid chemical form.
10. The number of ampules or vials if gaseous chemical form.
11. Molybdenum-99 content to USP limits.
12. The name of the patient, or the words, "Physician's Use Only", in the absence of a patient name.

(i) The immediate inner container label of a radiopharmaceutical to be distributed shall also be labeled with:
1. The standard radiation symbol.
2. The words, "Caution Radioactive Material".
3. The radionuclide.
4. The chemical form.
5. The name of the procedure.
6. The prescription number of the radiopharmaceutical.

(6) Minimum Requirement for Space, Equipment, Supplies, and Publication: In order to insure compliance with general safety requirements as set forth above, the following minimum requirements shall be met by a nuclear pharmacy, which operates pursuant to a permit issued by the Alabama Board of Pharmacy, and engages in providing radiopharmaceutical services. These requirements are in addition to the minimum requirements for space, equipment and supplies for other types of pharmacies, and those requirements of the State of Alabama Department of Public Health, Radiological Health Branch, for the control of radiation. Such minimum permit requirements are set forth as follows:

(a) Space - The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such nonradioactive pharmaceuticals from pharmacy areas.

(b) Equipment:
1. Fume hood
2. Shielded radiation containment drawing section
3. Dose calibrator
4. Well scintillation counters
5. Area rate meters
6. Geiger-Mueller (GM) survey meters
7. Refrigerator
8. Microscope
9. Hemocytometer
10. Leaded glass syringe and vial shields
11. Personnel radiation detection devices
12. Radioactive storage container and/or storage vault for waste materials

(c) Supplies:
1. Syringes and vials required to perform practice
2. Disposable gloves and protective lab coats
3. Appropriate supplies to ensure aseptic technique
4. Appropriate supplies to perform thin layer chromatography
5. Lead transport shields for syringes and vials
6. D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(7) Training Qualifications: A pharmacist licensed to practice pharmacy in this state, who performs a radiopharmaceutical service, shall, prior to engaging in such specialized practice, meet the minimum training requirements of didactic study, training and experience in the handling of radioactive material.

(a) A licensed pharmacist seeking to practice nuclear pharmacy in this state, shall submit to the Board of Pharmacy, a certificate of training and a course outline from an accredited college of pharmacy, or other program recognized by the State of Alabama Department of Public Health, Radiological Health Branch and the Alabama Board of Pharmacy, and a certificate of such training which provides a minimum of 200 clock hours of formal didactic training. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:
1. Radiation physics and instrumentation
2. Radiation Protection
3. Mathematics pertaining to the use and measurement of radioactivity
4. Radiation Biology

5. Radiopharmaceutical chemistry

(b) The minimum on-the-job training which shall be included in a radiopharmacy internship is five hundred (500) hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include, but shall not be limited to the following:

1. Ordering, receiving and unpackaging radioactive material safely, including performing related radiation surveys.

2. Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.

3. Calculating, preparing and verifying patient doses while maintaining radiation safety standards of shielding.

4. Following appropriate internal control procedures to prevent mislabeling.

5. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures and surveys.

6. Eluting Technetium-99 from generator systems, assaying the eluate for technetium-99m, for molybdenum-99 contamination, and processing the eluate with reagent radiopharmaceuticals.

7. Clinical practice concepts.

Author: ~~James W. McLane~~, Herb Bobo, R.Ph., Secretary
Statutory Authority: Code of Alabama 1975, § 34-23-92.
History: Adopted: June 8, 1989; Effective July 31, 1989; Amended .

Arizona Secretary of State - Ken Bennett

Arizona Administrative Code

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CHAPTER 23. BOARD OF PHARMACY

Supp. 11-4

Authority: A.R.S. § 32-1904 et seq.

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R4-23-681. General Requirements for Limited-service Nuclear Pharmacy

A. To be an authorized nuclear pharmacist, a pharmacist shall:
1. Hold a current pharmacist license issued by the Board; and
2. Be certified as a nuclear pharmacist by:
a. The Board of Pharmaceutical Specialties, or
b. A similar group recognized by the Arizona State Board of Pharmacy; or
3. Satisfy each of the following requirements:
a. Meet minimal standards of training for status as an authorized user of radioactive material, as specified by the Arizona Radiation Regulatory Agency and the United States Nuclear Regulatory Commission;
b. Submit certification of completion of a Board-approved nuclear pharmacy training program or other training program recognized by the Arizona Radiation Regulatory Agency, with 200 hours of didactic training in the following areas:
i. Radiation physics and instrumentation,
ii. Radiation protection,
iii. Mathematics pertaining to the use and measurement of radioactivity,
iv. Radiation biology, and
v. Radiopharmaceutical chemistry;
c. Submit evidence of a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of an authorized nuclear pharmacist in the following areas:
i. Procuring radioactive materials;
ii. Compounding radiopharmaceuticals;
iii. Performing routine quality control procedures;
iv. Dispensing radiopharmaceuticals;
v. Distributing radiopharmaceuticals;
vi. Implementing basic radiation protection procedures; and
vii. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and
d. Submit written certification, signed by a preceptor who is an authorized nuclear pharmacist, that the above training was satisfactorily completed.

B. Radiopharmaceuticals are prescription-only drugs that require specialized techniques in their handling and testing, to obtain optimum results and minimize hazards.
1. A person shall not sell, barter, or otherwise dispose of, or be in possession of any radiopharmaceutical except under the conditions detailed in A.R.S. § 32-1929.
2. A person shall not manufacture, compound, sell, or dispense any radiopharmaceutical unless the person is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist in accordance with A.R.S. § 32-1961 and these rules, with the exception of the following, if the following are licensed by the Arizona Radiation Regulatory Agency to use radiopharmaceuticals in compliance with A.R.S. § 30-673;
a. A medical practitioner who administers a radiopharmaceutical to the medical practitioner's patient as provided in A.R.S. § 32-1921(A),
b. A hospital nuclear medicine department, and
c. A medical practitioner's office.
3. The Board shall cooperate with the Arizona Radiation Regulatory Agency and other interested state and federal agencies, in the enforcement of these rules for the protection of the public. This cooperation may include exchange of licensing and other information, joint inspections, and other activities where indicated.

C. In addition to compliance with all the applicable federal and state laws and rules governing drugs, whether radioactive or not, a limited-service nuclear pharmacy permittee shall comply with all laws and rules of the Arizona Radiation Regulatory Agency and the U.S. Nuclear Regulatory Commission, including emergency and safety provisions.

D. A limited-service nuclear pharmacy permittee shall comply with the education, experience, and licensing requirements of the Arizona Radiation Regulatory Agency.

E. A limited-service nuclear pharmacy permittee shall ensure that radiopharmaceuticals are transferred only to a person or firm that holds a current Radioactive Materials License issued by the Arizona Radiation Regulatory Agency.

Historical Note

Adopted effective December 3, 1974 (Supp. 75-1). Amended subsections (A), (C) and (D) effective Aug. 12, 1988 (Supp. 88-3). Amended effective July 8, 1997 (Supp. 97-3).

R4-23-682. Limited-service Nuclear Pharmacy

A. Before operating a limited-service nuclear pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, and 32-1931, and R4-23-606.

B. A permit to operate a limited-service nuclear pharmacy shall be issued only to a person who is or employs an authorized nuclear pharmacist and holds a current Arizona Radiation Regulatory Agency Radioactive Materials License. A limited-service nuclear pharmacy permittee that fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License shall be immediately suspended pending revocation by the Board. A limited-service nuclear pharmacy permittee shall have copies of Arizona Radiation Regulatory Agency inspection reports available upon request for Board inspection.
1. A limited-service nuclear pharmacy permittee shall designate an authorized nuclear pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall be responsible to the Board:
a. For the operations of the pharmacy related to the practice of pharmacy and distribution of drugs and devices;
b. For communicating Board directives to the management, pharmacists, interns, and other personnel of the pharmacy; and
c. For the pharmacy's compliance with all federal and state pharmacy laws and rules.
2. An authorized nuclear pharmacist shall directly supervise all personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs.
3. An authorized nuclear pharmacist shall be present whenever the limited-service nuclear pharmacy is open for business.

C. A limited-service nuclear pharmacy permittee shall ensure that the limited-service nuclear pharmacy complies with the standards for personnel, area, security, sanitation, and general requirements in R4-23-608, R4-23-609, R4-23-610, R4-23-611, and R4-23-671.
1. A limited-service nuclear pharmacy shall contain separate areas for:
a. Preparing and dispensing radiopharmaceuticals,
b. Receiving and shipping radiopharmaceuticals,
c. Storing radiopharmaceuticals, and
d. Decaying radioactive waste.
2. The Board may require more than the minimum area in instances where equipment, inventory, personnel, or other factors cause crowding to a degree that interferes with safe pharmacy practice.

D. The pharmacist-in-charge shall designate in writing, by title and specific area, the persons who may have access to particular pharmacy areas.

E. A limited-service nuclear pharmacy permittee shall maintain records of acquisition, inventory, and disposition of radiopharmaceuticals, other radioactive substances, and other drugs in accordance with federal and state statutes and rules.
1. A prescription order, in addition to the requirements in A.R.S. § 32-1968(C) and R4-23-407(A), shall contain:
a. The date and time of calibration of the radiopharmaceutical,
b. The name of the procedure for which the radiopharmaceutical is prescribed, and
c. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product.
2. The lead container used to store and transport a radio-pharmaceutical shall have a label that, in addition to the requirements in A.R.S. § 32-1968(D), includes:
a. The date and time of calibration of the radiopharmaceutical,
b. The name of the radiopharmaceutical,
c. The molybdenum 99 content to USP limits,
d. The name of the procedure for which the radiopharmaceutical is prescribed,
e. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product,
f. The words "Caution: Radioactive Material," and
g. The standard radiation symbol.
3. The radiopharmaceutical container shall have a label that includes:
a. The date and time of calibration of the radiopharmaceutical;
b. The name of the patient, recorded before dispensing, if the radiopharmaceutical is therapeutic or for a blood product;
c. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product;
d. The name of the radiopharmaceutical;
e. The dose of radiopharmaceutical;
f. The serial number;
g. The words "Caution: Radioactive Material"; and
h. The standard radiation symbol.

F. The following minimum requirements are in addition to the requirements of the Arizona Radiation Regulatory Agency, the applicable U.S. Nuclear Regulatory Commission regulations, and the applicable regulations of the federal Food and Drug Administration. A limited-service nuclear pharmacy permittee shall provide:
1. In addition to the minimum pharmacy area requirements in R4-23-609:
a. An area for the storing, compounding, and dispensing of radiopharmaceuticals completely separate from pharmacy areas for nonradioactive drugs;
b. A minimum of 80 sq. ft. for a hot lab and storage area; and
c. A minimum of 300 sq. ft. of compounding and dispensing area;
2. The following equipment:
a. Fume hood, approved by the Arizona Radiation Regulatory Agency;
b. Laminar flow hood;
c. Dose calibrator;
d. Refrigerator;
e. Prescription balance, Class A, and weights or an electronic balance of equal or greater accuracy;
f. Well scintillation counter;

g. Incubator oven;
h. Microscope;
i. An assortment of labels, including prescription labels and cautionary and warning labels;
j. Glassware necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
k. Other equipment necessary for radiopharmaceutical quality control for products compounded or dispensed as required by the Arizona Radiation Regulatory Agency;
l. Current antidote and drug interaction information; and
m. Regional poison control phone number prominently displayed in the pharmacy area;
3. Supplies necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
4. A professional reference library consisting of a minimum of one current reference or text addressing each of the following subject areas:
a. Therapeutics,
b. Nuclear pharmacy practice, and
c. Imaging;
5. Current editions and supplements of:
a. A.R.S. §§ 30-651 through 30-696 pertaining to the Arizona Radiation Regulatory Agency,
b. Rules of the Arizona Radiation Regulatory Agency,
c. Regulations of the federal Food and Drug Administration pertaining to radioactive drugs,
d. Arizona Pharmacy Act and rules,
e. Arizona Uniform Controlled Substances Act, and
f. Radiological Health Handbook.

G. The pharmacist-in-charge of a limited-service nuclear pharmacy shall prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for pharmacy operations and drug distribution.

H. The written policies and procedures of a limited-service nuclear pharmacy shall include the following:
1. Prescription orders;
2. Clinical services and drug utilization management including:
a. Drug utilization reviews,
b. Inventory audits,
c. Patient outcome monitoring,
d. Drug information, and
e. Education of pharmacy and other health professionals;
3. Duties and qualifications of professional and support staff;
4. Radioactive material handling, storage, and disposal;
5. Drug product procurement;
6. Drug compounding, dispensing, and storage;
7. Investigational drugs and their protocols;
8. Patient profiles;
9. Quality management procedures for:
a. Adverse drug reaction reports;
b. Drug recall;
c. Expired and beyond-use-date drugs;
d. Medication or dispensing errors;
e. Radiopharmaceutical quality assurance;
f. Radiological health and safety;
g. Drug storage and disposition; and
h. Education of professional staff, support staff, and patients;
10. Recordkeeping;
11. Sanitation;
12. Security;
13. Drug delivery requirements for:
a. Transportation,
b. Security,
c. Radiological health and safety procedures,
d. Temperature and other environmental controls, and
e. Emergency provisions; and
14. Patient education.

Historical note

Adopted effective July 8, 1997 (Supp. 97-3). Amended by final rulemaking at 12 A.A.R. 3032, effective October 1, 2006 (Supp. 06-3).

R4-23-683. Reserved

through

R4-23-690. Reserved

R4-23-691. Repealed

Historical Note

Adopted effective Dec. 3, 1974 (Supp. 75-1). Amended effective Aug. 12, 1988 (Supp. 88-3). Amended effective November 1, 1993 (Supp. 93-4). Repealed effective July 8, 1997 (Supp. 97-3).

Arkansas

LAWS AND REGULATIONS

August 2011

MIKE BEEBE, GOVERNOR

JOHN CLAY KIRTLEY, PHARM.D.,
EXECUTIVE DIRECTOR

ARKANSAS STATE BOARD OF PHARMACY

101 E. CAPITOL, SUITE 218
LITTLE ROCK, AR 72201
PHONE: (501) 682-0190
FAX: (501) 682-0195
www.arkansas.gov/asbp

(2) An off-site order entry pharmacy shall comply with the provisions contained in regulations 04-02-0010 REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN PHARMACIES HOLDING PHARMACY PERMITS and 07-00-0008 ELECTRONIC PRESCRIPTION PROCESSING AND PATIENT CONFIDENTIALITY to the extent applicable for the specific processing activity and this section including:

(A) duties which must be performed by a pharmacist; and

(B) supervision requirements for pharmacy technicians.

(3) Off-site order entry may only be performed by a retail pharmacy as appropriately licensed by the Arkansas State Board of Pharmacy

(e) Notifications to patients.

(1) A pharmacy that outsources off-site prescription order entry to another pharmacy shall prior to outsourcing their prescription:

(A) notify patients that prescription processing may be outsourced to another pharmacy; and

(B) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

(f) Records. All pharmacies shall maintain appropriate records which identify, by prescription drug order, the name(s), initials, or identification code(s) of each pharmacist or pharmacy technician who performs a processing function for a prescription drug order. Any record generated in this process whether in a hard copy or electronic format shall be maintained for a minimum period of two years from the last date of entry. Such records may be maintained:

(1) separately by each pharmacy and pharmacist; or

(2) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

(g) In the operation of the off-site order entry, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times. (6/30/2007)

04-02-0100—NUCLEAR PHARMACY

The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice regulated by the Arkansas State Board of Pharmacy. As such, the following rules are

included to address those areas specific, or unique to, this specialty practice. These regulations are intended to supplement the regulations of other state and federal agencies.

(a) Definitions:

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

(2) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services, and shall be licensed by the Arkansas State Board of Pharmacy.

(3) "Practice of nuclear pharmacy" means 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 and other drugs.

(4) "Qualified nuclear pharmacist" means a pharmacist who holds a current license issued by the Arkansas State Board of Pharmacy, and who is certified as a nuclear pharmacist by a certification board recognized by the Arkansas State Board of Pharmacy, or satisfies each of the following requirements:

(A) Meets minimal standards of training for status as an authorized user of radioactive material, as specified by the Arkansas Department of Health, Division of Radiation Control and Emergency Management of the Nuclear Regulatory Commission.

(B) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a College of Pharmacy approved by the Arkansas State Board of Pharmacy, or other training program recognized by the Arkansas State Board of Pharmacy, with the minimum 200 hours apportioned as follows:

(i) Radiation physics and instrumentation
(ii) Radiation protection
(iii) Mathematics pertaining to the use and measurement of radioactivity
(iv) Radiation biology
(v) Radiopharmaceutical chemistry

(C) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

(i) Procuring radioactive materials
(ii) Compounding radiopharmaceuticals
(iii) Performing routine quality control procedures
(iv) Dispensing radiopharmaceuticals
(v) Distributing radiopharmaceuticals
(vi) Implementing basic radiation protection procedures
(vii) Consulting and educating the nuclear medicine community, pharmacists, other health professionals, and the general public.

(D) Has submitted an affidavit of experience and training to the Board of Pharmacy.

(5) "Quality assurance procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(6) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(7) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but which does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(8) "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, and consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(b) General requirements for pharmacies providing radiopharmaceutical services

(1) A permit to operate a nuclear pharmacy, providing radiopharmaceutical services, shall only be issued to a facility employing a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the nuclear pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the nuclear pharmacy.

(2) The permit to operate a nuclear pharmacy is effective only so long as the nuclear pharmacy also holds a current Arkansas Department of Health or Nuclear Regulatory Commission license.

(3) Nuclear pharmacies shall have adequate space and equipment commensurate with the scope of services required and provided. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping/receiving area; radioactive material storage area; and radioactive waste decay area. The application for a permit to operate a nuclear pharmacy shall include detailed floor plans and no material change may be made without the permission of the Board.

(4) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and must be totally enclosed and lockable.

(5) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive materials in accordance with Board and Arkansas Department of Health or Nuclear Regulatory Commission statutes and regulations.

(6) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance. The Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(7) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Arkansas Department of Health or Nuclear Regulatory Commission to possess, use, and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(8) A nuclear pharmacy, upon receipt of an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system, which writing or record shall contain at least the following:
(A) the name of the institution and prescriber, or prescriber's agent;
(B) the date of dispensing and the calibration time of the radiopharmaceutical;
(C) the name of the procedure;
(D) the name of the radiopharmaceutical;
(E) the dose or quantity of the radiopharmaceutical;
(F) the serial number assigned to the order for the radiopharmaceutical;
(G) any specific instructions;
(H) the initials of the person who dispensed the order.

Orders for routine diagnostic radiopharmaceuticals, which have been previously established by the nuclear pharmacist with the physician, may be taken by a pharmacy technician and entered into the computer. The nuclear pharmacist shall verify the label with the written order. However, whenever an order is for a therapeutic or blood-product radiopharmaceutical, the prescription order must be received by a nuclear pharmacist and the patient's name must be obtained and recorded prior to dispensing.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:
(A) the name and address of the pharmacy;
(B) the name of the prescriber;
(C) the date of dispensing;
(D) the serial number assigned to the order for the radiopharmaceutical;
(E) the standard radiation symbol;
(F) the words "Caution Radioactive Material";
(G) the name of the procedure;
(H) the radionuclide and chemical form;
(I) the amount of radioactivity and the calibration date and time;
(J) if a liquid, the volume;
(K) if a solid, the number of items or weight;
(L) if a gas, the number of ampoules or vials;
(M) molybdenum 99 content to USP limits; and
(N) the name of the patient or the words "Per Physician's Order" in the absence of a patient name. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label prior to dispensing.

(10) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:
(A) the standard radiation symbol;
(B) the words "Caution Radioactive Material";
(C) the identity of the radionuclide;
(D) the chemical form;
(E) the name of the procedure; and

(F) serial number of the radiopharmaceutical.

(11) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(12) Each nuclear pharmacy shall have a current copy of state and applicable federal regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

(c) Minimum equipment

The professional area of the pharmacy shall have equipment appropriate for the pharmacy's specific scope of practice which may include but is not limited to the following:

(1) Radionuclide Dose Calibrator;
(2) Refrigerator;
(3) Single or multiple channel scintillation counter with well-type NaI(Tl) or Ge(Li) detector;
(4) Radiochemical fume hood and filter system with suitable air sampling equipment;
(5) At least two GM survey meters (including one high-range meter);
(6) Microscope and hemacytometer;
(7) Supplies to perform quality assurance testing;
(8) Syringe and vial radiation shields;
(9) Lead-shielded drawing station;
(10) Decontamination supplies;
(11) Supplies to perform quality assurance testing;
(12) Lead transport shields for syringes and vials; and
(13) D.O.T. approved USA Type A, 7A approved transport containers and other labels and supplies for shipping radioactive materials. (10/14/98 and 11/1/2007)

04-03 REGULATIONS REGARDING RETAIL SPECIALTY PHARMACIES

04-03-0001—SPECIALTY PHARMACY PERMITS

The Board may issue a specialty pharmacy permit for a facility to provide unique aspects of pharmaceutical care to an identified patient population as provided in regulation 04-03-0001 *et seq.* Said specialty pharmacies and the pharmacists practicing therein shall comply with applicable federal and state laws and regulations, including Arkansas Pharmacy Law, A.C.A. § 17-92-101 *et seq.*, and Board Regulations, including without limitation regulations regarding retail pharmacies 04-02-0001 *et seq.*, which are not expressly superseded by the regulation applicable to the specific type of specialty pharmacy.

04-03-0002 METHADONE CLINIC SPECIALTY PHARMACY PERMIT

(a) Definitions:

(1) "Methadone clinic pharmacy" means the place in which a licensed professional prepares methadone or buprenorphine to be administered and/or dispensed to a patient of the clinic.

(2) "Dispensing" means the preparation of one or more doses of methadone or buprenorphine in properly labeled, patient specific containers and delivery of said drugs to the patient to consume away from the clinic; only a licensed pharmacist or physician holding a dispensing permit issued by the Arkansas State Medical Board shall dispense methadone.

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The Pharmacy Law
(Business and Professions Code 4000 et seq.)
Excerpts from the Business and Professions Code
Board of Pharmacy Regulations
(California Code of Regulations, Title 16, Section 1700 et seq.)
Excerpts from the California Uniform Controlled Substances Act
(Health and Safety Code 11000 et seq.)
Excerpts from the Confidentiality of Medical Information Act
(Civil Code 56 et seq.)
Excerpts from the Public Resources Code

Board of Pharmacy

Be Aware & Take Care

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.
Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.
The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

1708.2. Discontinuance of Business.
Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall follow official instructions given by the board applicable to the transaction.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4322 and 4333, Business and Professions Code; and 11205, Health and Safety Code.

1708.3. Radioactive Drugs.
A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.

1708.4. Pharmacist Handling Radioactive Drugs.
A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code

1708.5. Pharmacy Furnishing Radioactive Drugs.
A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.
A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.

1709. Names of Owners and Pharmacist in Charge.
(a) Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days.
(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days.
(c) The following shall constitute a transfer of permit and require application for a change of ownership: any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4058, 4101, 4111, 4112, 4113, 4120, 4124, 4130, 4133, 4141, 4149, 4160, 4161, 4196, 4201, 4304, 4305 and 4330, Business and Professions Code

1709.1. Designation of Pharmacist in Charge.
(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in- charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and

Colorado

DEPARTMENT OF REGULATORY AGENCIES
State Board of Pharmacy
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PHARMACY RULES AND REGULATIONS

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11.09.00 Symbols and Codes. Symbols and codes may be used to identify any manufacturer, distributor or repackager. If such symbols and codes appear in the records of a prescription drug outlet, the prescription drug outlet shall keep a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable and available for examination by the Board for at least two years.

12.00.00 NUCLEAR PHARMACY.

12.00.10 Authorized handling. It is unlawful to receive, possess or transfer radiopharmaceuticals, except in accordance with CRS 12-22-108. It is also unlawful for any person to provide radiopharmaceutical services unless he or she is a nuclear pharmacist acting in accordance with CRS Title 12, Article 22, and the regulations of the State Board of Pharmacy and regulations of the Colorado Department of Health, with the exception of an authorized practitioner for administration to his patients. No person may receive, acquire, possess, use, transfer or dispose of any radioactive material except in accordance with the conditions of any radioactive material license required by the Colorado Department of Health pursuant to CRS 25-11-101 et seq. The requirements of this regulation are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Radiation Control Agency.

12.00.20 Definitions.

12.00.21 A "nuclear prescription drug outlet" means a prescription drug outlet which deals with the preparation and delivery of radioactive material as defined in CRS 25-11-101.

12.00.22 "Nuclear pharmacist" means a pharmacist who holds an active pharmacist license with the board and has met the standards of training and experience for "Authorized User Status" in handling radioactive materials in accordance with either the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission.

12.00.23 "Radiopharmaceutical service" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals, and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of radiopharmaceuticals.

12.00.24 A "radiopharmaceutical" is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any such drug which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are 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.

12.00.25 "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on 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.

12.00.26 "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

12.00.27 "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

12.00.28 "Authorized practitioner" means a practitioner authorized by law to possess, use and administer radiopharmaceuticals, acting within the scope of such authority.

12.00.30 Requirements For Nuclear Prescription Drug Outlets. A nuclear prescription drug outlet shall only be managed by a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be in attendance at all times that the nuclear prescription drug outlet is open for business and shall be responsible for all operations of the registered area.

12.00.31 All nuclear prescription drug outlets shall have adequate space, commensurate with the scope of services required and provided. The nuclear prescription drug outlet area shall be separate from the areas for non-radioactive drugs and shall provide a radioactive storage and product decay area separate from and exclusive of the radioactive laboratory, compounding, dispensing, quality assurance and administrative area. Prior to registration, a nuclear prescription drug outlet that wishes to compound both radiopharmaceuticals and non-radiopharmaceuticals not directly pertaining to nuclear studies shall meet the space requirements set forth in Regulation 5.01.31. If a nuclear prescription drug outlet wishes to compound only radiopharmaceuticals, it shall not be required to meet the space requirements set forth in Regulation 5.01.31. All nuclear prescription drug outlets shall submit detailing drawing-to-scale floor plans to the board that have been approved by the state radiation control agency before approval of the registration.

12.00.32 Nuclear prescription drug outlets that compound both radiopharmaceuticals and non-radiopharmaceuticals not directly pertaining to nuclear studies shall maintain a professional library in compliance with regulation 5.01.31(f), regulation 12.00.32(a) through (d), and if applicable, regulation 5.01.32(a)(3). A nuclear prescription drug outlet that compounds only radiopharmaceuticals shall maintain and have available in the outlet or electronically a professional library in compliance with regulation 12.00.32(a) through (d) and shall be exempt from the requirements of regulation 5.01.31(f) and 5.01.32(a)(3). If an electronic library is provided, workstations must be provided and must be readily available for use by staff and board personnel. This library shall contain current copies of the following references which shall be maintained and readily available for use by staff and inspection by the board:

a. All parts of CRS Title 12, Article 22;

b. The current rules and regulations of the board of pharmacy;

c. The current rules and regulations of the State Radiation Control Agency and U.S. Nuclear Commission; and

d. Any other references that the pharmacist manager of the nuclear prescription drug outlet deems necessary.

12.00.33 A nuclear prescription drug outlet shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing non-radioactive drugs.

12.00.34 A nuclear prescription drug outlet shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided.

12.00.35 Nuclear prescription drug outlets which compound and dispense only radiopharmaceuticals shall be exempt from the security requirements of regulation 5.01.50 provided the following conditions are met:

a. Only individuals identified as having "Authorized User" status by the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission may enter the compounding/dispensing area in the absence of a pharmacist and only for the purpose of equipment maintenance.

b. The nuclear prescription drug outlet maintains a written record documenting such entry detailing the following information:

1) Date and time of entry;

2) Authorized users name;

3) Reason for entry; and

4) Signature of pharmacist manager.

Such record shall be maintained on the premises and available for inspection for at least two years from the date of entry.

12.00.40 General Requirements for Nuclear Pharmacists. A nuclear pharmacist shall:

a. Be a pharmacist licensed to practice in Colorado;

b. Meet the standards of training and experience for "authorized user status" in handling of radioactive materials in accordance with either the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission; and

c. Be specifically identified, by name, as an "authorized nuclear pharmacist" on either a radioactive materials license issued by the Colorado Department of Public Health and Environment or on a U.S. Nuclear Regulatory Commission master license.

12.00.45 Nuclear prescription drug outlets shall post, in a conspicuous area of the compounding / dispensing area of the outlet, and shall have readily available for inspection, the follow:

a. The original copy of the current registration with the pharmacy board;

b. The original copy, or a reference to its specific location in the outlet, of the most current radioactive materials license issued by the Colorado Department of Public Health and Environment;

c. A copy, or a reference to its specific location in the outlet, of the most current U.S. Nuclear Regulatory Commission master license which details a listing of its authorized nuclear pharmacists if the current radioactive license issued by the Colorado Department of Public Health and Environment references the outlet's U.S. Nuclear Regulatory Commission master license rather than detailing a listing of the outlet's authorized nuclear pharmacists itself; and

d. The outlet's current list of employees that complies with regulation 11.08.00.

12.00.64 Nuclear Compounding.

If a nuclear pharmacist compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation.

a. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the final compounded product.

b. The compounding of sterile radiopharmaceuticals shall comply with regulation 21.00.00, including all recordkeeping requirements.

12.00.70 Dispensing.

a. A radiopharmaceutical shall only be dispensed pursuant to a valid, patient-specific prescription order that is issued by an authorized practitioner.

b. A nuclear prescription drug outlet shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical assurance.

c. In addition to any labeling requirement of the board for non radiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with:

(1) The standard radiation symbol;

(2) The words "Caution – Radioactive Material";

(3) The name of the radiopharmaceutical;

(3) The amount of radioactive materials contained, in millicuries or microcuries;

(4) If a liquid, the volume in milliliters;

(5) The requested calibration time for the amount of radioactivity contained; and

(6) Expiration data, if applicable.

d. The immediate inner container shall be labeled with:

(1) The standard radiation symbol;

(2) The words "caution – radioactive material";

(3) The assigned serial number of the corresponding prescription order; and

(4) The name of the radiopharmaceutical.

e. The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

12.00.71 Records of Dispensing.

a. In addition to any requirement of the board for non-radiopharmaceutical prescription orders, the prescription order shall include the following:

(1) Address of the authorized practitioner and/or the address where the prescription is to be administered;

(2) The name of radiopharmaceutical;

(3) The amount of radioactive materials contained, in millicuries or microcuries; and

(4) Calibration time for the amount of radioactivity contained.

For the purposes of this regulation, the prescription drug outlets may record the address on the order or maintain it in a readily retrievable format.

b. A hard copy of every prescription order shall be readily retrievable and available for inspection for a period of two years from the date of any transaction relating to such order. If a nuclear prescription drug outlet dispenses only radiopharmaceuticals, prescription orders will be deemed to be readily retrievable and available if they are filed according to the date of dispensing. If a nuclear prescription drug outlet dispenses both radiopharmaceuticals and non-radiopharmaceuticals not directly pertaining to nuclear studies, all prescription orders will be deemed to be readily retrievable and available if they are filed according to the numerical sequence of the serial numbers assigned pursuant to regulation 2.01.10.

12.00.72 Distribution.

a. A nuclear prescription drug outlet may distribute a compounded radiopharmaceutical to a practitioner authorized by law to prescribe the

drug for the purposes of administration. Such distributions shall be limited to up to 10 percent of the total number of drug dosage units dispensed and distributed on an annual basis by such outlet.

b. A nuclear prescription drug outlet may redistribute NDA approved radiopharmaceuticals if the outlet does not process the radiopharmaceuticals in any manner or violate the product packaging.

c. The immediate outer container of the radiopharmaceutical to be distributed shall be labeled with:

(1) The standard radiation symbol;

(2) The words "Caution – Radioactive Material";

(3) "RX Only";

(4) The name of Radiopharmaceutical;

(5) The amount of radioactive materials contained, in millicuries or microcuries;

(6) If a liquid, the volume in milliliters;

(7) The requested calibration time for the amount of radioactivity contained;

(8) Expiration data, if applicable;

(9) The assigned batch (lot) number;

(10) Specific route of administration;

(11) Storage directions; and

(12) The name and address of the prescription drug outlet.

d. The immediate inner container shall be labeled with:

(1) The standard radiation symbol;

(2) The words "Caution – Radioactive Material";

(3) The assigned batch (lot) number; and

(4) The name of the radiopharmaceutical.

12.00.73 Records of Distribution.

a. A nuclear prescription drug outlet shall maintain records of acquisition and distribution of all radiopharmaceuticals in accordance with CRS Title 12, and CRS Title 25.

b. A nuclear prescription drug outlet must retain verification of each practitioner's license from the jurisdiction in which licensed on a current basis for each practitioner to whom it distributes compounded radiopharmaceuticals.

c. A nuclear prescription drug outlet that distributes radiopharmaceuticals shall record the following:

(1) The name of the radiopharmaceutical;

(2) The amount of radioactive materials contained, in millicuries or microcuries;

(3) If a liquid, the volume in milliliters;

(4) The requested calibration time for the amount of radioactivity contained;

(5) The date of distribution;

(6) The name and address of the authorized practitioner and the address where the preparation is to be administered; and

(7) The name and address of the distributing outlet.

d. Records of distribution shall be retained at the outlet for a period of not less than two years from the date of distribution.

13.00.00 DECLARATORY ORDERS.

13.00.10 Requests. Any person may petition the Board for a declaratory order to terminate controversies or to remove uncertainties as to the applicability to the petitioner of any statutory provision or of any rule or order of the Board.

Refer to existing definition of "person" in APA, rules or statute, if any.

13.00.11 The Board will determine, in its discretion and without notice to petitioner, whether to rule upon any such petition. If the Board determines that it will not rule upon such a petition, the Board shall promptly notify the petitioner of its action and state the reasons for such action.

13.00.12 In determining whether to rule upon a petition filed pursuant to this rule, the Board will consider the following matters, among others:

a. Whether a ruling on the petition will terminate a controversy or remove uncertainties as to the applicability to petitioner of any statutory provision or rule or order of the Board.

b. Whether the petition involves any subject, question, or issue which is the subject of a formal or informal matter or investigation currently pending before the Board or a court but not involving any petitioner. Whether the petition seeks a ruling on a moot or hypothetical question or will result in an advisory ruling or opinion.

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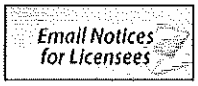

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- Motor Vehicles, long-term leasing, Chapter 743k
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  - Regulations on Written Disclosure on Resale of Motor Vehicles Replaced or Refunded by Manufacturer

(Added effective April 5, 2001.)

NUCLEAR PHARMACIES

Sec. 20-576-60. Definitions

As used in sections 20-576-60 to 20-576-63, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Agreement state" means any state that has entered into an agreement with the United States Nuclear Regulatory Commission or the Atomic Energy Commission under 42 U.S.C. § 2021;

(2) "Commission" means the Commission of Pharmacy;

(3) "Component" means any active or non-active ingredient of a drug product;

(4) "Department" means the Department of Consumer Protection;

(5) "Nuclear pharmacist" or "authorized nuclear pharmacist" means a pharmacist who holds a current pharmacist license issued by the commission, and who meets the following standards:

(A) has a current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(B) is identified as an authorized nuclear pharmacist on a United States Nuclear Regulatory Commission or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy;

(6) "Nuclear pharmacy technician" means a person who:

(A) works under the direct supervision of a nuclear pharmacist;

(B) is currently registered as a pharmacy technician with the department; and

(C) (i) has successfully completed a nuclear pharmacy technician training program provided by an accredited college program or an equivalent company sponsored program approved by the commission, or

(ii) is listed as an "Authorized User of Radioactive Materials" on the nuclear pharmacy's United States Nuclear Regulatory Commission or agreement state license;

(7) "Nuclear pharmacy" means a pharmacy that provides radiopharmaceutical services and holds

a Connecticut pharmacy license;

(8) "Practice of nuclear pharmacy" means 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 and other drugs;

(9) "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 required records;

(10) "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;

(11) "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclides with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator or eluates derived therefrom, 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 product, including, but not limited to, blood formed element, antibody or peptide, that is labeled with a radionuclide or solely intended to be labeled with a radionuclide;

(12) "Radiopharmaceutical compounding" means the preparation, mixing, assembling, packaging, or labeling of a radiopharmaceutical that:

(A) is the result of a practitioner's drug prescription order in the course of professional practice;

(B) is for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing;

(C) includes use of reagent kits and radiopharmaceuticals in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(D) is performed in accordance with the preparation instructions contained in the approved drug product labeling or other preparation directions as provided by the manufacturer;

(E) is 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

(F) may utilize professional judgment, scientific knowledge, literature evidence and other reference materials according to current standards of practice as the basis for employing any

deviations from the labeled preparation instructions or modifications to a radiopharmaceutical, if the final drug product, created as a result of any such deviations or modifications, is subjected to appropriate quality control testing necessary to confirm the presence of the desired radiopharmaceutical qualities;

(13)"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 the provision of pharmaceutical care; and

(14) "Reagent kit" means a sterile and pyrogen-free reaction vial containing nonradioactive chemicals, including, but not limited to, complexing agent (ligand), reducing agent, stabilizer, or dispersing agent.

(Added effective November 30, 2006.)

Sec. 20-576-61. General requirements for pharmacies providing radiopharmaceutical services

(a) A license to operate a nuclear pharmacy shall only be issued to a person who is, or who employs, a nuclear pharmacist.

(b) (1) A nuclear pharmacist shall:

(A) be responsible for all operations of the nuclear pharmacy;

(B) supervise the operation of only one nuclear pharmacy; and

(C) be present at all times that radiopharmaceutical services are being performed and at all times that the nuclear pharmacy is open for business.

(2) The license to operate a nuclear pharmacy shall be effective only if the pharmacy also holds appropriate federal and state licenses and permits to possess and distribute radioactive materials. Copies of all inspection reports prepared by any nuclear licensing agency shall be made available for department or commission inspection upon request.

(c) Nuclear pharmacies shall:

(1) have adequate space and equipment, commensurate with the scope of services required and provided:

(2) include, but are not limited to, the following areas: radiopharmaceutical preparation and dispensing area; radioactive material shipping and receiving area; radioactive material storage area and radioactive waste decay area;

(3) be secured from entry by unauthorized personnel;

(4) maintain records, including, but not limited to, the acquisition, inventory and disposition of all radiopharmaceuticals;

(5) compound and dispense radiopharmaceuticals that meet accepted standards of radiopharmaceutical quality, including, but not limited to, standards established by the United States Nuclear Regulatory Commission; and

(6) dispense radiopharmaceuticals only upon receipt of an order from a licensed practitioner or the practitioner's agent, or from a person authorized by the United States Nuclear Regulatory Commission or agreement state agency to possess such radiopharmaceuticals.

(d) (1) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with the regulations of the United States Nuclear Regulatory Commission and the Regulations of Connecticut State Agencies. A nuclear pharmacy may also furnish radiopharmaceuticals and other drug products for office use to these practitioners for individual patient use.

(2) Nuclear pharmacies may redistribute United States Food and Drug Administration approved radioactive drugs if the nuclear pharmacy does not process the radioactive drugs in any manner nor violate the product packaging. Drugs dispensed in this manner are not subject to the labeling requirements of section 20-576-62(c) of the Regulations of Connecticut State Agencies.

(Added effective November 30, 2006.)

Sec. 20-576-62. Records and labeling

(a) Upon receiving an order for a radiopharmaceutical, a nuclear pharmacy shall immediately reduce the prescription to writing or record the order in an automated data processing system. The written or electronic record shall contain at least the following:

(1) the name of the institution and prescribing practitioner or the practitioner's agent;

(2) the requested 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 prescription number assigned to the order;

(7) any specific instructions;

(8) the identity of the person who dispenses the prescription or medication order; and

(9) the patient's name if the prescription or medication order is for a therapeutic or blood-product radiopharmaceutical.

(b) The outer container (consisting of the radiation shielding) containing a radio-pharmaceutical to be dispensed shall be labeled with:

(1) the name and address of the pharmacy;

(2) the name of the prescribing practitioner;

(3) the date of dispensing;

(4) the prescription number;

(5) if radioactive, the standard radiation symbol and the words "Caution: Radioactive Material";

(6) the name of the procedure;

(7) the radionuclide and chemical form;

(8) the amount of radioactivity and the calibration date and time;

(9) the expiration time;

(10) the appropriate dosage units;

(11) if a solid, the number of items or weight;

(12) if a gas, the number of ampoules or vials; and

(13) the patient name when intended for individual therapeutic use, or the words "For

Physician Use" or "For Physician Use Only."

(c) The immediate inner container (containing the dose) 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;

(3) the standard radiation symbol; and

(4) the words "Caution: Radioactive Material."

(Added effective November 30, 2006.)

Sec. 20-576-63. Minimum equipment and supplies

(a) Each nuclear pharmacy shall have the following equipment and supplies:

(1) radiation detection and measuring instruments capable of accurately measuring quantities of radioactivity and radiation;

(2) radiation shielding;

(3) appropriate supplies and equipment for performing quality assurance testing;

(4) a refrigerator;

(5) materials for decontamination of accidental spills of radioactive materials; and

(6) appropriate supplies and equipment necessary for compounding and dispensing sterile parenteral radiopharmaceuticals.

(b) Each nuclear pharmacy shall have access to, or maintain on the premises, a copy of:

(1) the *United States Pharmacopoeia/National Formulary* (USP/NF), or *Remington: The Science and Practice of Pharmacy;* and

(2) the current rules and regulations of the Nuclear Regulatory Commission or agreement state.

(Added effective November 30, 2006.)

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Title 24 Regulated Professions and Occupations

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DEPARTMENT OF STATE

Division of Professional Regulation

2500 Board of Pharmacy

1.0 Pharmacist Licensure Requirements

1.1 Definitions

Words and terms defined in **Delaware Code** Title 1, Section 302 and Title 24, Section 2502 of the **Delaware Code** are applicable to these regulations. The following additional words and terms, when used within these regulations, shall have the following meaning unless the context clearly indicates otherwise or an alternate definition has been given:

"**Automated Data Processing System (ADPS)**" means a system utilizing computer software and hardware for the purposes of recordkeeping.

"**Cell**" means any container that holds the medication for automatic dispensing.

"**Central Prescription Processing**" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, DUR, claims adjudication, refill authorizations, and therapeutic interventions.

"**Common Database**" means a file or database created by an ADPS that enables authorized users to have common access to this file regardless of physical location.

"**Compounding**" means the art of the extemporaneous preparation and manipulation of drugs as a result of a practitioner's prescription order or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice, including the preparation of drugs in anticipation of drug orders based on routine, regularly observed prescribing patterns. Reconstitution of oral solutions is not considered compounding.

"**Computer**" means a programmable electronic device, capable of multifunctions including but not limited to storage, retrieval and processing of information.

"**Controlled Substance**" means those drug items regulated by Federal (CSA of 1970) and/or State Controlled (dangerous) Substances Act.

"**CRT**" means a Cathode Ray Tube used to impose visual information on a screen.

"**Delivery**" means the transfer of a dispensed prescription to the ultimate user (patient) or his/her agent.

"**Dispensing**" means to furnish or deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner; including the preparation, packaging, labeling or compounding necessary to prepare the drug for that delivery.

13.0 Nuclear Pharmacy Regulations

13.1 Purpose and Scope.

The Practice of Nuclear/Radiological Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by the Delaware Board of Pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice. Nuclear/Radiological Pharmacy Practice refers to patient-oriented and institutional services that embody the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

13.2 Definitions

"Authentication of Product History" means, but is not limited to, identifying the purchase sources, and any handling of any Component of a radiopharmaceutical.

"Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the product.

"Nuclear Pharmacy" means a Pharmacy providing radiopharmaceutical services or, as provided in Section 3 "Qualified Nuclear Pharmacist" means a currently licensed Pharmacist in the State of Delaware, who is certified as a Nuclear Pharmacist by a certification Board recognized by the Delaware Board of Pharmacy, or who meets the following standards set by the Delaware Board of Pharmacy:

Satisfied the minimum standards of training for "authorized user status" of radioactive material as included in the Nuclear Regulatory Commission (NRC) licensure guide.

Completed 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 NRC or the Office of Radiation Control (ORC), with emphasis in the following areas: radiation physics and instrumentation; radiation protection; mathematics of radioactivity; radiation biology; and radiopharmaceutical chemistry.

Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist.

"Radiopharmaceutical Quality Assurance" means, but is not limited to, 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.

"Radiopharmaceutical Service" means, but is not limited to, the procurement, storage, handling preparation, labeling, quality assurance testing, dispensing, delivery, recordkeeping, and disposal of radiopharmaceuticals and other drugs.

"Radiopharmaceuticals" are radioactive drugs as defined by the FDA.

13.3 General Requirements for Pharmacies Providing Radiopharmaceutical Services.

13.3.1 Nuclear Pharmacy License. A License to operate a Pharmacy providing radiopharmaceutical services shall only be issued to a Qualified Nuclear Pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a Qualified Nuclear Pharmacist. A Qualified Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business.

13.3.2 Nuclear Pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the State or as otherwise defined by the Delaware State Board of Pharmacy.

13.3.3 The Nuclear Pharmacy area shall be secured from unauthorized personnel.

13.3.4 Nuclear Pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with NRC statute(s) and regulation(s).

13.3.5 All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Office of Radiation Control and NRC before approval of the license.

13.3.6 Radiopharmaceuticals are to be dispensed only upon a Prescription Drug Order from a Practitioner authorized to possess, use, and administer radiopharmaceuticals.

13.3.7 The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Office of Radiation Control or NRC license. Copies of the Radiation Control Agency, ORC and NRC inspection reports shall be made available upon request for Board inspection.

9 DE Reg. 1253 (2/1/06)

Florida

Select Year: 2011 Go

The 2011 Florida Statutes

Title XXXII
REGULATION OF PROFESSIONS AND OCCUPATIONS

Chapter 465
PHARMACY

View Entire Chapter

465.0126 Nuclear pharmacist license; application, renewal, fees.—The department shall issue or renew a nuclear pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for nuclear pharmacist initial licensure or biennial renewal as established by the board by rule and receipt of a fee established by the board by rule not to exceed $250, which fee shall be in addition to the initial licensure or biennial renewal fee for pharmacists. The nuclear pharmacist shall be responsible for the compounding and the dispensing of nuclear pharmaceuticals, for maintaining all drug records required by law, for establishing drug handling procedures for the safe handling and storage of radiopharmaceuticals and medicinal drugs, for providing the security of the prescription department, and for complying with such other rules as relate to the practice of the profession of pharmacy. The nuclear pharmacist must have completed such additional training and must demonstrate such additional qualifications in the practice of nuclear pharmacy as is required by the board by rule in addition to licensure as a registered pharmacist. The board shall adopt rules necessary to implement and administer this section. The requirements of this section do not apply to hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

History.—s. 2, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

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Title XXXII
REGULATION OF PROFESSIONS AND OCCUPATIONS

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PHARMACY

465.0193 Nuclear pharmacy permits.—Any person desiring a permit to operate a nuclear pharmacy shall apply to the department. If the board certifies that the application complies with applicable law, the department shall issue the permit. No permit shall be issued unless a duly licensed and qualified nuclear pharmacist is designated as being responsible for activities described in s. 465.0126. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for the compounding and dispensing of nuclear pharmaceuticals.

History.—ss. 33, 118, ch. 83-329; ss. 15, 26, 27, ch. 86-256; s. 4, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

Florida

Rule Chapter: 64B16-28

Chapter Title: GENERAL REQUIREMENTS - PERMITS

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	64B16-28.101	Prescription Area Accessible to Inspection	2/2/2012
	64B16-28.102	Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment	5/4/2005
	64B16-28.1035	Patient Consultation Area	5/4/2005
	64B16-28.108	All Permits - Labels and Labeling of Medicinal Drugs	3/31/2005
	64B16-28.1081	Regulation of Daily Operating Hours	2/1/2012
	64B16-28.109	Prescription Department; Padlock; Sign: "Prescription Department Closed."	4/10/2005
	64B16-28.110	Outdated Pharmaceuticals	12/18/1974
	64B16-28.113	Permits; Single Entity; Single Location	1/30/1996
	64B16-28.114	Prescription Refills (Repealed)	10/5/2009
	64B16-28.118	Unit Dose and Customized Patient Medication Package Returns by In-patients	7/1/2002
	64B16-28.1191	Unclaimed Prescriptions	4/10/2005
	64B16-28.120	All Permits - Storage of Legend Drugs; Prepackaging	8/16/2010
	64B16-28.140	Record Maintenance Systems for Community, Special-Limited Community, Special-Closed Systems, Special-Parenteral/Enteral, and Nuclear Permits	10/15/2001

Florida

64B16-28.900 Definitions - Nuclear Pharmacy.

(1) A "nuclear pharmacy" is a pharmacy which provides radiopharmaceutical services.

(2) A "nuclear pharmacist" is a pharmacist who has met the training qualifications as described in Rule 64B16-28.903, F.A.C., and has been licensed by the Board of Pharmacy.

(3) A "radiopharmaceutical service" shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping and disposal of radiopharmaceuticals.

(4) A "radiopharmaceutical" is any substance defined as a drug by section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are 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.

(5) "Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on 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.

(6) "Authentication of product history" includes, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical or other drug.

Specific Authority 465.005 FS. Law Implemented 465.003(14), 465.022(1)(e) FS. History–New 1-7-76, Formerly 21S-3.01, Amended 4-4-88, Formerly 21S-3.001, Amended 7-31-91, 4-15-92, 10-1-92, Formerly 21S-28.900, 61F10-28.900, 59X-28.900, Amended 4-5-05.

64B16-28.901 Nuclear Pharmacy - General Requirements.

The process employed by any permit holder in this state concerning the handling of radioactive materials must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials. In order to insure the public health and safety in this respect, a nuclear pharmacy in this state shall meet the following general requirements:

(1) Each nuclear pharmacy shall designate a nuclear pharmacist as the prescription department manager who shall be responsible for compliance with all laws and regulations, both state and federal pertaining to radiopharmaceuticals and radiopharmaceutical services. A nuclear pharmacist must personally supervise the operation of only one nuclear pharmacy during all times when radiopharmaceutical services are being performed.

(2) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(3) Each nuclear pharmacy shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(4) All nuclear pharmacies shall provide a secured radioactive storage and decay area.

(5) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

(6) Radiopharmaceuticals are to be distributed only upon a prescription order from an authorized licensed medical practitioner or through the practitioner's agent.

(7) A nuclear pharmacist may transfer radioactive materials in accordance with all applicable laws and regulations.

(8) A nuclear pharmacist upon receiving an oral prescription order for a radiopharmaceutical shall immediately have the prescription order reduced to writing. The pharmacist may delegate this duty to a registered pharmacy technician only as authorized by Rule 64B16-27.410, F.A.C. The prescription order shall contain at least the following:

(a) The name of the user or his agent;

(b) The date of distribution and the time of administration of the radiopharmaceutical;

(c) The name of the procedure;

(d) The name of the radiopharmaceutical;

(e) The dose or quantity of the radiopharmaceutical;

(f) The serial number assigned to the prescription order for the radiopharmaceutical;

(g) Any specific instructions; and

(h) The initials of the person who received the prescription order.

(i) The patient's name must be obtained and recorded prior to dispensing, if the prescription order is for a therapeutic or blood product radiopharmaceutical.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The date of the original filling;

(d) The standard radiation symbol;

(e) The words "Caution Radioactive Material";

(f) The name of the procedure;

(g) The prescription order number of the radiopharmaceutical;

(h) The radionuclide and chemical form;

(i) The amount of radioactivity and the calibration date and time;

(j) The expiration date and time;

(k) The volume if a liquid;

(l) The number of items or weight, if a solid;

(m) The number of ampules or vials, if a gas;

(n) Molybdenum 99 content to USP limits, applies only to TC 99M products; and

(o) The name of the patient or the words "Physician's Use Only" in the absence of a patient name. If the prescription order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

(p) The initials of the pharmacist who dispensed the medication.

(10) The immediate inner container label of a radiopharmaceutical to be distributed shall be labeled with:
(a) The standard radiation symbol;
(b) The words "Caution Radioactive Material";
(c) The radionuclide;
(d) The chemical form;
(e) The prescription order number of the radiopharmaceutical.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.0126, 465.014 FS. History–New 1-7-76, Formerly 21S-3.03, Amended 12-11-86, 4-4-88, Formerly 21S-3.003, 21S-28.901, 61F10-28.901, Amended 2-26-95, Formerly 59X-28.901, Amended 4-5-05, 1-1-10.

64B16-26.303 Nuclear Pharmacist Licensure.

(1) A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be actively licensed as a nuclear pharmacist.

(2) A pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy a course outline from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy (a program comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists), and a certificate of training which provides a minimum of 200 clock hours of formal didactic training, which includes:

(a) Radiation physics and instrumentation (85 hours).

(b) Radiation protection (45 hours).

(c) Mathematics pertaining to the use and measurement of radioactivity (20 hours).

(d) Radiation biology (20 hours).

(e) Radiopharmaceutical chemistry (30 hours).

(3) Such academic training programs will be submitted to the Board of Pharmacy for approval by an accredited educational institution which operates under the auspices of or in conjunction with an accredited college of pharmacy.

(4) The minimum on-the-job training which shall be included in a radiopharmacy internship is 500 hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include but shall not be limited to the following:

(a) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys.

(b) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.

(c) Calculating, preparing and verifying patient doses, including the proper use of radiation shields.

(d) Following appropriate internal control procedures to prevent mislabeling.

(e) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys.

(f) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(g) Clinical practice concepts.

(5) If the didactic and experiential training required in this section have not been completed within the last seven (7) years, the applicant must have been engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven (7) years.

Specific Authority 465.005, 465.0126 FS. Law Implemented 465.0126 FS. History–New 1-18-05.

64B16-28.902 Nuclear Pharmacy - Minimum Requirements.

In order to insure compliance with the general safety requirements as previously set forth above, the following minimum requirements shall be met by a nuclear pharmacy. These requirements are in addition to the general requirements for space and equipment for other types of pharmacies, the requirements of the Department of Health for the control of radiation hazards, and the applicable requirements of the Federal Food and Drug Administration. Such minimum permit requirements are set forth as follows:

(1) Space:

(a) The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such radioactive pharmaceuticals from pharmacy areas which contain non-radioactive medicinal drugs;

(b) The Hot lab, storage area, and compounding and dispensing area shall be a minimum of 150 square feet.

(2) Equipment:

(a) Fume hood with appropriate air sampling equipment;

(b) Shielded radiation containment drawing station;

(c) Dose calibrator;

(d) Well scintillation counters;

(e) Area rate meters;

(f) Geiger-Mueller (GM) Survey meters;

(g) Refrigerator;

(h) Microscope;

(i) Syringe shields; and

(j) Personnel radiation detection devices.

(3) Supplies:

(a) Syringes and vials required to perform practice;

(b) Disposable gloves and protective lab coats;

(c) Appropriate supplies to ensure sterile practices for I.V. solutions;

(d) Appropriate supplies to perform thin layer chromotography;

(e) Lead transport shields for syringes and vials. No person shall utilize reusable unit dose transport containers for radioactive doses without either an effective process to decontaminate the transport container of blood and other biohazardous substances or an effective mechanism to avoid contamination of the transport container. No person shall re-use a unit dose transport container that remains contaminated with blood or other biohazardous subtances. Any unit dose transport container that is returned with the tamper-evident seal broken and the unit dose syringe included shall be considered to be contaminated.

(f) D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(4) Current references:

(a) Chapter 465, F.S.;

(b) Chapter 404, F.S.;

(c) Chapter 893, F.S.;

(d) Chapters 64B16-26 and 64B16-28, F.A.C., Rules of the Florida Board of Pharmacy;

(e) Chapter 64E-5, F.A.C., Rules of the Department of Health;

(f) Title 10 C.F.R., Code of Federal Regulations, FDA Regulations;

(g) Title 49 C.F.R., Code of Federal Regulations, Department of Transportation Regulations;

(h) United States Pharmacopeia/National Formulary;

(i) USP-DI.

It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

Specific Authority 465.005, 465.022 FS. Law Implemented 465.0193, 465.022(1) FS. History–New 1-7-76, Formerly 21S-3.04, Amended 12-11-86, 4-4-88, Formerly 21S-3.004, Amended 7-31-91, Formerly 21S-28.902, 61F10-28.902, Amended 2-26-95, Formerly 59X-28.902, Amended 4-26-01, 4-5-05.

Georgia

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 10. NUCLEAR PHARMACY LAW

§ 26-4-170. Short title

This article shall be known and may be cited as the "Nuclear Pharmacy Law."

HISTORY: Code 1981, § 26-4-170, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-171. Definitions

As used in this article, the term:

(1) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

(2) "Board" means the State Board of Pharmacy.

(3) "Compounding of radiopharmaceuticals" means the addition of a radioactive substance to nonradioactive substances or the use of a radioactive substance in preparation for single or multidose dispensation upon the prescription order of a physician who is licensed to use radioactive materials. Compounding of radiopharmaceuticals may include: loading and eluting of radionuclide generators; using manufactured reagent kits to prepare radiopharmaceuticals; preparing reagent kits; aliquoting reagents; formulation and quality assurance testing of radiochemicals for use as radiopharmaceuticals; and radiolabeling of compounds or products, including biological products, for use as radiopharmaceuticals.

(4) "Department" means the Department of Natural Resources.

(5) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(6) "Manufacturing of radiopharmaceuticals" means the preparation, derivation, or production of a product to which a radioactive substance is or will be added to provide a radiopharmaceutical for sale, resale, redistribution, or reconstitution.

(7) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical service.

(8) "Radiopharmaceutical" means radioactive drugs and chemical products used for diagnostic and therapeutic purposes and includes the terms radioactive pharmaceuticals, radioisotopes, and radioactive tracers.

(9) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on radiopharmaceuticals and their component materials 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.

(10) "Radiopharmaceutical service" means, but is not limited to, the compounding, dispensing, labeling, and delivering of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review; the maintenance of radiopharmaceutical quality assurance; and the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy.

HISTORY: Code 1981, § 26-4-171, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-172. License requirements generally

(a) All persons, firms, pharmacies, or corporations which receive, possess, transfer, or manufacture for sale or resale radiopharmaceuticals shall be licensed in accordance with the provisions of this article. No person may receive, acquire, possess, compound, or dispense any radiopharmaceutical except in accordance with the provisions of this article and the conditions of rules and regulations promulgated by the Board of Natural Resources for radioactive materials and administered by the department. The requirements of this article are in addition to, and not in substitution of, other applicable statutes and regulations administered by the State Board of Pharmacy or the department.

(b) Nothing in this article shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when his or her use of radiopharmaceuticals is limited to the diagnosis and treatment of his or her own patients.

(c) Nothing in this article shall be construed so as to require a licensed clinical laboratory, which is licensed by the Department of Community Health to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a nuclear pharmacy license, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals.

(d) Nothing in this article shall be construed to require a department of nuclear medicine which is located in a hospital of 250 beds or less, which has a board certified radiologist in the practice of nuclear medicine, and which is licensed by the department to handle radioactive materials to obtain the services of a nuclear pharmacist or to have a nuclear pharmacy license.

HISTORY: Code 1981, § **26-4-172**, enacted by Ga. L. 1999, p. 277, § 10; Ga. L. 2009, p. 453, § 1-4/HB 228.

§ 26-4-173. Applicant requirements

(a) An applicant for a license as a nuclear pharmacist shall:

(1) Be a currently licensed pharmacist in the State of Georgia;

(2) Meet the minimum requirements and be licensed to possess and use radioactive materials for medical use, as authorized by the department; and

(3) Have met all requirements for training and experience established by the board in rules and regulations promulgated pursuant to this authority; provided, however, rules and regulations prescribing training and experience requirements for nuclear pharmacists shall have first been approved by the department.

(b) A license as a nuclear pharmacist shall be issued to any pharmacist who makes application to the board, together with a required fee, and meets the requirements of subsection (a) of this Code section.

HISTORY: Code 1981, § 26-4-173, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-174. Nuclear pharmacy operators permit; separate entity; quality; maintain records; compliance of laws; authorized dispensing; transfer; labeling; redistribution

(a) A permit to operate a nuclear pharmacy shall only be issued in accordance with Article 6 of this chapter with the added designation that the pharmacist in charge be a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a licensed nuclear pharmacist. All acts of compounding and dispensing radiopharmaceuticals shall be performed by the nuclear pharmacist or by a pharmacist or pharmacy intern under the direct supervision and control of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the nuclear pharmacy and shall be in personal attendance at all times when the acts of compounding and dispensing are performed and the pharmacy is open for business.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services provided and, as required by rules and regulations promulgated by the board pursuant to implementation of this article, shall meet minimal space requirements established for all pharmacies in the state. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from unauthorized personnel.

(c) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with requirements of the board and the department.

(e) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs and pharmaceuticals.

(f) Radiopharmaceuticals are to be dispensed only upon prescription order by a physician who is authorized by the department to possess, use, and administer radioactive materials.

(g) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with department regulations for radioactive materials. A nuclear pharmacy may also furnish radioactive materials for use to physicians, for individual patient use in accordance with subsection (f) of this Code section.

(h) In addition to any labeling requirements required by rules and regulations of the board for nonradiopharmaceuticals, the immediate outer container of a radiopharmaceutical to be dispensed shall also be labeled as required in rules and regulations of the board and of the department.

(i) The amount of radioactivity dispensed in each individual preparation shall be determined by the nuclear pharmacist through radiometric methods immediately prior to dispensing.

(j) Nuclear pharmacies may redistribute federal Food and Drug Administration approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging. Such redistribution may only be made to another nuclear pharmacy or other authorized person or institution.

HISTORY: Code 1981, § 26-4-174, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-175. Meeting requirements of the board

Nuclear pharmacies shall meet all requirements for items and articles of equipment as required through rules and regulations of the board. Nuclear pharmacies shall also have equipment required for the safe handling and storage of radioactive materials, as established by rules of the department.

HISTORY: Code 1981, § 26-4-175, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-176. Limiting, suspending, or revoking license

The board may limit, suspend, or revoke licenses issued under the provisions of this article, or impose any other reasonable sanctions upon holders of such licenses upon proof of any of the violations specified in Code Sections 26-4-60 and 26-4-113.

HISTORY: Code 1981, § 26-4-176, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-177. Board refusing to grant license

The board may refuse to grant a license to any person, firm, or corporation for any of the grounds set forth in Code Sections 26-4-60 and 26-4-113. In addition, the board may refuse to grant a license if any applicant shall make any false statement in the application or cheats in any manner upon any examination administered pursuant to this article.

HISTORY: Code 1981, § 26-4-177, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-178. Authorized to promulgate rules

The board is authorized to promulgate rules and regulations to implement the provisions of this article.

HISTORY: Code 1981, § 26-4-178, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-179. Authority of department

Nothing in this article shall be construed to repeal the authority of the Department of Natural Resources to regulate the use of radioactive materials.

HISTORY: Code 1981, § 26-4-179, enacted by Ga. L. 1999, p. 277, § 10.

LINKS:

- **Definitions. Amended**
  480-25-.01
- **Applicability of Regulations**
  480-25-.02
- **Licensure of Nuclear Pharmacists. Amended**
  480-25-.03
- **Licensure of Nuclear Pharmacies. Amended**
  480-25-.04
- **Inspections**
  480-25-.05
- **Nuclear Pharmacy General Requirements**
  480-25-.06
- **Space Requirements**
  480-25-.07
- **Equipment. Amended**
  480-25-.08
- **Labeling. Amended**
  480-25-.09
- **Library. Amended**
  480-25-.10
- **Records**
  480-25-.11
- **Enforcement. Amended**
  480-25-.12
- **Severability**
  480-25-.13

480-25-.01 Definitions. Amended.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:
(a) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.
(b) "Board" means the State Board of Pharmacy.
(c) "Compounding of radiopharmaceuticals" means the addition of a radioactive substance to nonradioactive substances or the use of a radioactive substance in preparation for single or multidose dispensation upon the prescription order of a physician who is licensed to use radioactive materials. Compounding of radiopharmaceuticals may include: loading and eluting of radionuclide generators; using manufactured reagents; preparing reagent kits; aliquoting reagents; formulation and quality assurance testing of radiochemicals for use as radiopharmaceuticals, and radiolabeling of compounds or products, including biological products, for use as radiopharmaceuticals.
(d) "Department" means the Department of Human Resources.
(e) "Governing Body" or "Management" means the board of directors, trustees, partnership, corporation, association, person or group of persons who maintain and control the operation of the nuclear pharmacy, and who are legally responsible for its operation.
(f) "Internal Test Assessment" means, but is not limited to conducting those tests of a quality assurance necessary to ensure the integrity of the test.
(g) "Licensed Nuclear Pharmacist" means an authorization granted by the Board to a pharmacist to practice as a nuclear pharmacist.
(h) "Manufacturing of radiopharmaceuticals" means the preparation, derivation, or production of a product to which a radioactive substance is or will be added to provide a radiopharmaceutical for sale, resale, redistribution, or reconstitution.
(i) "Nuclear pharmacist" means a pharmacist who compounds and dispenses radiopharmaceuticals in the course of his/her pharmacy practice.
(j) "Nuclear Pharmacy" means a pharmacy providing radiopharmaceutical services.
(k) "Nuclear Pharmacy Permit" means an authorization granted by the Board to the governing body of a facility to operate a nuclear pharmacy.
(l) "Pharmacist" means an individual who is currently licensed to practice pharmacy under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.
(m) "Pharmacy Intern" means an individual who is currently licensed to practice as a pharmacy intern under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.
(n) "Physician" means an individual who is currently licensed to practice medicine under the provisions of O.C.G.A. Title 43, Chapter 34.
(o) "Radiopharmaceutical" means radioactive drugs and chemical products used for diagnostic and therapeutic purposes and includes the terms radioactive pharmaceuticals, radioisotopes, and radioactive tracers.
(p) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on

radiopharmaceuticals and their component materials 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.

(q) "Radiopharmaceutical service" means, but is not limited to, the compounding, dispensing, labeling, and delivering of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review; the maintenance of radiopharmaceutical quality assurance; and the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy.

(r) "Unit dose transport container" (a/k/a "lead pig") means a lead lined container designed to transport doses of radiopharmaceutical agents and prevent the emission of radiation or radioactive materials during the process. The terms "unit dose transport container" and "lead pig" may be used interchangeably.

Authority O.C.G.A. Secs. 26-4-27, 26-4-110, 26-4-130, 26-4-138, 26-4-171, 26-4-178. **History.** Original Rule entitled "Dangerous Drugs Identified" adopted as ER. 480-25-0.6-.01 F. June 17, 1980; eff. June 12, 1980, the date of adoption. **Amended:** ER. 480-25-0.7-.01 of same title adopted. F. Sept. 25, 1980; eff. Sept. 22, 1980, the date of adoption. **Amended:** Permanent Rule of same title adopted. F. Dec. 30, 1980; eff. Jan. 19, 1981. **Repealed:** New Rule entitled "Definitions" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.02 Applicability of Regulations.

(1) All persons who manufacture, possess, transport, or otherwise handle pharmaceuticals or radioactive materials intended for radiopharmaceutical use prior to their arrival at a nuclear pharmacy shall comply with the requirements of the Department's Rules and Regulations for Radioactive Materials, and the requirements of the Rules and Regulations of the Board.
(2) The requirements of these Rules and Regulations are in addition to, and not in substitution of, other applicable Rules and Regulations by the Department for radioactive materials and applicable Rules and Regulations promulgated by the Board for pharmacists and pharmacies.
(3) Nothing in these Rules and Regulations shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when his/her use of radiopharmaceuticals is limited to the diagnosis and treatment of his/her own patients.
(4) Nothing in these Rules and Regulations shall be construed so as to require a licensed clinical laboratory which is also licensed by the Department to handle radioactive materials to obtain the services of a nuclear pharmacist, or to have a nuclear pharmacy license, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals.
(5) Nothing in these Rules and Regulations shall be construed to require a department of nuclear medicine which is located in a hospital of 250 beds or less, which has a board certified radiologist in the practice of nuclear medicine, and which is licensed by the Department to handle radioactive materials to obtain the services of a nuclear pharmacist or to have a nuclear pharmacy license.

Authority O.C.G.A. Secs. 26-4-130, 26-4-138, 26-4-172, 26-4-178. **History.** Original Rule entitled "Applicability of Regulations" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.03 Licensure of Nuclear Pharmacists. Amended.

(1) Except as provided for in Rule 480-25-.02, all acts of compounding and dispensing radiopharmaceuticals in the State of Georgia shall be performed by persons licensed as nuclear pharmacists; provided, however, that licensed pharmacists and licensed pharmacy interns/externs under the direct supervision and control of a nuclear pharmacist may compound and dispense radiopharmaceuticals without being separately licensed as nuclear pharmacists.
(2) An applicant for a license as a nuclear pharmacist shall:
(a) Be a currently licensed pharmacist in the State of Georgia, and
(b) Submit to the Board a completed application and the appropriate fee, on forms to be provided by the Board, and an affidavit of training and experience which indicates that the applicant:
1. Meets the minimum requirements to use radioactive materials as required by the Department's Rules and Regulations for Radioactive Materials, and either
(i) Is certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties of the American Pharmaceutical Association; or
(ii) Has completed a minimum of 200 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy, and, completed a minimum of 500 hours of clinical nuclear pharmacy training:
(I) Under the direct supervision of a licensed nuclear pharmacist in a licensed nuclear pharmacy providing nuclear pharmacy service; or
(II) In a certified nuclear pharmacy residency program approved by the American Society of Hospital Pharmacists or the Board; or
(III) In a structured nuclear pharmacy training program of an accredited college of pharmacy.
(3) Pharmacists engaged in the practice of nuclear pharmacy in the State of Georgia prior to March 18, 1983 shall be exempt from the requirements listed in subsection (2)(b)1.(i) and (2)(b)1.(ii).
(4) A license as a nuclear pharmacist may be issued to any pharmacist who makes application to the Board, together with a required fee, and meets the requirements of these Rules and Regulations. The Board may refuse to issue a license for any of the grounds set forth in O.C.G.A. Section 26-4-60, and may also refuse to issue a license to an applicant who makes any false statement in the application or cheats in any manner upon any examination administered pursuant to these Rules and Regulations.
(5) Licenses shall be renewed biennially on odd numbered years by application to the Board for renewal.
(6) The Board may limit, suspend, or revoke licenses issued under the provisions of these Rules and Regulations, or impose any other reasonable sanctions upon holders of such licenses upon violation of these Rules and Regulations or violation of O.C.G.A. Section 26-4- 60.

Authority O.C.G.A. Secs. 26-4-28, 26-4-37, 26-4-117, 26-4-130, 26-4-138, 26-4-173, 26-4-176, 26-4-178, 43-1-4. **History.** Original Rule entitled "Licensure of Nuclear Pharmacists" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Amended:** F. Jan. 13, 1986; eff. Feb. 2, 1986. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.04 Licensure of Nuclear Pharmacies. Amended.

(1) No nuclear pharmacy shall be operated in the State of Georgia without a valid permit.
(2) The governing body of the facility shall submit a completed application with the required fee to the Board for a permit using forms provided by the Board.
(3) Separate applications and permits are required for nuclear pharmacies maintained on separate premises, even though they are owned or operated by the same person(s), business or corporation; and may be doing business under the same trade name.
(4) Permits are not transferable or assignable.
(5) The applicant shall comply with additional application requirements as may be required by the Board.
(6) Following inspection and evidence of compliance with these Rules and Regulations, the Board may issue a nuclear pharmacy permit to the applicant(s). The Board may refuse to issue a permit to any applicant for any of the grounds set forth in O.C.G.A. Section 26-4-113, and may also refuse to issue or revoke a permit if an applicant makes any false statements in the application.
(7) Permits shall be renewed biennially on even numbered years by application to the Board for renewal.
(8) The Board may limit, suspend, or revoke permits issued under the provisions of these Rules and Regulations, or impose any other reasonable sanctions upon holders of such permits upon violation of these Rules and Regulations or violation of O.C.G.A. Section 26-4- 113.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-130, 26-4-138, 26-4-170, 26-4-172, 26-4-174, 26-4-176 to 26-4-178, 43-1-4. **History.** Original Rule entitled "Licensure of Nuclear Pharmacies" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Amended:** F. Jan. 13, 1986; eff. Feb. 2, 1986. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.05 Inspections.

(1) Any nuclear pharmacy shall be open during all business hours for observation and examination by properly identified representatives of the Board and the Department.
(2) All nuclear pharmacies shall be inspected by the Board prior to licensure and may be inspected at the discretion of the Board or the Department to determine whether it continues to meet these requirements.

Authority O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-130, 26-4-138, 26-4-174, 26-4-178. **History.** Original Rule entitled "Inspections" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.06 Nuclear Pharmacy General Requirements.

(1) In addition to complying with these Rules and Regulations, nuclear pharmacies shall comply with the Rules and Regulations of the Board and with all applicable Federal and State laws and regulations pertaining to nonradioactive drugs and pharmaceuticals.
(2) The pharmacist in charge at a nuclear pharmacy shall be a licensed nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a licensed nuclear pharmacist. All acts of compounding and dispensing of radiopharmaceuticals shall be performed by the nuclear pharmacist or by a pharmacist or pharmacy intern, under the direct supervision and control of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the nuclear pharmacy and shall be in personal attendance at all times when the acts of compounding and dispensing are performed and the pharmacy is open for business.
(3) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.
(4) Radiopharmaceuticals are to be dispensed only upon prescription drug order by a practitioner who is authorized by the Department to possess, use, and administer radioactive materials.
(5) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with the Department Rules and Regulations for Radioactive Materials. A nuclear pharmacy may also furnish radioactive materials for use to practitioners, for individual patient use in accordance with subsection (4) of this regulation.
(6) The amount of radioactivity dispensed in each individual preparation shall be determined by the nuclear pharmacist through radiometric methods immediately prior to dispensing.
(7) Nuclear pharmacies may redistribute Federal Food and Drug Administration approved radiopharmaceuticals if the pharmacy does not possess the radiopharmaceuticals in any manner or violate the product packaging. Such redistribution may only be made to another nuclear pharmacy or other authorized person or institution.

Authority O.C.G.A. Secs. 16-13-71, 26-4-110, 26-4-130, 26-4-138, 26-4-174, 26-4-178. **History.** Original Rule entitled "Nuclear Pharmacy General Requirements" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.07 Space Requirements.

(1) Nuclear pharmacies shall have adequate space, commensurate with the scope of service required and provided and meet the minimal space requirements of all pharmacies in the State.
(2) Nuclear pharmacies shall have a minimum area, secured from unauthorized personnel, which comprise at least 600 square feet designed for the compounding and dispensing and quality assurance of radiopharmaceuticals.
(3) The foregoing nuclear pharmacy areas shall be exclusive from other pharmacy areas such as those for nonradioactive drugs and office space.
(4) Detailed floor plans shall be submitted to the Board before the permit is granted.
Authority O.C.G.A. Secs. 26-4-110, 26-4-130, 26-4-138, 26-4-174, 26-4-178. **History.** Original Rule entitled "Space Requirements" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.08 Equipment. Amended.

(1) In addition to other articles and equipment required by the Board for all pharmacies in the State, the nuclear pharmacy shall have:
(a) dose calibrator;
(b) vertical laminar flow hood;
(c) single or multiple channel scintillation analyzer;
(d) microscope and hemocytometer;
(e) adequate glassware, utensils, and gloves;
(f) calculator;
(g) laboratory incubator;
(h) water or oil bath;
(i) ultrasonic bath;
(j) aluminum ion test kit; and
(k) adequate apparatus and supplies for performing chromatography.
(2) Nuclear pharmacies shall also have equipment required for the safe handling and storage of radioactive materials, as required by the Department's Rules and Regulations for radioactive materials.
(3) Each nuclear pharmacy shall utilize unit dose transport containers, a/k/a lead pigs,
(a) Unit dose transport containers, a/k/a lead pigs, for radioactive doses shall include:
1. an effective tamper-evident seal;
2. an effective mechanism to avoid radioactive contamination; and
3. an effective system to prevent contamination of the transport container with blood, bodily fluids, or other biohazardous substances.
(b) No nuclear pharmacist or nuclear pharmacy shall re-use a unit dose transport container or lead pig that has been contaminated with blood, bodily fluids, or other hazardous substances.
(c) Any unit dose transport container or lead pig returned to a nuclear pharmacy with the tamper-evident seal broken and containing an exposed unit dose syringe shall be considered contaminated.
(d) Section 3 of this Rule shall not apply to:
1. an individual prescriber preparing radiopharmaceuticals for administration to his or her own patients;
2. transfer of radioactive material, not intended for use as a drug, to other legally authorized persons; and
3. the occasional transfer of bulk radiopharmaceuticals to other authorized entities or persons to meet shortages.
(e) Biohazardous prevention systems containing a barrier that if used properly eliminates or substantially reduces the potential for contamination of the unit dose transport container, or lead pig, would meet the requirements of these regulations. Improper use of such system resulting in ineffective sanitation of the unit dose transport container, or lead pig, would require that such containers be effectively sanitized prior to subsequent use or discarding of that container.

Authority O.C.G.A. Secs. 26-3-7, 26-3-17, 26-4-28, 26-4-110, 26-4-130, 26-4-138, 26-4-170, 26-4-172, 26-4-178, 43-1- 19. **History.** Original Rule entitled "Equipment" adopted. F. Mar. 9, 1984; eff. Mar. 29,

1984. **Amended:** F. Sept. 29, 1998; eff. Oct. 19, 1998. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.09 Labeling. Amended.

All radiopharmaceuticals dispensed from a nuclear pharmacy shall be dispensed in appropriate containers and labeled in accordance with the following:
(a) The immediate inner container shall be labeled with:
1. the identifying prescription number; and
2. the name of the radioactive drug.
(b) In addition to any labeling standards established by law the immediate outer container shall be labeled with:
1. the name of the radionuclide;
2. the chemical form;
3. the amount of radioactive material contained, in millicuries (mCi) or microcuries (uCi);
4. if a liquid, the volume expressed in cubiccentimeters (cc) or milliliters (ml);
5. the requested calibration time and date;
6. the words "For Physician Use Only" in the absence of the name of the patient;
7. the name and address of the institution where the radiopharmaceutical will be administered;
8. the expiration date and time of the radioactive drug;
9. auxillary instructions for use, if applicable;
10. name of the procedure for which drug is intended;
11. name of prescribing practitioner;
12. The standard radiation symbol; and
13. The words "**Caution — Radioactive Material**".

Authority O.C.G.A. Secs. 16-13-73, 26-3-7, 26-3-8, 26-3-17, 26-4-87, 26-4-130, 26-4-138, 26-4-174, 26-4-178. **History.** Original Rule entitled "Labeling" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.10 Library. Amended.

In addition to any reference material required by the Board of all pharmacies in the State, a nuclear pharmacy shall maintain a reference library which shall include the following:
(a) Current U.S. Pharmacopoeia/National Formulary with supplements or computer or electronic access to same;
(b) Computer or electronic access to Federal and State Laws and Regulations relating to pharmacy practice in Georgia;
(c) A minimum of three texts dealing with nuclear medicine;
(d) Current Department of Human Resources Rules and Regulations for Radioactive Materials.

Authority O.C.G.A. Secs. 26-4-37, 26-4-110, 26-4-111, 26-4-130, 26-4-138, 26-4-174, 26-4-178. **History.** Original Rule entitled "Library" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Amended:** F. Jan. 13, 1986; eff. Feb. 2, 1986. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.11 Records.

The nuclear pharmacy shall maintain acquisition and disposition records as required by the Board of all pharmacies in the State.

Authority O.C.G.A. Secs. 26-4-130, 26-4-138, 26-4-170, 26-4-178. **History.** Original Rule entitled "Records" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.12 Enforcement. Amended.

The enforcement and administration of these Rules and Regulations shall be as prescribed in the Georgia Administrative Procedure Act, O.C.G.A., Title 50, Chapter 13, Title 26, Chapter 4, and Title 43, Chapter.

Authority O.C.G.A. Secs. 26-4-130, 26-4-138, 26-4-170, 26-4-178, 43-1-19. **History.** Original Rule entitled "Enforcement" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

480-25-.13 Severability.

In the event that any rule, sentence, clause or phrase or any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain of full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Board of Pharmacy to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well-being of the people of the State.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-130, 26-4-138, 26-4-178. **History.** Original Rule entitled "Severability" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984. **Repealed:** New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Joint Committee on Administrative Rules

ADMINISTRATIVE CODE

TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS
PART 1330 PHARMACY PRACTICE ACT
SECTION 1330.540 NUCLEAR PHARMACY SERVICES

Section 1330.540 Nuclear Pharmacy Services

a) Pharmacies that provide and/or offer for sale radiopharmaceuticals shall, in addition to any other requirements of the Act and this Part, comply with this Section.

b) Prior to issuance of a pharmacy license to practice as a nuclear pharmacy:

1) The pharmacy shall provide a copy of its Illinois Radioactive Material License issued by the Illinois Emergency Management Agency in accordance with the Radiation Protection Act [420 ILCS 40].

2) The Division shall conduct an on-site inspection of the facility.

c) The pharmacy shall have:

1) Space commensurate with the scope of services provided, but at least 300 square feet; and

2) A radioactive storage and product decay facility separate from and exclusive of the "hot" laboratory, compounding, dispensing, quality assurance and office areas.

d) Each nuclear pharmacy shall have the following equipment:

1) Laminar flow hood;

2) Fume hood – minimum of 30 inches in height, which shall be vented through a filter with a direct outlet to the outside;

3) Dose calibrator;

4) Refrigerator;

5) Class A prescription balance or a balance of greater sensitivity;

6) Single-channel or multi-channel gamma scintillation counter;

7) Microscope;

8) Low level, thin-window portable radiation survey meter;

9) Drawing station – lead glass and lead lined;

10) Syringe shields; and

11) Energy Compensated Geiger Mueller (GM) Probe or ion chamber.

e) Each nuclear pharmacy shall have the following reference texts available:

1) The current edition or revision of the United States Pharmacopoeia – Dispensing Information;

2) The current edition or revision of the United States Pharmacopoeia/National Formulary;

3) State and federal regulations governing the use of applicable radioactive material; and

4) U.S. Public Health Service Radiological Health Handbook.

f) Pharmacist-in-Charge

1) The pharmacist-in-charge for a nuclear pharmacy shall meet the requirements set forth in subsection (i). The responsibilities of the pharmacist-in-charge shall include:

A) Supervision of all the activities of all employees as they relate to the practice of nuclear pharmacy;

B) Establishment and supervision of the record keeping system for the purchase, acquisition, disposition, sale, delivery, possession, storage and safekeeping of radiopharmaceuticals; and

C) Establishment and maintenance of security provisions, which shall include the following:

i) There shall be no public access to the pharmacy hot lab/dispensing area; and

ii) In the absence of a nuclear pharmacist, all radiopharmaceuticals shall be locked and accessible only to a nuclear pharmacist or a pharmacy technician under direct supervision of the pharmacist; except, a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals may have access to radiopharmaceuticals in the absence of a nuclear pharmacist.

2) Within 30 days after the change of a pharmacist-in-charge, the Division

shall be notified in writing by the departing pharmacist-in-charge.

g) Dispensing Radiopharmaceuticals

1) A radiopharmaceutical shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

2) No radiopharmaceutical shall be dispensed in the absence of a nuclear pharmacist except, a licensed medical practitioner authorized to possess, use, dispense and administer radiopharmaceuticals may dispense in the absence of a nuclear pharmacist.

3) The amount of radioactivity in a preparation for dispensing shall be determined by radiometric methods for each individual preparation at the time of preparation, and calibrated for the anticipated time of administration.

h) Labeling Requirements

1) In addition to the labeling requirements of pharmaceuticals, as stipulated in the Act, the immediate outer container of a radioactive drug, diagnostic agent or device to be dispensed shall also be labeled to include:

A) The standard radiation symbol;

B) The words "Caution – Radioactive Material";

C) The name of the radionuclide;

D) The name of the chemical form;

E) The amount of radioactive material contained, in milliCuries or microCuries, in the container contents at the time of calibration;

F) If the container contents are in liquid form, the volume in milliliters;

G) The requested calibration time for the amount of radioactivity contained;

H) The prescription number; and

I) The name or initials of the nuclear pharmacist filling the prescription.

2) The immediate container shall be labeled with:

A) The standard radiation symbol;

B) The words "Caution – Radioactive Material";

C) The name and address of the pharmacy;

D) The prescription number;

E) Name of radionuclide; and

F) Name of chemical form.

i) Nuclear Pharmacist Requirements. A nuclear pharmacist who serves as the pharmacist-in-charge of a nuclear pharmacy and all other pharmacists employed in the pharmacy shall provide evidence to the Division of the following:

1) Licensure as a pharmacist in the State of Illinois; and

2) That he/she is named as an authorized user, or works under the supervision of a pharmacist who is named as an authorized user, on a commercial nuclear pharmacy license issued by the Illinois Emergency Management Agency (IEMA) or, when a nuclear pharmacist who works under a broad medical license at a university or research hospital has been approved as a user by that institution's radiation safety committee in accordance with conditions of the license issued by IEMA.

j) Nothing in this Part shall prohibit the operation of a nuclear medicine laboratory or any other department that is operated under the direct supervision of a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

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Pharmacy Board [657] | Agency Listing

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CHAPTER 16
NUCLEAR PHARMACY PRACTICE

[Prior to 12/14/88, see Pharmacy Examiners Board 657—8.8(155A)]

657—16.1(155A) Purpose and scope. It is unlawful to receive, possess or transfer radioactive drugs except in accordance with the provisions of Iowa Code chapter 155A. It is also unlawful for any person to provide radiopharmaceutical services unless the person is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with the provisions of Iowa Code chapter 155A, board rules and rules of the environmental protection commission. It is not unlawful for a medical practitioner to receive, possess, or transfer radioactive drugs for administration to patients as provided in Iowa Code chapter 148. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions set forth by the environmental protection commission pursuant to the provisions of Iowa Code chapter 455B. The requirements of these nuclear pharmacy rules are in addition to and not in substitution for 657—Chapter 8 and other applicable provisions of rules of the board and the environmental protection commission or the public health department.

657—16.2(155A) Definitions.

"Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

"Board" means the Iowa board of pharmacy examiners.

"Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"Qualified nuclear pharmacist" means a person currently licensed to practice pharmacy in Iowa who meets the qualifications established by rule 657—16.3(155A).

"Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine the radiopharmaceuticals' suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

"Radiopharmaceutical service" means, but is not limited to, the preparation, dispensing, labeling and delivery of radiopharmaceuticals; the compounding of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, as necessary or required, of the therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

657—16.3(155A) General requirements for qualified nuclear pharmacist. A qualified nuclear pharmacist shall meet all requirements of either alternative one or alternative two established in subrules 16.3(1) and 16.3(2), respectively.

16.3(1) *Alternative one.* A qualified nuclear pharmacist shall:

a. Meet minimum standards of training for medical uses of radioactive materials; and

b. Be a currently licensed pharmacist in the state of Iowa; and

c. Submit an affidavit of experience and training to the board; and

d. Have completed one of the following nuclear pharmacy training alternatives:

(1) Received a minimum of 90 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy. In addition, the pharmacist shall have attained a minimum of 160 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy that provides nuclear pharmacy services or in a structured clinical nuclear

pharmacy training program of an accredited college of pharmacy.

(2) Successfully completed a nuclear pharmacy residency accredited by the American Society of Health-System Pharmacists (ASHP).

(3) Successfully completed a certificate program in nuclear pharmacy accredited by the American Council on Pharmaceutical Education (ACPE).

16.3(2) *Alternative two.* A qualified nuclear pharmacist shall:

a. Be a currently licensed pharmacist in the state of Iowa; and

b. Be certified by the Board of Pharmaceutical Specialties as a board-certified nuclear pharmacist (BCNP); and

c. Submit an affidavit of BCNP credentials to the board.

657—16.4(155A) General requirements for pharmacies providing radiopharmaceutical services.

16.4(1) *Qualified nuclear pharmacist.* A license to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist who shall be the pharmacist in charge of the pharmacy. The pharmacist in charge shall be responsible for, at a minimum, the requirements in rule 657—6.2(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist is responsible for all operations of the pharmacy and, except in emergency situations, shall be in personal attendance at all times that the pharmacy is open for business.

16.4(2) *Space requirements.* Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office areas.

16.4(3) *Personnel appropriately trained.* The pharmacist in charge shall be responsible for ensuring that all pharmacy personnel have been appropriately and adequately trained for their assigned tasks.

16.4(4) *Pharmacy support persons.* A pharmacy support person shall register with the board pursuant to the registration requirements of 657—Chapter 5. Alternatively, a pharmacy support person may register with the board as a pharmacy technician pursuant to the registration and national certification requirements of 657—Chapter 3.

16.4(5) *Records required.* Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules of the board and the environmental protection commission.

16.4(6) *Compliance with laws.* Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

16.4(7) *Prescription and office use.* Radioactive drugs shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals to practitioners for office use.

16.4(8) *Outer-container label.* In addition to any of the board's labeling requirements for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

a. The standard radiation symbol;

b. The words "Caution — Radioactive Material";

c. The name of the radionuclide;

d. The chemical form;

e. The amount of radioactive material contained, in millicuries or microcuries;

f. If the radioactive drug is a liquid, the volume in cubic centimeters;

g. The requested calibration time for the amount of radioactivity contained.

16.4(9) *Immediate-container label.* The immediate container shall be labeled with:

a. The standard radiation symbol;

b. The words "Caution — Radioactive Material";

c. The name of the pharmacy; and

d. The prescription number.

16.4(10) *Radioactivity.* The amount of radioactivity for each individual preparation shall be determined by radiometric methods immediately prior to dispensing.

16.4(11) *Redistribution.* A nuclear pharmacy may redistribute to another nuclear pharmacy or authorized party radioactive drugs that are the subject of an approved new drug application if the pharmacy does not process the radioactive drugs in any manner or violate the product packaging.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—16.5(155A) Library. Each nuclear pharmacy shall have access to the following references. References may be printed or computer-accessed and shall be current editions or revisions.

1. United States Pharmacopoeia/National Formulary, with supplements;
2. The Iowa Pharmacy Law and Information Manual;
3. State rules and federal regulations governing the use of applicable radioactive materials;
4. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—16.6(155A) Minimum equipment requirements. Each nuclear pharmacy shall maintain the following equipment for use in the provision of radiopharmaceutical services:

1. Laminar flow hood;
2. Dose calibrator;
3. Refrigerator;
4. Single-channel scintillation counter;
5. Microscope;
6. Autoclave, or access to one;
7. Incubator, or access to one;
8. Radiation survey meter;
9. Other equipment necessary for the radiopharmaceutical services provided as required by the board.

A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—Chapter 34.

657—16.7(155A) Training and utilization of pharmacy support persons. Nuclear pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

These rules are intended to implement Iowa Code sections 155A.4, 155A.13, 155A.28, and 155A.31.

[Filed 1/8/79, Notice 11/29/78—published 1/24/79, effective 2/28/79]
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[Filed ARC 8673B (Notice ARC 8380B, IAB 12/16/09), IAB 4/7/10, effective 6/1/10]

Kansas

KANSAS STATE
BOARD OF
PHARMACY
LAWS AND REGULATIONS

UPDATED January 2012

The law book listed below contains the current "unofficial" * pharmacy law and rules.

* The permanent statutes of the Kansas State Board of Pharmacy have been codified at Chapter 65 of the Kansas Statutes Annotated. The KSA's are published by the Secretary of State's Office and contain all of the "official" agency laws. Chapter 68 of the Kansas Administrative Rules contains all "official" agency rules and are published by the Secretary of State's Office. The KAR's contain the "official" agency rules and regulations.

Kentucky

Kentucky Legislature

Kentucky Administrative Regulations

TITLE 201
GENERAL GOVERNMENT CABINET

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Chapter 1 Board of Accountancy

Chapter 2 Board of Pharmacy

201 KAR 2:215. Nuclear pharmacy services.

RELATES TO: KRS Chapter 315
STATUTORY AUTHORITY: KRS 315.191(1)
NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy shall be responsible for imposing minimum standards in all settings where drug products are dispensed and to ensure the safety of all drug products provided to the citizens of the Commonwealth. This administrative regulation applies to pharmacies as defined in KRS 315.010. The requirement of these administrative regulations are in addition to, and not in substitution of, other applicable administrative regulations promulgated by the Cabinet for Human Resources for radioactive materials and applicable administrative regulations promulgated by the Kentucky Board of Pharmacy.

Section 1. Definitions. (1) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.
(2) "Radiopharmaceutical services" means those acts, services, operations and transactions necessary in the conduct, operation, management and control of a nuclear pharmacy, including, for example:
(a) The compounding, dispensing, labeling and delivery of radiopharmaceuticals;
(b) The participation in radiopharmaceutical utilization reviews; and
(c) The proper and safe storage and distribution of radiopharmaceuticals.
(3) "Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.
(4) "Radiopharmaceutical quality assurance" means the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, and it shall include, for example, internal test assessment, authentication of product history and the keeping of proper records.
(5) "Internal test assessment" means conducting those tests necessary to insure the integrity of the test.
(6) "Authentication of product history" means identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.
(7) "Authorized practitioner" means a practitioner duly authorized by applicable federal and state law to possess, use and administer radiopharmaceuticals. This person shall be named on a radioactive materials license issued by the Radiation Control Branch of the Cabinet for Human Resources.
(8) "Designated agent" means an individual who shall be under the direct supervision of an authorized practitioner and who shall be authorized to communicate that practitioner's instructions to a nuclear pharmacy.
(9) "Nuclear pharmacist" means a pharmacist licensed to practice in the Commonwealth of Kentucky and who meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Control Branch of the Cabinet for Human Resources.
(10) "Direct supervision" means that the supervising nuclear pharmacist shall be physically present in the general area or location where the supportive personnel are performing supportive duties and shall conduct in-process and final checks.

Section 2. General Requirements for Pharmacies Providing Radiopharmaceutical Services. (1) A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a pharmacy operating under the direct supervision of a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the licensed area and in personal attendance at all times that the pharmacy is open for business.
(2) Nuclear pharmacies may be exempted from the general space requirements for pharmacies, but shall:
(a) Have adequate space, commensurate with the scope of services required and meeting Radiation Control Branch, Cabinet for Human Resources, requirements established for all radioactive material licensees in the Commonwealth;
(b) Be separate from the pharmacy areas for nonradioactive drugs;
(c) Be inaccessible to all unauthorized personnel; and
(d) Have a radioactive storage and decay area.
(3) The process used for handling radioactive materials by any license holder shall involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials as approved in a Kentucky radioactive materials license. In order to ensure the public health and safety in this respect, a nuclear pharmacy shall first meet the following general environmental requirements where the handling of radiopharmaceutical materials takes place:
(a) Proper ventilation so that radioactive materials cannot be airborne from that environment to other nonoccupationally unrestricted areas;
(b) Proper location so that the receipt and dispersal of radioactive materials do not result in inadvertent and undesired contamination of other nonoccupationally labeled areas; and
(c) Proper design to allow radioactive materials to be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to ensure proper operation of the corresponding assay equipment.
(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with administrative regulations of the Radiation Control Branch of the Cabinet for Human Resources.
(5) A nuclear pharmacy, upon receiving an oral prescription for a radiopharmaceutical, shall immediately have the prescription reduced to writing or recorded in a data processing system, which writing or record shall contain at least the following:
(a) The name of the authorized user or his agent;
(b) The date of distribution and the time of administration of the radiopharmaceutical;
(c) The name of the procedure;
(d) The name of the radiopharmaceutical;
(e) The dose or quantity of the radiopharmaceutical;
(f) The serial number assigned to the order for the radiopharmaceutical;
(g) Any specific instructions; and
(h) The patient's name, whenever an order is for a therapeutic or blood-product radiopharmaceutical.
(6) The immediate outer container (shield) of a radioactive drug to be dispensed shall be labeled with the:
(a) Standard radiation symbol;
(b) Words, "Caution-Radioactive Material";
(c) Radionuclide;
(d) Chemical form;
(e) Amount of radioactive material contained in millicuries or microcuries;

(f) Volume in cubic centimeters, if a liquid;
(g) Requested calibration time for the radioactivity contained;
(h) Name, address, and telephone number of the nuclear pharmacy;
(i) Prescription number;
(j) Date; and
(k) Space for patient's name.
(7) The immediate container shall be labeled with the:
(a) Standard radiation symbol;
(b) Words, "Caution-Radioactive Material";
(c) Prescription number; and
(d) Name of the radiopharmaceutical.
(8) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.
(9) A nuclear pharmacist may transfer to authorized persons, in accordance with the provisions of a Kentucky radioactive materials license, radioactive materials not intended for drug use and radiopharmaceuticals intended for individual patient use.
(10) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies including those laws and regulations governing nonradioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Kentucky Board of Pharmacy may waive regulations pertaining to pharmacy licenses for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.
(11) Radioactive drugs are to be dispensed only upon a nonrefillable prescription order from a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.
(12) Prescription orders for delivery of radioactive drugs for use in the medical practice of a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.
(13)(a) A nuclear pharmacist in charge of a nuclear pharmacy shall have the authority to delegate to any qualified and properly trained person or persons, acting under his direct supervision, any nuclear pharmacy act which a reasonable and prudent nuclear pharmacist would find is within the scope of sound pharmaceutical judgment to delegate.
(b) The delegation shall only occur if, in the professional opinion of the delegating nuclear pharmacist-in-charge, the act may be properly and safely performed by the person to whom the act is delegated.
(c) The delegated act shall only be performed in its customary manner and not in violation of other statutes.
(d) Persons to whom nuclear pharmacy acts are delegated shall not hold themselves out to the public as being authorized to practice pharmacy.

Section 3. Minimum Requirements for Space, Equipment, Supplies, and Library. (1) Each nuclear pharmacy must meet the following requirements for space:
(a) The area for the storage, compounding, and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs;
(b) Hot lab and storage area shall be a minimum of 120 square feet; and
(c) The compounding and dispensing area shall be a minimum of 300 square feet.
(2) Each nuclear pharmacy shall be equipped with at least the following items of equipment:
(a) Dose calibrator;
(b) Refrigerator;
(c) Drawing station;
(d) Well scintillation counter;
(e) Microscope;
(f) Chromatagraphic apparatus or comparable means of effectively assuring tagging efficiency;
(g) Portable radiation survey meter; and
(h) Other equipment deemed necessary for radiopharmaceutical quality assurance for products compounded or dispensed as shall be determined by the Radiation Control Branch, Cabinet for Human Resources, and the Kentucky Board of Pharmacy.
(3) Each nuclear pharmacy shall have on the premises current editions or revisions of the following reference materials:
(a) United States Pharmacopedia-National Formulary with supplements;
(b) State statutes and administrative regulations relating to pharmacy;
(c) State and federal regulations governing the use of applicable radioactive materials; and
(d) Text relating to the practice of nuclear pharmacy and radiation safety.

Section 4. Radiopharmaceutical Quality Assurance. The holder of a nuclear pharmacy license shall be responsible for the radiopharmaceutical quality assurance of all radiopharmaceuticals, including biologicals, dispensed or manufactured. (19 Ky.R. 1462; Am. 1742; eff. 1-27-93.)

Louisiana

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 19. Nuclear Pharmacy

§1901. Cross References

A. For all regulations that apply to permitted nuclear pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1903. Definitions

A. As used in this chapter, the following terms shall have the meaning ascribed to them in this Section:
Nuclear Pharmacy – a board-approved facility limited to procuring, possessing, compounding, or dispensing radiopharmaceuticals or any interventional drug used in conjunction with nuclear medicine procedures. This definition shall not apply to hospital nuclear medicine departments and nuclear medicine clinics operating under the auspices of a licensed practitioner of medicine.
Radiation – any electromagnetic or ionizing radiation including gamma rays, X-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles.
Radioactive Material – any solid, liquid, or gas that emits radiation spontaneously.
Radiopharmaceutical – a drug that is a radioactive material and includes any drug that is intended to be made radioactive, as defined by the appropriate federal agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1905. Nuclear Pharmacy Permit Requirements

A. A nuclear pharmacy permit shall be required to operate a nuclear pharmacy department. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.
    1. A nuclear pharmacy shall have a Louisiana Radioactive Material License.
    2. Nuclear Pharmacist-in-Charge. A pharmacist-in-charge of a nuclear pharmacy operation shall be a qualified nuclear pharmacist, as defined in §1907, and shall be responsible for the entire nuclear pharmacy operation.
    3. Structural Requirements. A nuclear pharmacy shall provide adequate space separate and apart from other areas commensurate with the scope of service and with the following space requirements:
        a. Dispensing Area. The radiopharmaceutical compounding or preparation area shall be separate and apart from other facility areas and shall be not less than 300 square feet, which may include storage and decay areas. The pharmacy area shall be sufficient to provide a work environment for the safe handling, compounding, and dispensing of radiopharmaceuticals. This area shall be separate and inaccessible to non-pharmacy personnel.
        b. Delivery and Receipt Area. An area designated for the delivery and receipt of materials requiring after-hours handling by non-pharmacy personnel. This area shall be separate from the dispensing area of the pharmacy.
        c. Storage Area. A storage area sufficient to maintain the scope and content of unused and returned material for decay and disposal commensurate with the compounding and dispensing requirements of the facility.
        d. Maintenance. A nuclear pharmacy shall be well maintained, clean, orderly, lighted, and properly ventilated.

e. Plumbing. A sink equipped with hot and cold running water shall be located within the nuclear pharmacy. A sink located in a pharmacy lavatory or restroom shall not be sufficient to satisfy this requirement.

4. Equipment. There shall be adequate equipment commensurate with the scope of services required and provided by the facility.
5. Supplies. There shall be adequate supplies commensurate with the compounding and dispensing needs of the facility, as well as any other services provided for by the facility, including appropriate shielding and safety devices and any other supplies necessary for the safe and legal transport of materials compounded or dispensed from the facility. There shall be appropriate supplies for the safe handling and disposal of used and unused material by employees and staff of the facility. The appropriateness of personal protective equipment shall be reviewed on an annual basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1907. Qualified Nuclear Pharmacist

A. A qualified nuclear pharmacist shall be a currently licensed pharmacist in the state of Louisiana who is listed on a Louisiana Radioactive Material License.

B. Continuing Education. Nuclear pharmacists shall obtain at least five hours of the total required hours of Accreditation Council for Pharmacy Education (ACPE) or board-approved continuing education on those applications and procedures specific to nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

§1909. Labeling

A. Immediate Container. The immediate container that comes into direct contact with the radiopharmaceutical shall be labeled with:
   1. the standard radiation symbol;
   2. the words "Caution – Radioactive Material";
   3. the prescription control number;
   4. the name of the radionuclide; and
   5. the amount of radioactive material contained, in the appropriate unit of measure.

B. Outer Container. In addition to any labeling requirements of the board for non-radiopharmaceuticals, the outer container of a radiopharmaceutical to be dispensed shall also be labeled with:
   1. the standard radiation symbol;
   2. the words "Caution – Radioactive Material";
   3. the name of the radionuclide;
   4. the chemical form;
   5. the amount of material contained, in the appropriate unit of measure;
   6. the liquid volume expressed in cubic centimeters or milliliters, where applicable; and
   7. the calibration time and date for the amount of radioactivity contained.

C. The labeling requirements in this Section shall not apply to transport containers.

D. Practitioner Administered Compounds Labeling. All practitioner administered compounds, as defined in Chapter 25 of these regulations, shall be dispensed or delivered in a suitable container with a label containing the following information:
   1. pharmacist's name or initials;
   2. pharmacy's name, address, and telephone number;
   3. preparation name;
   4. prescription number or pharmacy-assigned identification number;
   5. lot number;
   6. beyond-use date;
   7. strength and concentration;
   8. practitioner's name; and
   9. special storage requirements, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§1911. Quality Control & Quality Assurance

A. Quality control of radiopharmaceuticals is required on all radiopharmaceuticals compounded in a nuclear pharmacy. Appropriate quality assurance procedures shall be developed and followed for the procurement, compounding, and dispensing of all pharmaceuticals in a nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 17: OPERATION OF NUCLEAR DRUG OUTLETS

Summary: This chapter incorporates by reference rules of the Maine Radiation Control Program applicable to nuclear drug outlets.

1. Compliance with Maine Radiation Control Program

The board hereby incorporates by reference into this chapter the following rules of the Department of Human Services, Bureau of Health, Division of Health Engineering:

1. Chapter 220, Part C, "Licensing of Radioactive Material (October 1, 2003);" and

2. Chapter 220, Part G, "Medical Use of Radioactive Material (June 1, 2003)."

Copies of these rules may be obtained from-

Maine Radiation Control Program
Department of Human Services
11 State House Station
Augusta, ME 04333

2. Obligations

A nuclear drug outlet shall register with the board as a retail drug outlet pursuant to Chapter 8 of the board's rules and is subject to all provisions of the board's rules that apply to retail drug outlets. A nuclear drug outlet shall comply with the rules identified in Section 1 of this chapter with respect to all aspects of radiopharmaceutical practice, including but not limited to the compounding, storage, dispensing, labeling and delivery of radioactive drugs; licensure by the Division of Health Engineering; and the employment and designation of authorized nuclear pharmacists. An authorized nuclear pharmacist shall comply with the rules identified in Section 1 of this chapter with respect to all aspects of radiopharmaceutical practice, including but not limited to the compounding, storage, dispensing, labeling and delivery of radioactive drugs; and the credentialing of such individual as an authorized nuclear pharmacist.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723

EFFECTIVE DATE:
November 8, 2004 - filing 2004-519

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Section 39B	Nuclear pharmacies	PREV NEXT

Section 39B. The board may, upon application, made in such manner and form as it shall determine, register an establishment for transacting business as a nuclear pharmacy as defined in section one of chapter ninety-four C. A nuclear pharmacy shall not perform any pharmacy functions other than the dispensing of radiopharmaceutical drug products. The board shall issue a permit to such person as its deems qualified to conduct such pharmacy; provided, however, that the board may deny such registration and may refuse to issue such 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. No such registration shall be made or permit issued in the case of a corporation unless it shall appear to the satisfaction of the board that the management of such nuclear pharmacy is in the hands of a registered pharmacist. Such permit shall expire on December thirty-first of each uneven numbered year following the date of its issue, and the fee therefor shall be determined annually by the commissioner of administration and finance under the provisions of section three B of chapter seven. The board shall, within one hundred and fifty days after the filing of an application, render a final decision denying or allowing registration. Failure to render such decision, except when failure to act is caused by the delay of the applicant, shall constitute an approval of the application and the permit shall be issued.

The board, in consultation with the department of public health shall promulgate regulations pertaining to the operation of nuclear pharmacies in the commonwealth. Such regulations may include procedures governing the dispensing of radiopharmaceutical drugs when the name of a patient to whom the drug is to be administered is not known at the time a prescription order is received, provided that such regulations shall allow a nuclear pharmacist up to seventy-two hours after dispensing a radiopharmaceutical drug to determine the patient's name and record such information on the appropriate form.

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CHAPTER 94C	CONTROLLED SUBSTANCES ACT	PREV NEXT
Section 20A	Radiopharmaceutical drugs	PREV NEXT

Section 20A. Notwithstanding any other provisions of this chapter, a prescription for a radiopharmaceutical drug shall be dispensed only to an individual authorized by the nuclear regulatory commission to possess and administer such drug.

Upon receiving an oral prescription for a radiopharmaceutical drug from an authorized practitioner, the nuclear pharmacist shall immediately reduce the prescription to writing and shall record the name, address and registration number of the practitioner and the name of any expressly authorized representative, the date of the prescription, the name and the dose of the radiopharmaceutical drug, the serial number assigned to the prescription by the dispensing nuclear pharmacy, the name of said nuclear pharmacy, the name and address of the patient and any specific instructions required. If the radiopharmaceutical drug is not administered, it shall be returned to the nuclear pharmacy to be disposed of in accordance with requirements established by the nuclear regulatory commission and any applicable law and the nuclear pharmacist shall note on the prescription form the amount of the radiopharmaceutical drug that has been returned and disposed of as required.

Massachusetts

247 CMR: BOARD OF REGISTRATION IN PHARMACY

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

Section

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.

13.02: continued

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.

13.03: continued

(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:

13.05: continued

(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.

13.05: continued

(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).

13.05: continued

(g) auxiliary warning labels, if any, as needed; and
(h) the expiration date or time.

(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 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.

(25) Only a nuclear pharmacy shall keep in stock or handle radiopharmaceuticals.

(26) No nuclear pharmacy shall require or permit the same nuclear pharmacist to remain on duty for more than 12 hours per day.

(27) 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).

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.

Michigan

DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

OFFICE OF HEALTH SERVICES

BOARD OF PHARMACY

RADIOPHARMACEUTICALS

(By authority conferred on the board of pharmacy by section 16145 of Act No. 368 of the Public Acts of 1978, being S333.16145 of the Michigan Compiled Laws)

R 338.3001 Definitions.

Rule 1. As used in these rules:

(a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

(b) "Board" means the state board of pharmacy.

(c) "Internal test assessment" means conducting those tests of a quality assurance system necessary to insure the integrity of the test.

(d) "Radiopharmaceutical" means a pharmaceutical, biological, or drug which has a radioactive entity.

(e) "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 their suitability for use in humans and animals.

(f) "Radiopharmaceutical service" means the compounding, dispensing, labeling, and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy.

History: 1979 AC.

R 338.3002 Professional conduct regarding radiopharmaceuticals.

Rule 2. It is the professional responsibility of a pharmacist and a pharmacy to conduct the radiopharmaceutical area of a pharmacy in a manner which is consistent with pertinent state and federal laws and regulations.

History: 1979 AC.

R 338.3003 Dispensing radiopharmaceuticals; restrictions.

Rule 3. A radiopharmaceutical shall only be dispensed to a person having authority to possess such drugs. A radiopharmaceutical shall not be dispensed directly to a patient.

History: 1979 AC.

R 338.3004 Labeling of radiopharmaceuticals.

Rule 4. (1) The immediate container of radiopharmaceuticals shall be labeled with all of the following:

(a) The standard radiation symbol.

(b) The words "Caution--Radioactive Material."

(c) The name, address, and telephone number of the pharmacy.

(d) The prescription number.

(2) The immediate outer container (within which has been placed the immediate container) shall be labeled with all of the following:
(a) The standard radiation symbol.
(b) The words "Caution--Radioactive Material."
(c) The radionuclide.
(d) The chemical form.
(e) The amount of radioactive material contained therein in millicuries or microcuries.
(f) If a liquid, the volume in milliliters.
(g) The requested calibration time for the amount of radioactivity contained therein.
(h) If a radiopharmaceutical is dispensed to a physician it shall be labeled "FOR PHYSICIAN USE ONLY."

History: 1979 AC.

R 338.3005 Requirements for pharmacist handling radiopharmaceuticals.
Rule 5. (1) The pharmacist directing radiopharmaceutical services shall develop, implement, supervise, and coordinate all of the services provided, which shall include at least the following: preparation, handling, storage, receiving, dispensing, disposition, radiopharmaceutical quality assurance, internal test assessment, authentication of product history, and pharmacology of radioactive drugs.
(2) A person performing tasks within the radiopharmaceutical area of a pharmacy shall be under the direct and effective supervision of a pharmacist, who shall be responsible for the adequacy and accuracy of the person's performance.
(3) A pharmacy directly or indirectly involved with radiopharmaceuticals shall adopt written policies and procedures containing an organizational description of authority and responsibilities associated with radiopharmaceuticals, which shall be updated as necessary. These policies and procedures shall be available to authorized representatives of the board.

History: 1979 AC.

R 338.3006 Housing of radiopharmaceutical area of pharmacy.
Rule 6. (1) All professional and technical equipment and supplies and radiopharmaceuticals shall be located in a suitable, well-lighted, and well-ventilated room or department having clean and sanitary surroundings.
(2) A pharmacy handling radiopharmaceuticals shall have an area for the compounding of radiopharmaceuticals. The area shall occupy not less than 300 square feet of space and shall include a prescription counter providing not less than 10 square feet of free working surface, excluding hood space. If more than 1 pharmacist is on duty at any 1 time, the free working surface shall be increased by not less than 4 square feet for each additional pharmacist. The prescription counter shall be kept clean and free of all material not being currently used in the compounding and dispensing of radiopharmaceuticals. The space behind the prescription counter shall be sufficient to allow free movement within the area and shall be free of obstructions.
(3) A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying not less than 25 square feet of space, separate from, and exclusive of, the hot laboratory, compounding, dispensing, quality assurance, and office areas.
(4) A pharmacy handling radiopharmaceuticals shall be maintained in an area separate from areas where nonradioactive drugs are maintained.

History: 1979 AC.

R 338.3007 Professional and technical equipment and supplies for pharmacies handling radiopharmaceuticals.

Rule 7. (1) A pharmacy handling radiopharmaceuticals shall meet all of the requirements of a pharmacy except that, upon request by a pharmacy which handles only radiopharmaceuticals, the board may waive a requirement which it finds is not pertinent to the handling of radiopharmaceuticals.

(2) The following reference books are required in a pharmacy handling radiopharmaceuticals; all books shall be current editions or revisions:

(a) United States pharmacopeia, with supplements.

(b) National formulary, with supplements.

(c) Michigan laws relating to pharmacy.

(d) Michigan state department of public health, division of radiological health, ionizing radiation rules, being R 325.5001 to R 325.5511 of the Michigan Administrative Code.

(e) United States public health service radiological health handbook.

(3) The following technical equipment is required in a pharmacy handling radiopharmaceuticals:

(a) Fume hood.

(b) Laminar flow hood.

(c) Dose calibrator.

(d) Prescription balance, sensitive to 30 milligrams.

(e) Refrigerator.

(f) Scintillation counter.

(g) Adequate supplies, such as glassware, utensils, gloves, shields, and remote handling devices.

(h) Autoclave, or access to one.

(i) Pyrogen oven, or access to one.

(j) Miscroscope.

(k) Portable radiation detectors capable of detecting 0.005 microcuries of any radionuclide handled or stored.

(l) Typewriter.

(m) Any other equipment necessary for radiopharmaceutical quality control for the products compounded or dispensed.

History: 1979 AC.

Minnesota

CHAPTER 6800

BOARD OF PHARMACY

PHARMACIES AND PHARMACISTS

Posted: *September 21, 2011*

RADIOACTIVE DRUGS

6800.8100 DEFINITIONS.

Subpart 1. **Manufacturers of radiopharmaceuticals.** Any person, firm, or hospital compounding, mixing, deriving, repackaging, or otherwise preparing a radioactive drug shall be licensed as a manufacturer, unless the drug is prepared for use by:

A. the medical facility to which the facility preparing the product is physically attached; or

B. an individual patient when the drug is being dispensed on the order of a licensed practitioner.

Subp. 2. **Nuclear pharmacy.** A nuclear pharmacy is any area, place, or premises described in a license issued by the board with reference to plans approved by the board where radioactive drugs are stored, prepared, manufactured, derived, manipulated, compounded, or dispensed.

Subp. 3. **Radiopharmaceutical.** A radiopharmaceutical is any substance defined as a drug in section 201 (g) (1) of the Federal Food, Drug, and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that contain trace quantities of naturally occurring radionuclides.

Subp. 4. **Nuclear pharmacy practice.** "Nuclear pharmacy practice" refers to a patient-oriented pharmacy service that embodies the scientific knowledge and professional judgment required for the assurance of the safe and effective use of radiopharmaceuticals and other drugs.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

Posted: *September 21, 2011*

6800.8200 SCOPE.

Parts 6800.8100 to 6800.8700 are applicable to pharmacies and manufacturers dealing with radiopharmaceuticals; provided, however, that parts 6800.0100 to 6800.5600 shall also be applicable to such pharmacies, unless specifically exempted by parts 6800.8100 to 6800.8700 or are in direct conflict with them, in which case parts 6800.8100 to 6800.8700 apply.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

Posted: *September 21, 2011*

6800.8300 MINIMUM STANDARDS.

Proof of adequate space and equipment for storage, manipulation, manufacture, compounding, dispensing, safe handling, and disposal of radioactive material must be submitted to and approved by the board before a pharmacy license is issued by the board.

Compliance with all laws and regulations of the U.S. Nuclear Regulatory Commission and other applicable federal and state agencies shall be deemed minimal compliance with this part. Further requirements, as the board in its opinion finds necessary and proper for health and safety in the production, compounding, dispensing, and use of radiopharmaceuticals, may be imposed as a condition of licensure. A pharmacy exclusively handling radioactive materials may be exempt from the building and equipment standards of parts 6800.0700, 6800.0800, 6800.0910, 6800.0950, 6800.1050, and 6800.2150 if the board finds it is in the public interest.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 18 SR 1145*

Posted: *September 21, 2011*

6800.8400 PHARMACISTS HANDLING RADIOPHARMACEUTICALS.

A pharmacist handling radiopharmaceuticals must be competent in the preparation, handling, storage, receiving, dispensing, disposition, and pharmacology of radiopharmaceuticals. The pharmacist must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the board. Education and experience in nonapproved programs may be accepted if, in the opinion of the board, the programs provide a level of competence substantially the same as approved programs.

Statutory Authority: *MS s 151.06*

History: *17 SR 1279; 18 SR 1145*

Posted: *September 21, 2011*

6800.8500 PHARMACIST-IN-CHARGE.

A pharmacy handling radiopharmaceuticals shall not function without having a pharmacist who is competent in the preparation, handling, storage, receiving, dispensing, disposition, and pharmacology of radiopharmaceuticals in charge of the licensed premises. A qualified nuclear pharmacist shall be a currently licensed pharmacist in Minnesota and either be certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties or meet the following standards:

A. have received a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy, with emphasis in the following areas:

(1) radiation physics and instrumentation;

(2) radiation protection;

(3) mathematics of radioactivity;

(4) radiation biology; and

(5) radiopharmaceutical chemistry;

B. attain a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist; and

C. submit an affidavit of experience and training to the Board of Pharmacy.

Personnel performing tasks within the pharmacy shall be under the immediate and direct supervision of the pharmacist competent in handling radiopharmaceuticals.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

Posted: *September 21, 2011*

6800.8550 LABELING OF RADIOPHARMACEUTICALS.

Subpart 1. **Immediate container of bulk radiopharmaceutical product.** Each compounded container must bear a label containing the following information:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation; and

C. radiopharmaceutical lot number.

Subp. 2. **Outer container of bulk radiopharmaceutical product.** Each individual prepared dose must bear a label containing the following information:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation;

C. amount of radioactivity;

D. calibration date and time;

E. expiration date and time;

F. volume - if liquid, weight - if solid, number of vials or ampoules - if gas, number of capsules - if capsules;

G. added substances, such as stabilizers and preservatives;

H. radiopharmaceutical lot number;

I. name, address, and telephone number of nuclear pharmacy, if it is to be transferred for commercial distribution; and

J. initials of preparing nuclear pharmacist, if it is to be transferred for commercial distribution.

Subp. 3. **Immediate container of each radiopharmaceutical dispensed.** Each individual prepared dose must bear a label containing the:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation;

C. radiopharmaceutical prescription or lot number; and

D. patient name.

Subp. 4. **Outer container of each radiopharmaceutical dispensed.** Each individual prepared dose must bear a label containing the:

A. standard radiation symbol with words "Caution - Radioactive Material";

B. radiopharmaceutical name or its abbreviation;

C. amount of radioactivity;

D. calibration date and time;

E. expiration date and time;

F. volume - if liquid, or weight - if solid, and number of vials or ampoules - if gas;

G. added substances, such as stabilizers and preservatives;

H. radiopharmaceutical prescription or lot number;

I. name, address, and telephone number of nuclear pharmacy;

J. patient name; and

K. initials of dispensing nuclear pharmacist.

Statutory Authority: *MS s 151.06*

History: *36 SR 237*

Posted: *September 21, 2011*

6800.8600 ACQUISITION, STORAGE, AND DISTRIBUTION.

Only radiopharmaceuticals which are approved by the U.S. Food and Drug Administration or which are investigational drugs having IND or NDA status may be dispensed by a nuclear pharmacy.

Radioactive materials shall be kept locked and secure from unauthorized personnel.

Radiopharmaceuticals shall not be transferred, distributed, or dispensed to any person or firm not licensed or authorized to receive or possess the drugs.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

Posted: *September 21, 2011*

6800.8700 RECORD KEEPING.

A pharmacist handling radiopharmaceuticals shall maintain records of acquisition and disposition of radiopharmaceuticals for at least two years.

In the case of investigational radiopharmaceuticals, the pharmacy records shall include an investigators protocol for the preparation of radiopharmaceuticals, 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 radiopharmaceutical is a qualified investigator.

Additional records shall be maintained as required by statute or rule of any other state or federal agency.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

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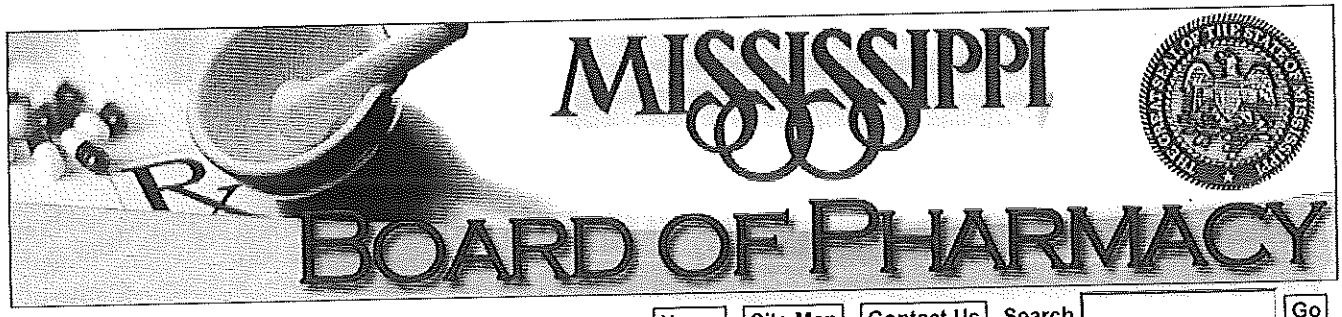

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ARTICLE XXVII NUCLEAR/RADIOLOGIC PHARMACY

In addition to all other applicable sections of the Mississippi Code of 1972, ARTICLE XXVII of the Mississippi Board of Pharmacy Regulation pertains specifically to nuclear pharmacy and radiopharmaceuticals.

1. DEFINITIONS

A. Authentication of product history means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical;

B. A nuclear pharmacy is a pharmacy providing the services of storing, compounding, dispensing, labeling, or distributing radiopharmaceuticals;

C. Practice of Nuclear Pharmacy means 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 and other related drugs;

D. A qualified licensed professional means an individual (such as a physician, nurse, or technologist) who possesses a current state license if applicable, and who has sufficient training and experience to safely handle radiopharmaceuticals as defined by the Mississippi State Department of Health, Division of Radiological Health;

E. A qualified nuclear pharmacist means a currently licensed pharmacist in the state of Mississippi who is certified by the Mississippi State Department of Health, Division of Radiological Health, or who meets the following standards:

(1) Minimum standards of training for "authorized user status" of radioactive materials as defined by Mississippi State Department of Health, Division of Radiological Health;

(2) Completed a minimum of two hundred (200) contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Mississippi Board of Pharmacy, and United States Nuclear Regulatory Commission or Agreement State Agency, with emphasis in the following areas:

(a) Radiation Physics and Instrumentation;
(b) Radiation Protection;
(c) Mathematics of Radioactivity;
(d) Radiation Biology;
(e) Radiopharmaceutical Chemistry.

(3) Attain a minimum of five hundred (500) hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

F. Nuclear pharmacy technician means a person who works under the supervision of a qualified nuclear pharmacist and who is currently registered with the Mississippi Board of Pharmacy. The duties and responsibilities of these personnel must be consistent with their training and experience;

G. Radiopharmaceutical is any substance defined as a drug in Section 201(g) (1) of the Federal Food, Drug and Cosmetic Act which also contains unstable nuclei which undergo spontaneous disintegration with the emission of nuclear radiation;

Radiopharmaceuticals also include any non-radioactive reagent kit or radionuclide generator which is intended to be used in the preparation of radiopharmaceutical doses;

H. Radiopharmaceutical Service means, but shall not be limited to the procurement, storage, handling, compounding, quality control testing, dispensing, delivery, recordkeeping, and disposal of radiopharmaceutical and other drugs as well as quality control procedure, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics and any other activities required for provision of pharmaceutical care;

I. Radiopharmaceutical Compounding means the preparation, mixing assembling, packaging, or labeling of a reagent kit or biological substance with radioactivity;

J. Radiopharmaceutical quality control means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential and prepared radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans or animals;
Assurance that variances in the processes are clearly identified, assessed and improved upon if necessary is required for adequate quality control. All quality control procedures must be a set of planned, defined, and systematic activities to provide adequate confidence that the product optimally fulfils professional expectations and requirements;

K. The restricted area of a Nuclear Pharmacy is an area with limited access for the purpose of protecting individuals against the undue risks from exposure to radiation and radioactive materials. Generally, the restricted area(s) consists of the compounding/dispensing area, radioactive material storage area, and radioactive dose return or breakdown area.

2. NUCLEAR PHARMACY STANDARDS AND EQUIPMENT

Written procedures and policy showing proof of adequate space and equipment for all operations involving radioactive material must be submitted to the Mississippi Board of Pharmacy along with a certified copy of the RADIOACTIVE MATERIAL LICENSE issued by the Mississippi State Department of Health, Division of Radiological Health, before a permit to operate as a Nuclear Pharmacy is issued.
Compliance with applicable radiation protection regulations of the Mississippi State Department of Health, Division of Radiological Health, is further required. Violation of rules and regulations established by the Mississippi State Department of Health, Division of Radiological Health, that directly affects public health and safety, shall serve as prima facie evidence of violation of this ARTICLE.

The restricted area of a nuclear pharmacy shall have at least the following supplies and equipment:

A. Radiation detection and measuring instruments capable of accurately measuring quantities of radioactivity and radiation;

B. Refrigerator, microscope, and a hemacytometer;

C. Radiochemical fume hood and filter system with suitable air sampling equipment if storing or dispensing volatile substances;

D. Laminar air flow hood and appropriate supplies to ensure sterile practices for parental solutions;
E. Syringes, vials, filters, and other necessary supplies needed to compound and dispense any oral or sterile parenteral drug product;
F. Adequate shielding for syringes vials drawing stations and returned dose storage area:
G Materials needed for decontamination;
H. All supplies needed to perform quality control testing;
I. Appropriate shielding for the transportation of D. O. T. approved outer transport containers;
J. Required labels and other supplies for proper shipment of radioactive material.

A pharmacy exclusively handling radiopharmaceuticals may be exempt from the general requirements of conventional pharmacies as regards to equipment and inventory.

3. OPERATION OF A NUCLEAR PHARMACY

A. Nuclear Pharmacy License. A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy.
B. Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided.
C. The nuclear pharmacy restricted area shall be secured from unobserved entry and/or unauthorized personnel.
D. Nuclear pharmacies shall maintain complete and accurate records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials, in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health.
E. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health.
F. Radiopharmaceuticals are to be dispensed only upon receipt of a prescription drug order, from a licensed practitioner or his agent. Validation that he is authorized to possess, use or administer radiopharmaceuticals is required.
G. Nuclear pharmacies shall, in addition to this ARTICLE XXVII and the Mississippi State Department of Health, Division of Radiological Health's applicable regulations, comply with any applicable requirements of other governing agencies regarding its daily operations and the disposal of any biohazardous medical waste.

4. DISPENSING OF RADIOPHARMACEUTICALS

Radiopharmaceuticals shall be dispensed/transferred only to a licensed practitioner authorized by the Nuclear Regulatory Commission and/or the Mississippi State Department of Health, Division of Radiological Health to possess, use, and administer such drug. A radiopharmaceutical shall be dispensed for medical use only upon receipt of a prescription or medication order from such authorized practitioner. Otherwise, a radiopharmaceutical

may be transferred to a person who is authorized by federal or state law to possess and use such drug for non-medical applications. All prescriptions/orders shall be readily retrievable if requested by any governing agency.

A. A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall have the prescription order reduced to writing or recorded in a data processing system, which the written or electronic record shall contain at least the following:
   (1) The name of the institution and prescriber or if applicable, the 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 activity of the dose or quantity of the radiopharmaceutical;
   (6) The serial number assigned to the order for the radiopharmaceutical;
   (7) Any specific instructions;
   (8) The initials of the pharmacist who dispensed the order.

Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

B. The immediate outer container transportation shield of a radiopharmaceutical to be dispensed shall be labeled with:
   (1) The name and address of the pharmacy and prescriber;
   (2) Activity dispensed, expiration date and time, calibration time, serial number, and date of dispensing;
   (3) The standard radiation symbol and the words "Caution Radioactive Material";
   (4) The name of the procedure and the radiopharmaceutical, including pharmacy lot number associated with dose;
   (5) If a liquid, the volume; if a gas, the number of ampules or vials; and if a solid, the number of items or weight;
   (6) Molybdenum 99 content to USP limits (<0.15 mCi Mo-99 per 1.0 mCi Tc 99m at time of administration or expiration);
   (7) The name of the patient or the words "per physician order" in the absence of a patients name.

When the prescription is for a therapeutic or blood product radiopharmaceutical, the patient's name shall appear on the label. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

C. The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:
   (1) Identity of the radiopharmaceutical and the serial number;
   (2) The standard radiation symbol and the words "Caution Radioactive Material";
   (3) The chemical form;
   (4) The name of the procedure and date dispensed.

D. For a radiopharmaceutical intended for a specific patient, the immediate inner container shall be labeled with:
   (1) The standard radiation symbol and the words, "Caution - Radioactive Material";
   (2) The prescription number and name of patient;
   (3) Identity and activity or quantity, of the radiopharmaceutical.

When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND) the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form or letter, and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

Nevada

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NRS 454 - Poisons, Dangerous Drugs and Hypodermics

NRS 585 - Food, Drugs and Cosmetics; Adulterations; Labels: Brands

NRS 639 - Pharmacists and Pharmacy

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NAC 453 - Controlled Substances

NAC 454 - Poisons; Dangerous Drugs and Hypodermics

NAC 585 - Food, Drugs and Cosmetics; Adulterations; Labels: Brands

NAC 639 - Pharmacists and Pharmacy

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NRS 639.2321 Nuclear pharmacy: Direct supervision of preparation and distribution of radiopharmaceuticals required; qualifications of managing pharmacist; nuclear pharmacist required on premises.

1. Any person who prepares or distributes radiopharmaceuticals must be under the direct supervision of a nuclear pharmacist.
2. The managing pharmacist of a nuclear pharmacy must be a nuclear pharmacist.
3. A nuclear pharmacist must be on the premises during the hours a nuclear pharmacy is open for business.

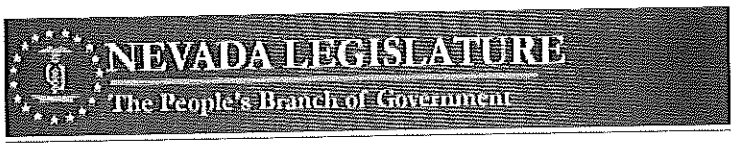
(Added to NRS by 1989, 1750; A 1995, 292)

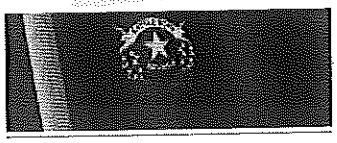
NRS 639.2322 Nuclear pharmacy: Oral orders; prohibition on refill of prescription for radiopharmaceutical.

1. Except as otherwise provided in subsection 2, a managing pharmacist of a nuclear pharmacy may delegate to any person, under the direct supervision of the managing pharmacist, the authority to accept oral orders from a practitioner or the designated agent of a practitioner.
2. An oral order may be used for a radiopharmaceutical which is not prescribed for a specific patient. An oral order which is designated for a specific patient must be accepted only by a nuclear pharmacist or registered intern acting under the direct supervision of a nuclear pharmacist.
3. A prescription for a radiopharmaceutical must not be refilled.
4. As used in this section, "designated agent" means a person who is authorized to communicate a practitioner's instructions to a nuclear pharmacy.

(Added to NRS by 1989, 1750)

Nevada





NEVADA ADMINISTRATIVE CODE

Containing All Permanent Regulations of State Agencies
Adopted under chapter 233B of NRS

Classified, Arranged, Revised, Indexed and Published
(Pursuant to NRS 233B.062 to 233B.065 inclusive)

by the
LEGISLATIVE COUNSEL
STATE OF NEVADA

Please direct any questions or suggestions
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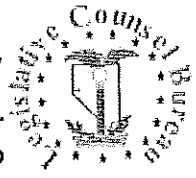

NUCLEAR PHARMACIES

NAC 639.5802 Definitions. (NRS 639.070) As used in NAC 639.5802 to 639.584, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.5804 to 639.5814, inclusive, have the meanings ascribed to them in those sections.
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5804 "Agreement state" defined. (NRS 639.070) "Agreement state" means any state with which the Nuclear Regulatory Commission has entered into an effective agreement pursuant to section 274(b) of the Atomic Energy Act of 1954, 42 U.S.C. § 2021(b).
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5806 "Authentication of product history" defined. (NRS 639.070) "Authentication of product history" means identifying the purchasing source, the ultimate destination and any intermediate handling of any component of a radiopharmaceutical or other drug.
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5808 "Procedures to assure the quality of radiopharmaceuticals" defined. (NRS 639.070) "Procedures to assure the quality of radiopharmaceuticals" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including, but not limited to, authentication of product history and maintenance of any records required by an appropriate regulatory agency.
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.581 "Qualified nuclear pharmacist" defined. (NRS 639.070) "Qualified nuclear pharmacist" means a nuclear pharmacist who meets the requirements set forth in NAC 639.5818.
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5812 "Radiopharmaceutical services" defined. (NRS 639.070) "Radiopharmaceutical services" means the procurement, storage, handling, compounding, preparation, labeling, testing to control the quality of, dispensation, distribution, transfer, recordkeeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs. The term includes procedures to assure the quality of radiopharmaceuticals, radiological health activities, consulting activities associated with the use of radiopharmaceuticals, health physics and any other activities required for the provision of pharmaceutical care.
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5814 "Testing to control the quality of radiopharmaceutical" defined. (NRS 639.070) "Testing to control the quality of radiopharmaceutical" means the performance of appropriate chemical, biological and physical tests on a compounded radiopharmaceutical and the interpretation of the resulting data to determine its suitability for use in humans and animals.
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5816 "Radiopharmaceutical" interpreted. (NRS 639.070) The Board interprets the term "radiopharmaceutical" as defined in NRS 639.0143 to include any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.
(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5818 Nuclear pharmacist: Certification; training and instruction; affidavit of experience and training. (NRS 639.070) A nuclear pharmacist must hold a current license issued by the Board and must:
1. Be certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, an affiliate of the American Pharmacists Association; or
2. Satisfy each of the following requirements:
(a) Meets minimum standards of training for status as an authorized user of radioactive material and is licensed by the Nuclear Regulatory Commission or an agreement state.
(b) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy

and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy or a training program recognized by the Nuclear Regulatory Commission or an agreement state. The minimum required hours must be apportioned as follows:

(1) Radiation physics and instrumentation (85 hours);
(2) Protection against radiation (45 hours);
(3) Mathematics pertaining to the use and measurement of radioactivity (20 hours);
(4) Radiation biology (20 hours); and
(5) Radiopharmaceutical chemistry (30 hours).

(c) Has attained a minimum of 500 hours of clinical or practical training in nuclear pharmacy under the supervision of a qualified nuclear pharmacist in the following areas, as described in the current Nuclear Pharmacy Practice Standards adopted by the American Pharmacists Association:

(1) Procuring radioactive materials;
(2) Compounding radiopharmaceuticals;
(3) Performing routine testing to control the quality of radiopharmaceuticals;
(4) Dispensing radiopharmaceuticals;
(5) Distributing radiopharmaceuticals;
(6) Carrying out basic procedures for protection against radiation; and
(7) Consulting and educating persons engaged in nuclear medicine, patients, pharmacists, other health professionals and the general public.

(d) Has submitted an affidavit of experience and training to the Board.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.582 Permit to operate. (NRS 639.070) The Board will issue a permit to operate a nuclear pharmacy only to a person who is a qualified nuclear pharmacist or who employs a qualified nuclear pharmacist. The permit to operate a nuclear pharmacy is effective only as long as the pharmacy also holds a current license issued by the Nuclear Regulatory Commission. Copies of reports of any inspection conducted by the Nuclear Regulatory Commission must be made available on request for inspection by the Board.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5822 Space and equipment requirements; floor plan. (NRS 639.070) A nuclear pharmacy must have adequate space and equipment commensurate with the scope of services it provides and must meet the minimum space requirements established for all pharmacies in the State. A nuclear pharmacy must include, but is not limited to, an area for the:

1. Preparation and dispensation of radiopharmaceuticals.
2. Shipment and receipt of radioactive material.
3. Storage of radioactive material.
4. Decay of radioactive waste.

➥ An application for a permit to operate a nuclear pharmacy must include a detailed floor plan of the nuclear pharmacy. The Board must approve any subsequent material change to the floor plan.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5824 Security. (NRS 639.070) A nuclear pharmacy must be totally enclosed and be able to be locked to prevent access by unauthorized personnel.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5826 Records. (NRS 639.070) The records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials of a nuclear pharmacy must be maintained in accordance with the statutes and regulations of the Board, the Nuclear Regulatory Commission or an agreement state.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5828 Quality assurance procedures for radiopharmaceuticals. (NRS 639.070) A nuclear pharmacy must compound and dispense radiopharmaceuticals in accordance with the accepted procedures to assure the quality of radiopharmaceuticals.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.583 Dispensing or transferring radiopharmaceuticals. (NRS 639.070) A radiopharmaceutical must be dispensed only pursuant to a prescription order received from a licensed practitioner authorized by the Nuclear Regulatory Commission or an agreement state to possess, use and administer such a drug. A radiopharmaceutical may be transferred to a person who is authorized to possess and use such a drug for nonclinical applications.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5832 Oral order for radiopharmaceutical: Requirement to keep record; contents of record. (NRS 639.070) After receiving an oral order for a radiopharmaceutical, a nuclear pharmacy immediately must reduce the order to writing or record the order in a data processing system and must include, without limitation, the following information:

1. The name of the institution and the prescriber or prescriber's agent.
2. The date of dispensation 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 of the prescriber.
8. The initials of the person who received the order.
9. The initials of the person who dispensed the order.
10. If an order is for a radiopharmaceutical for therapeutic use or use in a blood product, the name of the patient must be obtained and recorded before dispensing the radiopharmaceutical.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5834 Outer shield of radiopharmaceutical container: Label required; contents of label. (NRS 639.070) The immediate outer shield of the container of a radiopharmaceutical to be dispensed must be labeled with:

1. The name and address of the pharmacy.
2. The name of the prescriber.
3. The date of dispensation.
4. The serial number assigned to the order for the radiopharmaceutical.
5. The standard radiation symbol.
6. The words "CAUTION RADIOACTIVE MATERIAL."
7. The name of the procedure.
8. The radionuclide and chemical form.
9. The amount of radioactivity and the date and time of the calibration.
10. If the radiopharmaceutical is a liquid, the volume.
11. If the radiopharmaceutical is a solid, the number of items or weight.
12. If the radiopharmaceutical is a gas, the number of ampules or vials.
13. The molybdenum 99 content in accordance with the limitations prescribed in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.
14. The name of the patient or the words "Physician's Use Only" in the absence of a patient's name.
15. If the prescription is for a radiopharmaceutical for therapeutic use or use in a blood product, the patient's name must appear on the label. The requirements of this subsection are met if the name of the patient is readily retrievable from the prescriber upon demand.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95; A by R035-06, 9-18-2008)

NAC 639.5836 Inner label of radiopharmaceutical container; contents. (NRS 639.070) The immediate inner label of a container of a radiopharmaceutical to be dispensed must be labeled with:

1. The name of the pharmacy.
2. The standard radiation symbol.
3. The words "CAUTION RADIOACTIVE MATERIAL."
4. The identity of the radionuclide.
5. The chemical form.
6. The name of the procedure.
7. The serial number assigned to the order for the radiopharmaceutical.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.5838 Records of nuclear pharmacy when radiopharmaceutical is dispensed pursuant to investigational new drug application: Contents. (NRS 639.070) If a radiopharmaceutical is dispensed pursuant to the authority of an investigational new drug application approved by the United States Food and Drug Administration, the records of a nuclear pharmacy must include:

1. An investigator's protocol for the preparation of the radiopharmaceutical;
2. A copy of the approval form or letter of the internal review board of the institution; and
3. A letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

NAC 639.584 Required equipment. (NRS 639.070) A nuclear pharmacy must have the following equipment:

1. A radionuclide dose calibrator.
2. A refrigerator.
3. A single or multiple channel well scintillation counter containing the isotopes sodium iodide, thallium, germanium and lithium.
4. A radiochemical fume hood and filter system with suitable equipment for sampling air.
5. An area survey meter.
6. At least two Geiger Mueller survey meters, including one high-range meter.
7. A microscope and hemacytometer.
8. A laminar airflow hood and appropriate supplies to ensure sterile practices for parenteral solutions.
9. Radiation shields for syringes and vials.
10. A lead-shielded drawing station.
11. Decontamination supplies.
12. Appropriate supplies to perform procedures to assure the quality of radiopharmaceuticals.
13. Lead transport shields for syringes and vials.
14. USA Type A, 7A transport containers approved by the Department of Transportation and other labels and supplies for shipping radioactive materials.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

New Hampshire

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- Important Legal Time Limits

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State of New Hampshire Board of Pharmacy
57 Regional Drive | Concord, NH 03301
(603) 271-2350 | Fax: (603) 271-2856
pharmacy.board@nh.gov

PART Ph 405 STANDARDS OF PRACTICE FOR NUCLEAR/RADIOLOGIC PHARMACY

Ph 405.01 Purpose and Scope. The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the state board of pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice. These rules shall supplement the rules/regulations of other state and federal agencies.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05

Ph 405.02 Definitions.

(a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(b) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services.

(c) "Practice of nuclear pharmacy" means 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 and other drugs.

(d) "Quality assurance procedures" means all activities necessary to guarantee the integrity of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by the department of health and human services, bureau of radiological health.

(e) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(f) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. The term 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. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(g) "Radiopharmaceutical service" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05

Ph 405.03 General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) A permit to operate a pharmacy, which provides radiopharmaceutical services shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The nuclear pharmacist who licenses the pharmacy shall hold a current license issued by the board, and shall be either certified as a nuclear pharmacist by the board of pharmaceutical specialties or satisfy each of the following requirements:

(1) Meets minimal standards of training for status as authorized user of radioactive material, as specified by the department of health and human services, bureau of radiological health;

(2) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy, or other training program recognized by the department of health and human services, bureau of radiological health;

(3) The 200 hours of instruction referenced in (2) above shall be apportioned as follows:

a. Radiation physics and instrumentation, 85 hours;

b. Radiation protection, 45 hours;

c. Mathematics pertaining to the use and measurement of radioactivity, 20 hours;

d. Radiation biology, 20 hours; and

e. Radiopharmaceutical chemistry, 30 hours;

(4) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

a. Procuring radioactive materials;

b. Compounding radiopharmaceuticals;

c. Performing routine quality control procedures;

d. Dispensing radiopharmaceuticals;

e. Distributing radiopharmaceuticals;

f. Implementing basic radiation protection procedures; and

g. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and

(5) Has submitted an affidavit of experience and training to the board.

(c) The permit to operate a nuclear pharmacy shall be effective only so long as the pharmacy also holds a current license issued by the department of health and human services, bureau of radiological health. Copies of the bureau of radiological health inspection reports shall be available at the pharmacy for board inspection.

(d) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and meeting minimal space requirements established for all pharmacies in the state.

(e) All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

(1) Radiopharmaceutical preparation/dispensing area;

(2) Radioactive material shipping/receiving area;

(3) Radioactive material storage area; and

(4) Radioactive waste decay area.

(f) The application for a permit to operate a nuclear pharmacy shall be the same as in Ph 304.01 and Ph 304.02.

(g) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and shall be totally enclosed and lockable.

(h) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with the board and the department of health and human services, bureau of radiological health statutes and rules.

(i) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the department of health and human services, bureau of radiological health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(j) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(k) The writing or record required by (i) above shall contain at least the following:

(1) The name of the institution and prescriber, or prescribers' 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 initials of the person who received the order; and

(9) The initials of the person who dispensed the order.

(l) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall be obtained and recorded prior to dispensing.

(m) 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 order for the radiopharmaceutical;

(5) The standard radiation symbol;

(6) 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) If a liquid, the volume;

(11) If a solid, the number of items or weight;

(12) If a gas, the number of ampules or vials;

(13) Molybdenum 99 content to USP limits; and

(14) The name of the patient or the words "Physician's Use Only" in the absence of a patient name.

(n) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(o) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name of the pharmacy;

(2) The standard radiation symbol;

(3) The words "Caution Radioactive Material";

(4) The identity of the radionuclide;

(5) The chemical form;

(6) The name of the procedure; and

(7) Serial number of the radiopharmaceutical.

(p) When a radiopharmaceutical is dispensed under the authority of an investigational new drug application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, and a letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(q) Each nuclear pharmacy shall have a current copy of the United States Pharmacopeia/National Formulary (USP/NF), USP-DI, and a current copy of state and federal rules and regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05

Ph 405.04 Minimum Equipment. The pharmacy shall have at least the following equipment:

(a) A radionuclide dose calibrator;

(b) A refrigerator;

(c) A single or multiple channel scintillation counter with well-type NaI(Tl) or Ge(Li) detector;

(d) A radiochemical fume hood and filter system with air sampling equipment;

(e) An area survey meter;

(f) At least 2 GM survey meters including one high-range meter;

(g) A microscope and hemacytometer;

(h) A laminar air flow hood and appropriate supplies to ensure sterile practices for parenteral solutions;

(i) Syringe and vial radiation shields;

(j) A lead-shielded drawing station;

(k) Decontamination supplies;

(l) Supplies to perform quality assurance testing;

(m) Lead transport shields for syringes and vials; and

(n) New Hampshire department of transportation approved USA Type A - 7A approved transport containers and other labels and supplies for shipping radioactive materials.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05

New Jersey

CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:1-15.1 and 45:14-47.

Source and Effective Date

R.2010 d.090, effective May 17, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Chapter Expiration Date

Chapter 39, State Board of Pharmacy, expires on May 17, 2015.

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was adopted and became effective prior to September 1, 1969.

Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989. See: 20 N.J.R. 1648(a), 21 N.J.R. 1712(a).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1994 d.351, effective June 16, 1994. See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b), 26 N.J.R. 3878(a).

Subchapter 12, Nuclear Pharmacies, was recodified from Subchapter 11 by R.1994 d.476, effective September 19, 1994. See: 26 N.J.R. 1303(a), 26 N.J.R. 3878(b).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1999 d.214, effective June 16, 1999. See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Subchapter 10, Automated Medication Systems, was adopted as R.2000 d.28, effective January 18, 2000. See: 31 N.J.R. 2293(b), 32 N.J.R. 317(a).

Subchapter 3A, Continuing Education, was adopted as R.2003 d.130, effective March 17, 2003. See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

Chapter 39, State Board of Pharmacy, was readopted as R.2005 d.25, effective December 10, 2004. See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Subchapter 2, Licensure Requirements, was renamed Requirements for Initial Licensure; Subchapter 2A, Requirements for Reciprocal Licensure, was adopted in part as new rules and recodified in part from Subchapter 3, Licensure by Reciprocity; Subchapter 3, Licensure by Reciprocity, was renamed Registered Pharmacist Requirements; and Subchapter 8, Pharmacy Training Sites, was repealed by R.2009 d.247, effective August 3, 2009. See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

Chapter 39, State Board of Pharmacy, was readopted as R.2010 d.090, effective May 17, 2010. As a part of R.2010 d.090, Subchapter 3, Registered Pharmacist Requirements, was renamed Pharmacist Requirements; and Subchapter 6, Registered Pharmacist-in-Charge; Pharmacy Personnel, was renamed Pharmacist-in-Charge; Pharmacy Personnel, effective June 21, 2010. See: Source and Effective Date. See, also, section annotations.

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In (a), substituted "an ISO class 5" for "a class 100". Former N.J.A.C. 13:39-11.21, Controlled environment: anteroom, recodified to N.J.A.C. 13:39-11.20.

13:39-11.22 Laminar air flow hoods not in a clean room for compounded sterile preparations

Institutional pharmacy ISO class 5 laminar air flow hoods not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in the compounding of sterile preparations. Such hoods shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.23 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "ISO class 5" for "class 100" and "engaging in the compounding of sterile preparations" for "engaging in sterile product preparation". Former N.J.A.C. 13:39-11.22, Vertical air laminar flow hoods, recodified to N.J.A.C. 13:39-11.21.

13:39-11.23 Controlled environment for compounded sterile preparations: self-contained sterile glove boxes

Self-contained ISO class 5 glove boxes, barrier isolation technology or the equivalent not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in the compounding of sterile preparations. Such boxes shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.24 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "ISO class 5" for "class 10 to class 100" following "Self contained" and "engaging in the compounding of sterile preparations" for "engaging in sterile product preparation". Former N.J.A.C. 13:39-11.23, Laminar air flow hoods not in a clean room, recodified to N.J.A.C. 13:39-11.22.

13:39-11.24 Library references

In addition to the minimum reference library mandated in N.J.A.C. 13:39-5.8, each pharmacy engaged in compounding shall contain recognized references pertinent to specialized compounding preparations.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.25 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-11.24, Controlled environment: self-contained sterile glove boxes, recodified to N.J.A.C. 13:39-11.23.

13:39-11.25 Disposal of drugs and materials

All unused drugs and materials used in the compounding of preparations, including antineoplastic agents, shall be disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E-48.1 et seq., P.L. 1989, c.34), so as not to endanger the public health.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.26 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "compounding of preparations" for "preparation of sterile admixture products" preceding "including antineoplastic agents". Former N.J.A.C. 13:39-11.25, Library references, recodified to N.J.A.C. 13:39-11.24.

13:39-11.26 Security

The compounding area and its contents and other areas where compounded preparations are present shall be secured, so as to prevent access by unauthorized personnel.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.27 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "compounding" for "sterile admixture" following "The" and "compounded preparations" for "sterile admixture drugs" following "area and its contents and other areas where". Former N.J.A.C. 13:39-11.26, Disposal of drugs and materials, recodified to N.J.A.C. 13:39-11.25.

13:39-11.27 Reserved

Recodified to N.J.A.C. 13:39-11.26 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Section was "Security".

SUBCHAPTER 12. NUCLEAR PHARMACIES

13:39-12.1 Definitions

The following words and terms when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise.

"Authentication of product history" includes, but is not limited to, identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

"Authorized practitioner" means a practitioner duly authorized by applicable Federal and State law to possess, use and administer radiopharmaceuticals.

"Designated agent" means an individual under the direct supervision of a practitioner authorized to communicate the practitioner's instructions to the nuclear pharmacy.

"Immediate personal supervision" means that the pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"Internal test assessment" includes, but is not limited to, conducting those tests necessary to insure the integrity of the test.

"Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or in the FDA's Nuclear Pharmacy Guidelines and which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

"Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on 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.

"Radiopharmaceutical service" includes, but is not limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; and the offering of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Deleted "Direct supervision"; added "Immediate personal supervision".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In definition "Immediate personal supervision", deleted "registered" preceding the first occurrence of "pharmacist".

13:39-12.2 General requirements for pharmacies providing radiopharmaceutical service

(a) The application for a specialized retail permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a site employing a qualified nuclear pharmacist. All personnel performing tasks in the preparing and distribution of drugs shall be under the immediate personal supervision of the nuclear pharmacist who shall be responsible for all nuclear operations of the licensed area and shall be in personal attendance at all times when the nuclear pharmacy is open for business. On or after April 5, 2011, nuclear pharmacies shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the radiopharmaceutical services, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in performing radiopharmaceutical services pursuant to this subchapter, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of the services performed shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each service is performed. Such documentation shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal United States Nuclear Regulatory Commission or its successor's requirements and the requirements established by the State of New Jersey Bureau of Radiation Protection. The nuclear pharmacy shall be separate from the pharmacy areas for non-radioactive drugs and shall be inaccessible to all unauthorized personnel. All pharmacies handling radiopharmaceuticals shall be provided with a radioactive storage and decay area. A nuclear pharmacy dispensing radioactive drugs may be exempted from the general space requirements for pharmacies.

(c) The process used for handling radioactive materials by any license holder must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution, and disposal of radioactive materials. In order to ensure the public health, safety, and welfare, a nuclear pharmacy shall first meet the following general requirements:

1. The environment where the handling of radioactive materials takes place shall be properly ventilated so that

radioactive materials cannot be airborne from that environment to other non-occupationally unrestricted areas;

2. The environment shall be properly located so that the receipt and dispersal of radioactive materials does not result in inadvertent and undesired contamination of other non-occupationally labeled areas; and

3. The area shall be designed in such a manner that radioactive materials can be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to insure proper operation of the corresponding assay equipment.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules and regulations of the United States Nuclear Regulatory Commission.

(e) The immediate outer container of a radioactive drug to be dispensed shall be labeled with the following:

1. The standard radiation symbol;

2. The words, "CAUTION—RADIOACTIVE MATERIAL";

3. The radionuclide;

4. The chemical form;

5. The amount of radioactive material contained in millicuries or microcuries;

6. If a liquid, the volume in milliliters;

7. The requested calibration time for the radioactivity contained;

8. The name, address, and telephone number of the nuclear pharmacy;

9. The prescription number; and

10. The date and patient's name, if available.

(f) The immediate container shall be labeled with the following:

1. The standard radiation symbol;

2. The words, "CAUTION—RADIOACTIVE MATERIAL";

3. The name of the radiopharmaceutical.

(g) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(h) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with the regulations of the United States Nuclear Regulatory Commission or its successor. A nuclear pharmacy may furnish radiopharmaceuticals to these practitioners for patient use.

(i) Nuclear pharmacies shall comply with all applicable laws and regulations of Federal and State agencies including those laws and regulations governing non-radioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Board of Pharmacy may waive rules pertaining to pharmacy permits for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.

(j) Radioactive drugs are to be dispensed only upon a nonrefillable prescription order from a United States Nuclear Regulatory Commission licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.

(k) Prescription orders for delivery of radioactive drugs for use in the medical practice of a United States Nuclear Regulatory Commission licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.

(*l*) A qualified nuclear pharmacist shall have the authority to delegate to any qualified and properly trained person or persons, acting under his or her immediate personal supervision, any nuclear pharmacy act which a reasonable and prudent pharmacist would find is within the scope of sound pharmaceutical judgment to delegate. Such delegation may only occur if, in the professional opinion of the qualified nuclear pharmacist, the act may be properly and safely performed by the person to whom the pharmacy act is delegated. The delegated act may only be performed in its customary manner, not in violation of other statutes. The person to whom a nuclear pharmacy act is delegated shall not hold himself or herself out to the public as being authorized to practice pharmacy.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a) and (*l*), substituted "immediate personal" for "direct".
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote (a).

13:39-12.3 General requirements for a nuclear pharmacist

(a) A qualified nuclear pharmacist shall meet the following requirements:

1. He or she is a pharmacist licensed to practice in the State of New Jersey; and

2. He or she meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the United States Nu-

clear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

13:39-12.4 Minimum requirements for space, equipment, supplies, and library

(a) Each nuclear pharmacy must meet the following requirements for space:

1. The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for non-radioactive drugs;

2. Hot lab and storage area shall be a minimum of 120 square feet; and

3. The compounding and dispensing area shall be a minimum of 300 square feet.

(b) Each nuclear pharmacy shall be equipped with at least the following items of equipment:

1. Dose calibrator;

2. Refrigerator;

3. Drawing station;

4. Well scintillation counter;

5. Microscope;

6. Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;

7. Radiation survey equipment of the appropriate type and calibration to detect quantities of radioactive materials as prescribed in the appropriate radioactive material licenses; and

8. Other equipment deemed necessary for radiopharmaceutical quality control for products compounded or dispensed as may be determined by the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

(c) Each nuclear pharmacy shall have on the premises the following, up-to-date reference books:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;

2. State statutes and rules relating to pharmacy;

3. State and Federal regulations governing the use of applicable radioactive materials; and

4. Text relating to the practice of nuclear pharmacy and radiation safety.

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (c), rewrote the introductory paragraph and 1.

13:39-12.5 Quality control

The holder of a nuclear pharmacy permit shall be responsible for the radioactive quality control of all drugs, including biologicals, dispensed or manufactured. Radioactive pharmaceutical quality controls include, but are not limited to, the carrying out and interpretation of data resulting from chemical, biological and physical tests on potentially radioactive pharmaceuticals to determine the suitability for use in humans and other animals, including internal test assessment and authentication of product history.

New Mexico

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Pharmacy: Rules and Laws

The text of our rules is available at the official site of the New Mexico Administrative Code.

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Chapter 19 - Pharmacists

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TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 18 NUCLEAR PHARMACY

16.19.18.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, 1650 University Blvd, NE - Ste. 400B, Albuquerque, NM 87102, (505) 841-9102.
[02-15-1889...02-15-96; 16.19.18.1 NMAC - Rn, 16 NMAC 19.18.1, 03-30-02]

16.19.18.2 SCOPE: All individuals and entities that provide radiopharmaceutical products or services or engage in the practice of nuclear pharmacy, including owners of nuclear pharmacies.
[02-15-96; 16.19.18.2 NMAC - Rn, 16 NMAC 19.18.2, 03-30-02]

16.19.18.3 STATUTORY AUTHORITY: Section 61-11-6.A.(1) NMSA 1978 authorizes the Board of Pharmacy to adopt, regularly review and revise rules and regulations necessary to carry out the provisions of the Pharmacy Act. Section 61-11-6.A.(3) directs the Board to provide for the registration and annual renewal of licenses of pharmacists. Pursuant to 61-11-6.A.(6), the Board is authorized to provide for the licensing of retail pharmacies, nonresident pharmacies and wholesale drug distributors and to provide for the inspection of their facilities and activities.
[02-15-96; A, 05-30-98; 16.19.18.3 NMAC - Rn, 16 NMAC 19.18.3, 03-30-02]

16.19.18.4 DURATION: Permanent.
[02-15-96; 16.19.18.4 NMAC - Rn, 16 NMAC 19.18.4, 03-30-02]

16.19.18.5 EFFECTIVE DATE: February 15, 1996 unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.
[02-15-96; A, 05-30-98; 16.19.18.5 NMAC - Rn, 16 NMAC 19.18.5, 03-30-02]

16.19.18.6 OBJECTIVE: The objective of Part 18 of Chapter 19 is to recognize and provide for the specialization of nuclear pharmacy and to protect the public health and welfare of New Mexico citizens by establishing standards for the practice.
[02-15-96; 16.19.18.6 NMAC - Rn, 16 NMAC 19.18.6, 03-30-02]

16.19.18.7 DEFINITIONS:

A. 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 same and efficacious use of radiopharmaceuticals and other drugs.

B. "Nuclear Pharmacy" means a pharmacy which provides radiopharmaceutical services, and shall be licensed by the Board as a wholesaler and/or retail pharmacy.

C. "Qualified Nuclear Pharmacist" means a pharmacist currently licensed by the Board who meets either of the following criteria:

(1) Must be currently certified as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties or

(2) Must have successfully completed the requirements of Paragraph 7.C.2.a., and meet a minimum of 250 contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally-accredited college of pharmacy or other training program sponsored by an ACPE-accredited provider of continuing pharmaceutical education, with the minimum 250 contact hours apportioned according to 7.C.2.b. and 7.C.2.c:

(a) Must have attained a minimum of 500 contact hours of experiential training in nuclear pharmacy under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

(i) procurement of radioactive materials;
(ii) compounding of radiopharmaceuticals;
(iii) maintenance of a quality assurance program;
(iv) dispensing of radiopharmaceuticals;
(v) distribution of radiopharmaceuticals;
(vi) implementation of basic health and safety practices and procedures;
(vii) provision of information and consultation related to the practice of nuclear pharmacy and the use of radiopharmaceuticals:
(viii) monitoring of outcomes in patients who receive radiopharmaceuticals and related ancillary medications;
(ix) research and development of radiopharmaceuticals.

(b) 200 hours in the following five areas:

(i) radiation physics and instrumentation;
(ii) radiation protection;
(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiation biology;
(v) radiopharmaceutical chemistry; and
(c) 50 hours in the clinical use of radiopharmaceuticals.

(3) "Radiopharmaceutical Services" means the procurement, storage, handling, compounding, 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, and any other activities required for provision of pharmaceutical care.

(4) "Quality Control Testing" means the performance of appropriate chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(5) "Quality Assurance Procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(6) "Authentication of Product History" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(7) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons 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. The term 'radiopharmaceutical' also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

D. Any pharmacist who has been legally listed on a radioactive material license for a nuclear pharmacy in the State of New Mexico for at least six months prior to the effective date of these regulations, is exempt from Paragraphs 7.C.1 and 7.C.2.

[05-29-94, 05-30-98; 16.19.18.7 NMAC - Rn, 16 NMAC 19.18.7, 03-30-02]

16.19.18.8 LICENSING REQUIREMENTS FOR A NUCLEAR PHARMACY:

A. The licensing provisions contained in this section are in addition to, and not a substitute for, general licensing requirements for all pharmacies in New Mexico.

B. Any pharmacy that will provide radiopharmaceutical services must obtain a nuclear pharmacy license from the Board.

C. A nuclear pharmacy shall employ one or more qualified nuclear pharmacists. The application for a nuclear pharmacy license must include documentation that all pharmacists who provide radiopharmaceutical services in the nuclear pharmacy meet the criteria specified for a qualified nuclear pharmacist.

[05-20-94; 16.19.18.8 NMAC - Rn, 16 NMAC 19.18.8, 03-30-02]

16.19.18.9 REQUIREMENTS FOR OPERATION OF A NUCLEAR PHARMACY:

A. A nuclear pharmacy shall meet the requirements of 16 NMAC 19.6 of the Board, except as provided for in this section.

B. A qualified nuclear pharmacist shall be in personal attendance when the nuclear pharmacy is open for business.

C. A nuclear pharmacy shall meet minimum space requirements established for all pharmacies in the state (see 16 nmac 19.6.10, with the exception that the space may be interrupted.)

D. The nuclear pharmacy shall maintain records of procurement, inventory and disposition of all radioactive drugs and other radioactive materials.

E. A nuclear pharmacy shall have a current copy of city, state, and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

F. The following minimum equipment requirements for a nuclear pharmacy are in lieu of those contained in 16.19.6.11.A NMAC, Paragraphs 11.A.6-11.A.9; 11.A.12-11.A.14; 11.A.18; 11.A.20 and 11.1.21 (the remainder of Sub-Section 11.A remains in force):

(1) Radionuclide Dose Calibrator;
(2) Refrigerator;
(3) Single or multiple channel scintillation counter with well-type NaI(T1) or Ge(Li) detector ;
(4) Radiochemical fume hood and filter system;
(5) Area rate meter;
(6) At least two (2) GM survey meters;
(7) Microscope and hemacytometer;
(8) Laminar air flow hood and/or biologic safety cabinet;
(9) Syringe and vial radiation shields;
(10) Lead-shielded drawing station;
(11) Decontamination supplies;

[05-20-94; 16.19.18.9 NMAC - Rn, 16 NMAC 19.18.9, 03-30-02]

16.19.18.10 REQUIREMENTS FOR PROVISION OF RADIOPHARMACEUTICAL SERVICES:

A. Medications shall be dispensed from a nuclear pharmacy in accordance with the requirements contained in 16 NMAC 19.6, except as provided for in this section.

B. A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Nuclear Regulatory Commission or an equivalent agreement state agency to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

C. In addition to other labeling requirements of the Board for nonradioactive drugs, the outer container shield of a radiopharmaceutical to be dispensed or transferred shall also be labeled with the following information:

(1) the standard radiation symbol;
(2) the words "Caution -- Radioactive Materials";
(3) the radionuclide;
(4) the chemical form;
(5) the amount of radioactivity and the calibration date and time;
(6) the expiration date and time;
(7) if a liquid, the volume;
(8) if a solid, the number of dosage units or weight;
(9) if a gas, the number of ampules or vials;
(10) the name of the patient (required only for radiolabeled blood components and all radiopharmaceuticals intended for therapeutic use.).

D. The inner container (e.g., syringe, vial, etc.) used to dispense or transfer a radiopharmaceutical shall be labeled with the following information:

(1) the standard radiation symbol;
(2) the prescription or lot number;
(3) the name of the radiopharmaceutical;
(4) the name of the patient (required only for radiolabeled blood components and all radiopharmaceuticals intended for therapeutic use.)

E. A licensed nuclear pharmacy, upon receiving a verbal prescription for a radiopharmaceutical, shall immediately have the prescription reduced to writing or recorded in a data processing system. The writing and/or record shall contain at least the following information, in addition to other requirements of the Board:

(1) the name of the institution represented;
(2) the date of the prescription;
(3) the name and dose of the radiopharmaceutical;
(4) the name of the procedure;
(5) the requested date/time of calibration (tentative date/time of administration) of the prescribed radiopharmaceutical;
(6) the name of the patient (required for radiolabeled blood components and all radiopharmaceuticals intended for therapeutic use.);
(7) any specific instructions, if required.

F. Whenever a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (INDA), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

G. Pharmacists practicing at a facility licensed under 16 NMAC 19.18 are exempt from 16.19.4.22.5 NMAC through 16.19.4.22.7 NMAC.

[05-20-94; 16.19.18.10 NMAC - Rn, 16 NMAC 19.18.10, 03-30-02]

HISTORY OF 16.19.18 NMAC;
Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center and Archives:
Regulation No. 18, Nuclear Pharmacy, 4-20-94.

History of Repealed Material: [RESERVED]

Other History: 16 NMAC 19.18, Pharmacists - Nuclear Pharmacy, filed 02-02-96, reformatted and renumbered to 16.19.18 NMAC, Nuclear Pharmacy, effective 03-30-2002.

NEW YORK

New York Codes, Rules and Regulations, Title 10

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Revised: May 2010

Effective Date: 01/01/1989
Title: Section 405.15 - Radiologic and nuclear medicine services

405.15 Radiologic and nuclear medicine services.

(a) General provisions for diagnostic and therapeutic radiologic services. The hospital shall maintain or have available diagnostic radiologic services defined for purposes of this subdivision as imaging services utilizing diagnostic radiation equipment or devices which emit radiation by virtue of the application of high voltage. If therapeutic services are provided, they shall meet the requirements established in subdivision (b) of this section in addition to the requirements of this subdivision. In addition, the hospital shall meet the standards of Part 16 of the State Sanitary Code.

(1) The hospital shall maintain or have available radiologic services according to the needs of the patients as determined by the governing body in consultation with the medical staff and the administration.

(2) Radiologic services shall be provided only on the order of physicians or, consistent with State law, of those other practitioners authorized by the medical staff and governing body to order such services.

(3) Safety for patients and personnel. The radiologic services shall be free from hazards for patients and personnel. Written policies and procedures affecting safety shall be implemented and available for inspection.

(i) Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards and radiation hazards. This includes adequate shielding for patients and personnel, as well as appropriate storage, use and disposal of radioactive materials.

(ii) Any existing or potential hazards identified through periodic inspection by local or State health authorities shall be corrected promptly.

(iii) Personnel shall be instructed in radiation safety principles; and radiation monitoring practices shall be adequate to ensure compliance with all regulatory requirements.

(iv) Radiologic procedures requiring the use of contrast media or fluoroscopic interpretation and control shall be performed with the active participation of a qualified specialist in diagnostic radiology or a physician qualified in a medical speciality related to the radiographic procedure. Emergency equipment and staff trained in its use shall be available for anaphylactic shock reactions from contrast media.

(4) Personnel. The hospital shall provide qualified personnel adequate to supervise and conduct the services. For radiologic tests, the following personnel standards shall apply for the purposes of this subdivision:

(i) a full-time or part-time radiologist who is a board certified or board admissible in radiology shall direct the clinical aspects of the organization and delivery of radiologic services. That radiologist or another individual qualifed by education and experience shall direct the administrative aspects of the services;

(ii) radiologic tests shall be interpreted by a board certified or board admissible radiologist, except that radiologic tests may be interpreted by practitioners within their field of specialization who are granted privileges to interpret such test by the governing body and the medical staff in consultation with the director of radiologic services pursuant to the credentialing process in the hospital;

(iii) the services of qualified radiologists, qualified practitioners, and licensed radiologic technologists shall be sufficient and available to meet the needs of the patients. A licensed technologist shall be on duty or available at all times and function in accordance with Article 35 of the Public Health Law and Part 89 of this Title.

(iv) Use of the radiologic equipment and administration of radiologic procedures shall be limited to personnel who are currently licensed and designated as qualified by the hospital in accordance with any applicable licenses and regulations.

(5) Records. Records of radiologic services including interpretations, consultations and therapy shall be filed with the patient's record, and duplicate copies shall be kept in the radiology department/service. All films, scans and other image records shall be referenced in the patient's medical record and retained in the patient's medical record, radiology department/service or in another central location accessible to appropriate staff.

(i) Requests by the attending practitioner for x-ray examination shall contain a concise statement of reasons for the examination which shall be authenticated by the requestor.

(ii) The radiologist or other practitioner who performs radiology services shall authenticate reports of his or her interpretations.

(iii) The hospital shall retain films, scans and other image records which have not been incorporated in the medical record for at least six years or three years after a minor patient reaches the age of majority.

(b) Therapeutic radiology or radiation oncology. Therapeutic radiology or radiation oncology services shall be provided in accordance with the following:

(1) no facility providing the service shall refuse treatment of a patient on the basis of the referring practitioner or practitioner's facility affiliation, if any;

(2) institutions shall provide services for patients who cannot attend treatment sessions during normal day shift working hours;

(3) therapeutic radiology or radiation oncology services shall utilize four or more megavoltage (MEV) or cobalt teletherapy units with a source-axis distance of 80 or more centimeters and rotational capabilities as the primary unit in a multi-unit radiotherapy service or as the sole unit in a smaller radiotherapy unit;

(4) a therapeutic radiology service shall be headed by a board admissible or board certified radiation therapist or a general radiologist who devotes at least 80 percent of his/her time to the practice of therapeutic radiology and who treats not fewer than 175 patients per year;

(5) a therapeutic radiology service shall have on staff:

(i) one full-time New York State licensed radiation therapy technologist for every MEV unit; and

(ii) a full-time registered professional nurse with appropriate education and experience;

(6) a facility with a therapeutic radiology service shall have on staff or through formal arrangements:

(i) a board admissible or board certified medical oncologist, hematologist or other specialist who devotes at least 80 percent of his/her practice to medical oncology and who treats not fewer than 175 oncology patients per year; and

(ii) A radiological physicist who will be involved in treatment, planning and dosimetry as well as calibrating the equipment, and who holds a degree in physics and who is either certified or admissible for certification by the American Board of Radiology or the American Board of Health Physicists; or

(a) a person holding a degree in physics and having full-time radiation therapy experience; or

(b) a physicist in training or a dosimetrist supervised by a part-time radiological physicist;

(7) the therapeutic radiology service shall be part of a multidisciplinary approach to the management of cancer patients, involving a variety of specialists in a joint treatment program, either through formal arrangement or in the facility;

(8) each patient shall have a treatment plan in his/her medical records;

(9) each therepeutic radiology service shall have access, either through formal arrangements or in the facility, to a full range of diagnostic services, including ultrasound, hematology, pathology, CT scanners, nuclear medicine and diagnostic radiology;

(10) each facility providing therapeutic radiology services shall have access to the full range of rehabilitation therapies, including but not limited to physical therapy, occupational therapy, vocational training, and psychological counseling services for its radiotherapeutic patients;

(11) a radiation therapy program operating an MEV unit with photon or electron beam energies greater than 10 MEV's must be a part of a comprehensive program of cancer care which includes surgical oncology, medical oncology, pathology and diagnostic radiology. In addition such program shall meet the following standards:

(i) there shall be two full-time equivalent radiation oncologists on staff who are board-certified in radiation oncology or have equivalent training and experience and whose professional practices are limited to radiation oncology;

(ii) there shall be a full-time medical radiation physicist assigned to the radiation therapy program for the treatment planning of patients; and

(iii) there shall be a simulator available within the radiation therapy program used for producing precise mock-ups of geometric relationships of treatment equipment to a patient and yielding high quality diagnostic radiographs of the treatment portals.

(c) Nuclear medicine services. If the hospital provides nuclear medicine services, those services shall meet the needs of the patients in accordance with generally acceptable standards of practice. Nuclear medicine services shall be ordered only by a physician whose Federal or State licensure and staff privileges allow such referrals.

(1) Organization and staffing. The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.

(i) The clinical aspect of the organization and delivery of nuclear medicine services shall be directed by

a physician who is qualified in nuclear medicine and named in the facility's New York State Health Department or New York City Health Department radioactive materials license as authorized to use radiaoctive materials in humans. The administrative aspects of these services shall be directed by that physician or another individual qualifed for such duties by education and experience.

(ii) The qualifications, training, functions, and responsibilities of all nuclear medicine personnel shall be specified by the clinical service director in accordance with applicable regulations and approved by the medical staff and the hospital.

(2) Delivery of service. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with generally acceptable standards of practice and pertinent laws, rules and regulations.

(i) In-house preparation of radiopharmaceuticals shall be by, or under the direct supervision of, an appropriately trained registered pharmacist or a physician whose use of radioactive materials is authorized in the facility's New York State Health Department or New York City Health Department radioactive materials license.

(ii) If clinical laboratory tests are performed in the nuclear medicine service, the service shall meet the requirement for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control in accordance with the requirements of section 405.16 of this Part.

(3) Facilities. The hospital shall provide equipment and supplies which are appropriate for the types of nuclear medicine services offered and shall maintain such for safe and effective performance. The equipment shall be:

(i) maintained in safe operating condition; and

(ii) inspected, tested, and calibrated at least annually by qualified personnel and at the intervals specified in the hospital's quality assurance program.

(4) Records. The hospital shall maintain authenticated and dated reports of nuclear medicine interpretations, consultations and procedures.

(i) The hospital shall maintain copies of nuclear medicine reports which have not been incorporated into the patient's medical record for at least six years or three years after the patient reaches the age of majority.

(ii) Interpretation of the results of nuclear medicine procedures shall be made by a physician authorized in the facility's New York State Health Department or New York City Health Department radioactive materials license, or a physician under his/her tutelage. Interpretations may be made in consultation with the referring practitioner or other practitioners. The authorized physician, or physicians in tutelage, shall authenticate and date the interpretations of these tests.

Volume: C

North Carolina Rules

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.

North Dakota

ARTICLE 61-05
RADIOPHARMACEUTICAL SERVICES

CHAPTER 61-05-01
RADIOPHARMACEUTICAL SERVICES

61-05-01-01. Purpose and scope. It is unlawful to receive, possess, or transfer radioactive drugs, except in accordance with North Dakota Century Code chapter 43-15, this Article and the North Dakota Radiological Health Rules in Article 33-10. It is also unlawful for any person to provide radiopharmaceutical services unless that person is a pharmacist meeting the qualifications of North Dakota Administrative Code Section 61-05-01-04, or a person acting under the direct supervision of a pharmacist meeting those qualifications and acting in accordance with North Dakota Century Code chapter 43-15, ~~and~~ state board of pharmacy regulations and ~~regulations of~~ the North Dakota Radiological Health rules, in Article 33-10~~department of health~~, with the exception of a medical practitioner, who is listed as an authorized user on a radioactive materials license, for administration to the practitioner's patients. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions of ~~any~~ radioactive material license on which the person is an authorized user, as required by the North Dakota department of health pursuant to North Dakota ~~Century~~ Administrative Code ~~chapters 23-20 and 23-20.1~~ article 33-10. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of regulations of the state board of pharmacy and the North Dakota department of health.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC~~28-32-02,~~ 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14),43-15-36

61-05-01-02. Definitions.

1. "Authentication of product history" includes identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

2. "Internal test assessment" includes conducting those tests of a quality assurance necessary to ensure the integrity of the test.

3. "Radiopharmaceutical quality assurance" includes 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.

4. "Radiopharmaceutical service" includes the compounding, dispensing, labeling, and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of radiopharmaceuticals.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC~~28-32-02,~~ 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-03. General requirements for pharmacies providing radiopharmaceutical services.

1. A nuclear pharmacy providing radiopharmaceutical services shall only be managed by a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of the nuclear pharmacist. The nuclear pharmacist is responsible for all operations of the licensed area and shall be ~~in personal attendance~~ physically present at all times that the pharmacy is open for business. In emergency situations, in the nuclear pharmacist's absence, the nuclear pharmacist may designate one or more other qualified licensed professionals, who are authorized users, listed by name, on a radioactive materials license, to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals, only if the single dose is already prepared by a qualified nuclear pharmacist, for the immediate emergency and must document such withdrawals in the control system.

2. Nuclear ~~P~~pharmacies providing radiopharmaceuticals shall have adequate space, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. The area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least twenty-five square feet [2.32 square meters] of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office area. A pharmacy handling radioactive drugs exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy before approval of the license.

3. Nuclear ~~P~~pharmacies providing radiopharmaceutical services shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.

4. Nuclear ~~P~~pharmacies providing radiopharmaceutical services shall maintain records of acquisition and disposition of all radioactive drugs and byproduct material for the duration of the license.

5. Nuclear ~~P~~pharmacies providing radiopharmaceutical services shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

6. Radioactive drugs are to be dispensed only upon a ~~prescription~~ request from a licensee~~medical practitioner~~ authorized to possess, use, and administer radiopharmaceuticals. A pharmacist providing radiopharmaceutical services may transfer to authorized persons radioactive materials not intended for drug use, in accordance with North Dakota rules and regulations pertaining to radiation control.

7. A ~~prescription for a~~ radiopharmaceutical ~~shall be for an individual patient~~ may be provided only to a facility licensed under North Dakota Administrative Code article 33-10, with an authorized user for the radioactive drug requested. A nuclear pharmacy must have on file a copy of the current radioactive materials license for the licensed facility requesting any radioactive drug before the radioactive drug is permitted to be dispensed to that facility. The radioactive drug must be delivered to the authorized address in the license for receipt, logging in, testing for contamination, determining the current activity and then the dose is available to be administered to a patient. ~~A pharmacy may furnish radiopharmaceuticals for office use only to medical practitioners authorized to possess, use, and administer radiopharmaceuticals for an individual patient.~~

8. In addition to any labeling requirements of the state board of pharmacy for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:
   (a) the standard radiation symbol;
   (b) the words "Caution–Radioactive Material";
   (c) the radionuclide;
   (d) the chemical form;
   (e) the amount of radioactive material contained, in millicuries or microcuries;
   (f) if a liquid, the volume in ~~cubic centimeters~~ milliliters;
   (g) the requested calibration time for the amount of radioactivity contained.

9. The immediate container shall be labeled with:
   (a) the standard radiation symbol;
   (b) the words "Caution–Radioactive Material";
   (c) the name, address, and telephone number of the pharmacy; and
   (d) the prescription number.

10. The amount of radioactivity shall be determined by dose calibrator or other appropriate radiometric methods for each individual dose immediately prior to dispensing.

11. ~~P~~Nuclear pharmacies may redistribute national food and drug administration approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02,~~43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-04. General requirements for nuclear pharmacists to manage a nuclear pharmacy providing radiopharmaceutical services. A qualified nuclear pharmacist shall:

1. Meet minimal standards of training for medical uses of radioactive material.

2. ~~Be a currently licensed pharmacist~~ Hold a current, active license to practice pharmacy in this state.

3. Have ~~received~~ completed a minimum of seven hundred contact hours in a structured educational program consisting of didactic instruction in nuclear pharmacy and clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program ~~from an accredited college of pharmacy~~, with emphasis in the following areas:

   a. Radiation physics and instrumentation
   b. Radiation protection
   c. Mathematics pertaining to the use and measurement of radioactivity
   d. Chemistry of byproduct material for medical use
   e. Radiation biology
   f. Shipping, receiving and performing related radiation surveys
   g. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides
   h. Calculating, assaying and safely preparing dosages for patients or human research subjects
   i. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures

4. ~~Attain a minimum of one hundred sixty hundred hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program in an accredited college of pharmacy.~~ Obtain written attestation, signed by an authorized nuclear pharmacist stating that the pharmacist has completed the requirements of this section and has achieved a level of competence sufficient to function independently as an authorized nuclear pharmacist and submit that to the Board of Pharmacy, or;

5. Submit evidence ~~an affidavit of experience and training~~ to the state board of pharmacy that the pharmacist is certified by a specialty board whose certification has been recognized under 10 CFR 35.55(a).

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02~~,43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-05. Library. Each nuclear pharmacy providing radiopharmaceutical services shall have current editions or revisions of:

1. United States Pharmacopoeia National Formulary, with supplements.

   ~~National Formulary, with supplements.~~
2. Current issues of the Journal of Nuclear Medicine or online access
3. State laws and regulations relating to pharmacy.
4. State and federal regulations governing the use of applicable radioactive materials, including North Dakota Radiological Health Rules, Article 33-10.
5. ~~United States public health service, Radiological Health Handbook.~~
   Nuclear Medicine: The requisites – by Thrall and Ziessman
6. ~~Nuclear Medicine by Blahd.~~
   Principles and Practice of Nuclear Medicine – by Early and Sodee
7. ~~Medical Radiation Physical by Hendree.~~
   Nuclear pharmacy – by Chilton and Witcofski
8. ~~Medical Radiation Biology by Pizzarello and Wetcofske.~~

   Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine – by Kowalski and Phelan
9. ~~P.D.R. for Radiology and Nuclear Medicine.~~
10. ~~Principles of Radioisotope Methodology by Chase and Rabinwotz.~~
11. ~~Current issues of Journal of Nuclear Medicine.~~

The board of pharmacy recognizes that the library needed will depend on the type of radiopharmaceutical services offered. Variations in the required library may be granted by the board of pharmacy.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02,~~43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-06. Minimum equipment requirements. Each pharmacy providing radiopharmaceutical services shall have the following equipment:

1. RArea radiation ~~laboratory~~ monitor ~~(~~a which is stationary ~~one~~ and away from other activity~~)~~.
2. ~~Gamma counter~~ Dose calibrator and well counter.
3. Portable ~~ionization chamber~~ survey meter, capable of measuring up to 2000 mR/hr ~~(to~~ for determineing contamination and for other physic procedures~~)~~
4. Sufficient quantity of lead bricks, lead plates, leaded glass of high density, and leaded or tungsten syringe shields.
5. Refrigerator with freezer with temperature monitoring capabilities.
6. Class A prescription balance or balance of greater sensitivity.
7. Single, or multi-channel scintillation counter.
8. ~~Pyrogen oven.~~Sink with hot and cold running water.

9. ~~Portable radiation survey meter~~ Wipe test counter capable of detecting 0.005 microcuries of the radionuclides in question.

10. Chromatographic equipment.

11. ~~Fumer~~ Annually calibrated fume hood, if handling volatile radioactive materials.

12. Chemical exhaust hood, if handling large quantities of chemicals .

13. Electronic balance, or Class A prescription balance.

14. Lighted microscope /hemocytometer.

15. ~~Auto clave for steam sterilization.~~ ISO Class 5 Laminar flow dispensing hood.

16. ~~Dry heat oven (for heat sterilization and to dry glassware).~~ Forceps / tongs for remote handling of material.

17. Hotplate and/or heat block.

18. ~~Lead shielded water bath.~~ Class II Bio-safety cabinet for handling blood samples for labeling.

19. Glassware.

20. Other equipment necessary for radiopharmaceutical services provided as required by the board of pharmacy.

The board of pharmacy recognizes that the equipment needed will depend on the type of radiopharmaceutical services offered. Variations for required equipment may be granted by the board of pharmacy.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02,~~ 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

Ohio

Chapter 4729-15 Nuclear Pharmacies

4729-15-01 Definitions.

As used in Chapter 4729-15 of the Administrative Code:

(A) "Class 100 environment" means an atmospheric environment that contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100 environment is equivalent to ISO class 5.

(B) "Class 100,000 environment" means an atmospheric environment that contains no more than one hundred thousand particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100,000 environment is equivalent to ISO class 8.

(C) "Nuclear pharmacist" shall be a licensed pharmacist holding a current identification card in the state of Ohio, and meets the following standards:

(1) Be certified as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or

(2) Meet minimal standards of training for an "authorized user" of radioactive material or for an "authorized nuclear pharmacist (ANP)" designation by the proper nuclear regulatory agency, the United States nuclear regulatory commission, or the appropriate state agency including:

(a) Have received a minimum of two hundred contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy or a program approved by the nuclear regulatory commission, with emphasis in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics of radioactivity;

(iv) Radiation biology;

(v) Radiopharmaceutical chemistry.

(b) Attain a minimum of five hundred hours of clinical nuclear pharmacy training under the supervision of a pharmacist trained in nuclear pharmacy and who is an "authorized user" or an "authorized nuclear pharmacist" as defined by the nuclear regulatory commission.

(D) "Nuclear pharmacy" is a pharmacy where prescriptions for radiopharmaceuticals are filled or where radiopharmaceuticals are compounded or dispensed by a pharmacist licensed by the proper authorities to receive, possess, and use such drugs. A nuclear pharmacy shall be licensed by the United States nuclear regulatory commission or the appropriate state nuclear regulatory agencies, other appropriate state agencies, and by the state board of pharmacy.

(E) "Radiopharmaceutical," a dangerous drug as defined in division (F) of section 4729.01 of the Revised Code, 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 which is intended to be used in the preparation of any such article.

Replaces: 4729-15-01

Effective: 01/01/2010

R.C. 119.032 review dates: 12/01/2014

Promulgated Under: 119.03

Statutory Authority: 3719.28, 4729.26

Rule Amplifies: 3719.01, 4729.01

Prior Effective Dates: 4/1/78, 9/1/89, 7/1/94, 3/1/99, 2/1/05

4729-15-02 Responsibility for nuclear pharmacy.

A nuclear pharmacist shall maintain supervision and control of radiopharmaceuticals as provided in division (B) of section 4729.55 of the Revised Code.

(A) The responsible nuclear pharmacist whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.

(B) The responsible nuclear pharmacist is responsible for maintaining adequate supervision and control over the dangerous drugs acquired and dispensed by the terminal distributor of dangerous drugs and maintaining all records required by this chapter and federal law to be kept at the establishment or place described in the license.

(C) If there is a change in the responsible nuclear pharmacist, the board of pharmacy shall be notified within thirty days thereof of the date of change and the name of the new responsible nuclear pharmacist.

(1) This notice to the board of pharmacy shall be made by completing, signing, and returning the form supplied by the board by regular mail or by verified facsimile transmission.

(2) A complete inventory of the controlled substances on hand shall be taken, pursuant to federal regulations, with the new responsible nuclear pharmacist. The new responsible nuclear pharmacist shall be responsible for the accuracy of this inventory.

Effective: 01/01/2009

R.C. 119.032 review dates: 09/26/2008 and 12/01/2013

Promulgated Under: 119.03

Statutory Authority: 4729.26

Rule Amplifies: 4729.54, 4729.55, 4729.57

Prior Effective Dates: 4/1/1978, 9/1/1989, 7/1/1994, 1/1/2004

4729-15-03 Minimum standards for a nuclear pharmacy.

(A) A nuclear pharmacy shall comply with all applicable local, state, and federal requirements. If a nuclear pharmacy compounds parenteral or sterile product prescriptions other than radiopharmaceuticals or biohazardous materials, the pharmacy shall also comply with rule 4729-19-04 of the Administrative Code.

(B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile radiopharmaceutical prescriptions. The policy and procedure manual shall include at a minimum:

(1) A quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education;

(2) Justification for the chosen beyond use dates of compounded products;

(3) Proper handling, storage, and disposal of drugs, radiopharmaceuticals, and radioactive waste;

(4) Proper handling, storage, and disposal of biohazardous materials, if applicable;

(5) Handling of spills and exposure to radioactive and biohazardous materials;

(6) Proper documentation and reporting of adverse events;

(7) Procedures to resolve conflicts when sterile product preparation may interfere with radiation safety practices and equipment. These procedures should use the principle of as clean as reasonably achievable.

The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy agent.

(C) Physical requirements

(1) The facility shall have a designated area with access limited to authorized personnel for preparing sterile radiopharmaceutical products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood or other primary engineering control devices that provide a class 100 environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(2) The facility compounding radiopharmaceutical prescriptions shall have appropriate:

(a) Primary engineering control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; at a minimum, there shall be a physical barrier separating the area where biohazardous products such as human blood are prepared; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air.

(b) Shielding of radioactive materials;

(c) Compounding devices and equipment;

(d) Storage conditions for drugs, radiopharmaceuticals, and biohazardous materials;

(e) Appropriate disposal containers for used needles, syringes, etc.

(3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(4) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to meet the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) Disposal of radioactive and/or biohazardous waste

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure that there is a system for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the public health.

(F) Health care professional counseling

When appropriate, a nuclear pharmacist shall be involved in discussing with each health care professional responsible for receiving, storing, and administering a radiopharmaceutical product, the following matters:

(1) Dosage form, dosage, calibrated activity, route of administration, and duration of therapy;

(2) Special directions and precautions for preparation and administration;

(3) Proper storage; and

(4) Stability or incompatibilities of the medication.

(G) Quality assurance

(1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities.

(2) At a minimum, there shall be written quality assurance programs developed that address:

(a) Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training;

(b) Continued verification of compounding accuracy and including when possible physical inspection of end products;

(c) Continued verification of automated compounding devices;

(d) Continued verification that appropriate beyond use dates are being assigned to compounded products;

(e) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. If bulk compounding of sterile products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine;

(f) All clean rooms and laminar flow hoods shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operation efficiency shall be maintained for at least three years.

Effective: 01/01/2010

R.C. 119.032 review dates: 09/28/2009 and 12/01/2014

Promulgated Under: 119.03

Statutory Authority: 4729.26

Rule Amplifies: 4729.54, 4729.55

Prior Effective Dates: 2/1/05

4729-15-04 Labeling of radiopharmaceuticals.

All radiopharmaceuticals dispensed for use by inpatients of an institutional facility are exempt from the labeling requirements of rule 4729-17-10 of the Administrative Code. All radiopharmaceuticals dispensed for use by outpatients are exempt from the labeling requirements of rule 4729-5-16 of the Administrative Code.

(A) No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:

(1) The standard radiation symbol.

(2) The words "Caution - Radioactive Material."

(3) The prescription number.

(4) The radionuclide and chemical form.

(B) No radiopharmaceutical may be dispensed unless a tamper-evident seal is applied and a label is affixed to the outer or 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 seventy-two-hour exemption is allowed to obtain the name of the patient. No later than seventy-two 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 telephone number of the nuclear pharmacy, and the name and address of the nuclear pharmacy as it appears on the terminal distributor of dangerous drugs license.

(9) The name of the end authorized user, who must also be a prescriber as defined in section 4729.01 of the Revised Code.

(10) The lot number of the preparation.

Effective: 01/01/2009

R.C. 119.032 review dates: 09/26/2008 and 12/01/2013

Promulgated Under: 119.03

Statutory Authority: 3715.69, 3719.28, 4729.26

Rule Amplifies: 3715.64, 3719.08

Prior Effective Dates: 4/1/1978, 9/1/1989, 7/1/1994, 3/1/1999

4729-15-05 Prohibitions.

(A) No person shall receive, possess, or transfer radiopharmaceuticals except in accordance with section 4729.51 of the Revised Code.

(B) No person, other than a nuclear pharmacist, shall be personally in full and actual charge of a nuclear pharmacy.

(C) No person shall conduct a nuclear pharmacy except in accordance with section 4729.28 of the Revised Code, state board of pharmacy rules, regulations of the United States nuclear regulatory commission or the appropriate state nuclear regulatory agencies, and regulations of other appropriate state agencies.

(D) No person shall utilize resuable unit dose transport containers for radioactive dosages without either an effective process to decontaminate the transport container of blood or other biohazardous substances or an effective mechanism to avoid contamination of the transport container.

(E) No person shall re-use a unit dose transport container that remains 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.

(F) This rule does not apply to:

(1) An individual prescriber who prepares radiopharmaceuticals for administration to the prescriber's patients as provided in section 4729.29 of the Revised Code.

(2) The transfer of radioactive material not intended for use as a drug to authorized persons.

(3) The occasional transfer of bulk quantities of radiopharmaceuticals to other authorized persons to meet shortages.

R.C. 119.032 review dates: 09/26/2008 and 09/26/2013

Promulgated Under: 119.03

Statutory Authority: 3715.69, 3719.28, 4729.26

Rule Amplifies: 3715.63, 3719.09, 4729.27, 4729.28, 4729.51

Prior Effective Dates: 4/1/1978, 9/1/1989, 7/1/1994, 3/1/1999, 4/27/2007

3701:1-58-20 Training for an authorized nuclear pharmacist.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(A) Is certified by a specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (B)(2) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the "American Council on Pharmaceutical Education" (ACPE) or have passed the "Foreign Pharmacy Graduate Examination Committee" (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least four thousand hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than two thousand hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(B) Has achieved the following requirements:

(1) Has completed seven hundred hours in a structured educational program consisting of both:

(a) Two hundred hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Supervised practical experience in a nuclear pharmacy involving:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid medical events in the administration of radioactive material; and

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (A)(1), (A)(2), and (A)(3) or (B)(1) of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Replaces: 3701:1-58-20

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

Promulgated Under: 119.03

Statutory Authority: 3748.02, 3748.04

Rule Amplifies: 3748.04

Prior Effective Dates: 8/15/2005

3701:1-46-43 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use.

(A) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to Chapter 3701:1-58 of the Administrative Code or equivalent regulations of an agreement state will be approved if:

(1) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;

(2) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered with the United States food and drug administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 C.F.R. 207.20(a) (as published in the April 1, 2009 Code of Federal Regulations);

(b) Registered or licensed with a state agency as a drug manufacturer;

(c) Licensed as a pharmacy by a state board of pharmacy;

(d) Operating as a nuclear pharmacy within a federal medical institution; or

(e) A positron emission tomography (PET) drug production facility registered with a state agency.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) The applicant satisfies the following labeling requirements:

(a) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half -life greater than one hundred days, the time may be omitted.

(b) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(B) A licensee described by paragraph (A)(2)(c) or (A)(2)(d) of this rule:

(1) May prepare radioactive drugs for medical use, as defined in rule 3701:1-38-01 of the Administrative Code, provided that the radioactive drug is prepared by either an authorized nuclear

pharmacist, as specified in paragraphs (B)(2) and (B)(3) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in rule 3701:1-58-14 of the Administrative Code.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an authorized nuclear pharmacist as defined in rule 3701:1-58-01 of the Administrative Code,

(b) This individual meets the requirements specified in paragraph (B) of rule 3701:1-58-20 of the Administrative Code and rule 3701:1-58-22 of the Administrative Code and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (B)(4) of this rule.

(3) The actions authorized in paragraphs (B)(1) and (B)(2) of this rule are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in rule 3701:1-38-01 of the Administrative Code) as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) The individual practiced at a pharmacy at a government agency or federally recognized indian tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission.

(5) Shall provide to the director a copy of:

(a) Each individual's certification by a specialty board whose certification process has been recognized by the United States nuclear regulatory commission or an agreement state as specified in paragraph (A) of rule 3701:1-58-20 of the Administrative Code with the written attestation signed by a preceptor as required by paragraph (B)(2) of rule 3701:1-58-20 of the Administrative Code; or

(b) The United States nuclear regulatory commission or agreement state license; or

(c) The permit issued by a United States nuclear regulatory commission master materials licensee; or

(d) The permit issued by a licensee or United States nuclear regulatory commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(e) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission; and

(f) State pharmacy licensure or registration, no later than thirty days after the date that the licensee allows, under paragraphs (B)(2)(a) and (B)(2)(c) of this rule, the individual to work as an authorized nuclear pharmacist.

(C) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(D) Nothing in this rule relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs.

Effective: 10/04/2010

R.C. 119.032 review dates: 06/28/2010 and 10/01/2015

Promulgated Under: 119.03

Statutory Authority: 3742.02, 3748.04

Rule Amplifies: 3748.04

Prior Effective Dates: 10/20/2002, 8/15/05, 1/20/08, 12/22/08

Oklahoma

OKLAHOMA PHARMACY LAWBOOK

2010

Laws and Rules Pertaining to the Practice of Pharmacy

Oklahoma Statutes, Title 59, Chapter 8. - Drugs and Pharmacy

UNOFFICIAL

and

Title 535. Oklahoma State Board of Pharmacy

UNOFFICIAL

*Official copies of the laws may be obtained from the statute books. Official copies of the rules may be obtained from the Oklahoma Secretary of State, Office of Administrative Rules.

Compiled and Published by
The Oklahoma State Board of Pharmacy
December 2010

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96]

SUBCHAPTER 17. NUCLEAR PHARMACY

Section

[Source: Added at 14 Ok Reg 3027, eff 7-11-97]

535:15-17-1. Purpose

The rules of this Subchapter are to accomplish the purposes of the Oklahoma Pharmacy Act, as specified in 59 O.S., Section 353.18 (A) thereof, by implementing rules of a licensed nuclear pharmacy. Nuclear pharmacy is hereby recognized as a specialty of pharmacy practice. As such, the following rules address those areas specific or unique to this specialty practice. These regulations are intended to supplement the regulations of other state and federal agencies.
[Source: Added at 14 Ok Reg 3027, eff 7-11-97]

535:15-17-3. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Authentication of Product History" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"Nuclear Pharmacy" means a pharmacy which provides radiopharmaceutical services and shall be licensed by the Board as a retail pharmacy.

"Practice of Nuclear Pharmacy" means 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 and related drugs.

"Qualified Nuclear Pharmacist" means a pharmacist who holds a current license issued by the Board, and who is either listed as an authorized user on a radioactive material users license or certified as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties or satisfies each of the following requirements:

(A) Meets minimal standards of training for status as an Authorized Nuclear Pharmacist (ANP), as specified by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency.

(B) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy, or other

training program recognized by the Nuclear Regulatory Commission, with the following subjects covered:

(I) radiation physics and instrumentation,

(ii) radiation protection,

(iii) mathematics pertaining to the use and measurement of radioactivity,

(iv) radiation biology,

(v) radiopharmaceutical chemistry;

(C) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas, as described in the current American Pharmaceutical Association (APhA) Nuclear Pharmacy Practice Standards:

(i) procuring radioactive materials,

(ii) compounding radiopharmaceuticals,

(iii) performing routine quality control procedures,

(iv) dispensing radiopharmaceuticals,

(v) distributing radiopharmaceuticals,

(vi) implementing basic radiation protection procedures,

(vii) consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public;

(D) Keeps documentation of experience and training available in the pharmacy for Board review.

"Quality Assurance Procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

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

"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.

"Radiopharmaceutical" means any substance 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. The term "radiopharmaceutical" also includes any product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

[**Source:** Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 24 Ok Reg 2262, eff 7-1-07]

535:15-17-5. General requirements

(a) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The nuclear pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The permit to operate a nuclear pharmacy is effective only so long as the pharmacy also holds a current Radioactive Material License issued by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency. Copies of inspection reports from Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency shall be available for Board inspection.

(c) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping/receiving area; radioactive material storage area; and radioactive waste decay area.

(d) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and must be totally enclosed and lockable.

(e) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with Board and Nuclear Regulatory Commission statutes and regulations.

(f) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance, including compounded sterile products. 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 professional standards.

(g) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission or appropriate agreement state nuclear regulatory agency to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications as described in 535:15-17-5 subsection (k) below Separate records will be kept for these transfers and sales, see drug supplier permit rules in 535:15-7.

(h) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(1) This writing or record shall contain at least the following:

(A) the name of the institution and prescriber, or prescribers' agent;
(B) the date of dispensing (or calibration) and the calibration time of the radiopharmaceutical;
(C) the name of the procedure;
(D) the name of the radiopharmaceutical;
(E) the dose or quantity of the radiopharmaceutical;
(F) the serial number assigned to the order for the radiopharmaceutical;
(G) any specific instructions; and
(H) the initials of the pharmacist who dispensed the order.

(2) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

(i)

(1) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:
(A) the name and address of the pharmacy;
(B) the name of the prescriber;
(C) the date of dispensing (or calibration);
(D) the serial number assigned to the order for the radiopharmaceutical;
(E) the standard radiation symbol;
(F) the words "Caution Radioactive Material";
(G) the name of the procedure;
(H) the radionuclide and chemical form;
(I) the amount of radioactivity and the calibration date and time;
(J) if a liquid, the volume;
(K) if a solid, the number of items or weight;
(L) if a gas, the number of ampules or vials;
(M) the expiration date and time; and,
(N) the name of the patient or the words e.g. "Per Physician's Orders" in the absence of a patient name.

(2) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this sub-section shall be met when the name of the patient is readily retrievable from the physician upon demand.

(j) The inner container label of a radiopharmaceutical to be dispensed shall be labeled with, but not limited to:
(1) the standard radiation symbol;
(2) the identity of the radionuclide;
(3) the amount of radioactivity and the calibration date and time;
(4) the name of the procedure; and
(5) serial number of the radiopharmaceutical.

(k) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the institutional radiation safety committee or equivalent radioactive use oversight committee approval, a copy of the Institutional Review Board approval

form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.
(l) Each nuclear pharmacy shall have an adequate library and a current copy of state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.
[Source: Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 15 Ok Reg 3272, eff 7-13-98; Amended at 24 Ok Reg 2262, eff 7-1-07]

535:15-17-7. Minimum equipment
(a) A nuclear pharmacy shall be exempt from the physical requirements in Section 535:15-3-4, Subsections (3) through (8) and (10) through (11).
(b) The professional area of the pharmacy shall have at least the following equipment:

(1) Radionuclide Dose Calibrator;
(2) Refrigerator;
(3) Single or multiple channel scintillation counter with solid state detector (e.g. NaI(Tl) or Ge(Li));
(4) Radiochemical fume hood and filter system with suitable air sampling equipment when dispensing or preparing volatile radiopharmaceuticals;
(5) Area survey meter;
(6) At least two GM survey meters (including one high-range meter);
(7) Microscope and hemacytometer, when dispensing or preparing particle size dependent radiopharmaceuticals;
(8) Laminar airflow hood and appropriate supplies to ensure sterile practices for parenteral solutions;
(9) Syringe and vial radiation shields;
(10) Appropriate shielded drawing station;
(11) Decontamination supplies;
(12) Appropriate supplies to perform quality assurance testing;
(13) Appropriate transport shields for syringes and vials; and
(14) Transport containers which meet the U.S. Department of Transportation regulations, and other labels and supplies for shipping radioactive materials.

[Source: Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 24 Ok Reg 2264, eff 7-1-07]

535:15-17-9. Library reference books or computer sources
A pharmacy library shall contain the following current reference books or computer sources:

(1) **Oklahoma law books.** The latest copy of the Oklahoma State Board of Pharmacy, Laws and Rules and Regulations Pertaining to the Practice of Pharmacy and a recent copy of the Oklahoma State Bureau of Narcotics & Dangerous Drug Control's Rules and Regulations.
(2) Reference compendia necessary to practice Nuclear Pharmacy safely within federal and state requirements.

[Source: Added at 14 Ok Reg 3027, eff 7-11-97]

Oregon State Archives

800 Summer St NE Salem OR 97310
503 373 0701 | Mon-Fri: 8am-4:45pm

The Oregon Administrative Rules contain OARs filed through June 15, 2012

QUESTIONS ABOUT THE CONTENT OR MEANING OF THIS AGENCY'S RULES?
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BOARD OF PHARMACY

DIVISION 42

NUCLEAR PHARMACIES AND PHARMACISTS

855-042-0005

Purpose and Scope

(1) Any person who provides radiopharmaceutical services shall be a nuclear pharmacist or working under the supervision of a nuclear pharmacist and shall act in accordance with the State Board of Pharmacy and State Radiation Control Agency rules.

(2) These rules shall not apply to anyone who is an "authorized practitioner" as that term is defined in these rules.

(3) The requirements imposed by these nuclear pharmacy rules shall apply in addition to, and not in place of, any other requirements contained in rules of the State Board of Pharmacy, the State Radiation Control Agency, or any other state or federal agency.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

855-042-0010

Definitions

(1) A "Nuclear Pharmacy" is a pharmacy providing radiopharmaceutical services.

(2) "Nuclear Pharmacist" means a licensed pharmacist who has met the requirements of these rules regarding training, education, and experience, and has received a letter of notification from the board indicating the board recognizes the pharmacist, based on evidence submitted, as qualified to provide radiopharmaceutical services.

(3) "Radiopharmaceutical Services" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery or radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(4) A "Radiopharmaceutical" is any substance defined as a drug in Section 201(g)(1) of the federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such

as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on 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.

(6) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

(7) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

(8) "Authorized Practitioner" means a practitioner duly authorized by law to possess, use, and administer radiopharmaceuticals.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

855-042-0015

Nuclear Pharmacies

(1) Every nuclear pharmacy shall have a nuclear pharmacist designated on the nuclear pharmacy registration as the pharmacist-in-charge who shall be responsible for the nuclear pharmacy's compliance with laws and rules, both state and federal, pertaining to the practice of nuclear pharmacy. All personnel performing tasks in the preparation and distribution of radio-pharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacy pharmacist-in-charge shall see that directives from the board are communicated to the owner(s), management, other pharmacists, and interns of the nuclear pharmacy. A pharmacist may be pharmacist-in-charge for no more than one nuclear pharmacy at any one given time.

(2) Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradio-pharmaceuticals and shall be secured from access by unauthorized personnel. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Radiation Control Agency before approval of the registration.

(3) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with accepted professional standards of radiopharmaceutical quality assurance.

(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable rules of the state Board of Pharmacy, the State Radiation Control Agency and other state and federal agencies.

(5) For nuclear pharmacies handling radiopharmaceuticals exclusively, the State Board of Pharmacy may waive regulations pertaining to the pharmacy registration for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(6) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(7) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(8) Prescriptions or medication orders for radiopharmaceuticals shall include:

(a) The name of the practitioner and/or institution;

(b) The name of the radiopharmaceutical;

(c) The amount of radioactivity to be contained in millicuries, microcuries, or the SI equivalent at calibration;

(d) The date and time of calibration, and volume.

(9) In addition to any labeling requirements of the state Board of Pharmacy for nonradiopharmaceuticals, the outer container of any radiopharmaceutical to be dispensed shall also be labeled with:

(a) The prescription number and the patient's name (of the words **"Physician Use Only"** in the absence of the name of the patient);

(b) The standard radiation symbol;

(c) The words **"Caution -- Radioactive Material"**;

(d) The name of the radiopharmaceutical;

(e) The lot number;

(f) The amount of radioactive material contained in millicuries, microcuries, or their SI equivalent;

(g) If a liquid, the volume in milliliters;

(h) The requested calibration date and time; and

(i) Expiration date and/or time, if applicable;

(j) Specific concentration of radioactivity;

(k) The name and address of the practitioner and/or institution that ordered the radiopharmaceuticals.

(10) The immediate inner container of a radiopharmaceutical shall be labeled with:

(a) Standard radiation symbol;

(b) The words **"Caution -- Radioactive Material"**; and

(c) The name and prescription number of the radiopharmaceutical;

(d) The prescription number;

(e) The name of the nuclear pharmacy;

(f) The date; and

(g) The amount of radioactive material in millicuries, microcuries, or their SI equivalent.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) Nuclear pharmacies may redistribute NDA (New Drug Application) approved radiopharmaceuticals to authorized persons if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have the current revisions of state laws and rules of the State Board of Pharmacy and State Radiation Control Agency.

(14) The nuclear pharmacy shall maintain a reference library commensurate with the level of radiopharmaceutical service to be provided and shall include, in addition to the requirements listed in OAR 855-041-0040;

(a) Oregon radiation control regulations;

(b) **CFR Title 10, Parts 0-199**, with current amendments; and

(c) **CFR Title 49, Parts 106-199**, with current amendments.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87; PB 1-1994, f. & cert. ef. 2-2-94

855-042-0025

Minimum Equipment Requirements

(1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the State Board of Pharmacy and Radiation Control Agency before approval of the license.

(2) The State Board of Pharmacy may, for good cause shown, waive rules pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

Rhode Island

RULES AND REGULATIONS PERTAINING TO PHARMACISTS, PHARMACIES AND MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

[R5-19.1-PHAR]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

March 1985

As Amended:

May 1986
August 1986
April 1987
April 1988
October 1988 (E)
January 1989
September 1989 (E)
December 1989
May 1990
October 1990 (T)
September 1992 (E)
February 1993 (E)
April 1993
November 1993
February 1994
July 1996
July 1997
February 2000
July 2000 (E)
November 2000 (E)
December 2000
April 2001
August 2001 (E)
December 2001 (E)
December 2001 (E)
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
January 2002
July 2002
December 2002
May 2003
June 2003 (E)
October 2003 (E)
December 2003
February 2004
December 2004
July 2005
October 2005
June 2006
January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
April 2007
July 2007
January 2008
April 2009
July 2009 (E)
November 2009 (E)
January 2010

information on the patient profiles. The consultant pharmacist shall:

- υ review the drug and biological regimen of each resident monthly.
- υ report any irregularities to the attending physician and director of nurses. Reports shall show evidence of review and response; and
- υ document in writing the performance of such review, which documentation shall be kept on file by the facility and shall be made accessible to inspectors upon request.

16.1.4 A unit dose drug dispensing system or automated dispensing device may be utilized for the dispensing of drugs to patients in a licensed hospital, nursing facility or hospice facility. Such systems or devices shall be utilized in accordance with regulations herein.

Section 17.0 *Pharmaceutical Services: Nuclear/Radiologic Pharmacies*

17.1 The practice of nuclear/radiologic pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the Board. This section applies only to pharmacies which are preparing and distributing, or redistributing radioactive material, not simply handling such material.

Policies and Procedures

17.2 These rules and regulations herein shall not apply to a nuclear medicine department within a medical institution which is licensed by another agency.

17.3 Nuclear pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials, in accordance with the provisions of the *Rules and Regulations for the Control of Radiation (R23-1.3RAD).*

17.4 All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the Department and the state Office of Occupational and Radiological Health before approval of the license.

17.5 Radiopharmaceuticals are to be dispensed only upon a prescription drug order, from a practitioner authorized to possess, use and administer radiopharmaceuticals.

17.6 The permit to operate a nuclear pharmacy is conditional upon an approved state Office of Occupational and Radiological Health license. Copies of the Office of Occupational and Radiological Health inspection reports shall be made available upon request for Board inspection.

Personnel

17.7 A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the

pharmacy and shall be in personal attendance at all times that the pharmacy is open for business.

17.8 The nuclear pharmacy area shall be secured from unauthorized personnel.

Physical Requirements

17.9 Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state or as otherwise defined by the Board.

Section 18.0 *Nonresident Pharmacies*

18.1 *Licensure* - In order to ship, mail, or deliver prescription drugs and/or devices to a patient in this state, a non-resident pharmacy must be licensed by the Board and shall comply with all statutory and regulatory requirements as stated herein.

18.2 *Agent of record* - Each nonresident pharmacy that ships, mails, or delivers prescription drugs and/or devices to a patient in this state shall designate a resident agent in this state for service of process. Any such nonresident pharmacy that does not so designate a registered agent and that ships, mails, or delivers prescription drugs and/or devices in this state, shall be deemed an appointment by such nonresident pharmacy of the Secretary of State to be its true and lawful attorney upon whom may be served all legal process in any action or proceeding against such pharmacy growing out of or arising from such delivery. A copy of any such service of process shall be mailed to the nonresident pharmacy by the complaining party by certified mail, return receipt requested, postage prepaid, or by international certified mail, return receipt requested, postage prepaid, at the address of such nonresident pharmacy as designated on the pharmacy's application for licensure in this state. If any such pharmacy is not licensed in this state, service on the Secretary of State in this state only shall be sufficient service.

18.3 *Conditions of Licensure* - As conditions of licensure, the nonresident pharmacy must comply with the following:

a) maintain, at all times a valid unexpired license, permit or registration to operate the pharmacy in compliance with the laws of the state or province of Canada in which it is located;

b) provide a description of any final disciplinary action(s) by licensing boards in other states or provinces of Canada; and

c) provide all information requested by the Board.

18.4 A pharmacy license will be issued to the owner who meets the requirements established pursuant to the Act and the rules and regulations herein. The owner of each pharmacy shall receive a license of location, which shall entitle the owner to operate such pharmacy at the location specified, or such other temporary location as the director may approve, for the period ending on 30 September. Each such owner shall at the time of filing provide proof of

South Carolina

South Carolina Legislature

South Carolina Code of Laws
Unannotated
Current through the end of the 2011 Session

DISCLAIMER

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Title 40 - Professions and Occupations

CHAPTER 43.

SOUTH CAROLINA PHARMACY PRACTICE ACT

SECTION 40-43-10. Short title; purpose of chapter; severability.

This chapter may be cited as the "South Carolina Pharmacy Practice Act". The purpose of this chapter is to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, permitting, control, and regulation of all sites or persons, in or out of this State, that distribute, manufacture, possess, or sell drugs or devices within this State, as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual.

The practice of pharmacy shall center around the provision of pharmacy care services and assisting the patient to achieve optimal therapeutic outcomes.

If a provision of this chapter is declared unconstitutional or illegal, or the applicability of this chapter to a person, pharmacy, or circumstance is held invalid by a court of competent jurisdiction, the constitutionality or legality of the remaining provisions of this chapter and the application of this chapter to other persons, pharmacies, and circumstances are not affected and shall remain in full force and effect without the invalid provision or application.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-20. License required.

Except as otherwise provided in this chapter, it is unlawful for an individual to engage in the practice of pharmacy unless currently licensed pursuant to this chapter.

HISTORY: 1998 Act No. 366, Section 1.

SECTION 40-43-30. Definitions.

For purposes of this chapter:

(1) "Administer" means the direct application of a drug or device pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion, topical application, or any other means.

(2) "Biological safety cabinet" means a containment unit suitable for the preparation of low-to-moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation Standard 49.

(3) "Board" or "Board of Pharmacy" means the State Board of Pharmacy.

(4) "Brand name" means the proprietary or trade name placed upon a drug, its container, label, or wrapping at the time of packaging.

(5) "Chart order" means a lawful order from a practitioner for a drug or device for patients of a hospital or extended care facility, or such an order prepared by another person and signed by a practitioner either immediately or at another time, issued for a legitimate medical purpose within the practitioner's course of legitimate practice and including orders derived on behalf of a practitioner from a practitioner approved drug therapy management.

(6) "Class 100 environment" means an atmospheric environment which contains less than one hundred particles 0.5 microns in diameter per cubic foot of air.

(7) "Compounding" means the preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or 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 or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. The term compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(8) "Confidential information" means information maintained in a patient's records or which is communicated to a patient as part of patient counseling, which is privileged and may be released only to the patient, to those practitioners and pharmacists where, in the pharmacist's professional judgment, release is necessary to protect the patient's health and well being, and to other persons or governmental agencies authorized by law to receive such confidential information.

(9) "Cytotoxic agent" means a drug that has the capability of killing living cells.

(10) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration.

(11) "Designated agent" means a person employed by an authorized practitioner to transmit, either orally or electronically, a prescription drug order on behalf of the authorized practitioner to the pharmacist. The authorized practitioner accepts the responsibility for the correct transmission of the prescription drug order.

Section 40-43-86

(6) No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing:

(a) the standard radiation symbol;

(b) the words "Caution–Radioactive Material"; and

(c) the prescription number.

(7) No radiopharmaceutical may be dispensed unless a label is affixed to the outer or delivery container bearing the:

(a) standard radiation symbol;

(b) words "Caution--Radioactive Material";

(c) radionuclide and chemical form;

(d) activity and date and time of assay;

(e) volume if in liquid form;

(f) requested activity and the calibrated activity;

(g) prescription number;

(h) patient name or space for patient name. Where the patient's name is not available at the time of dispensing, a seventy-two hour exemption is allowed to obtain the name of the patient. No later than seventy-two hours after dispensing the radiopharmaceutical, the patient's name shall become a part of the prescription drug order to be retained for two years;

(i) name and address of the nuclear pharmacy;

(j) name of the practitioner; and

(k) lot number of the prescription.

South Carolina

SECTION 40-43-87. Nuclear/radiologic pharmacy practice; regulations set by Nuclear Regulatory Commission; revocati regarding violations of state or federal law; space and equipment requirements.

(A) Nuclear/radiologic pharmacy practice refers to a patient-oriented service that embodies the scientific knowledge anc promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs. Nuclear regulations established by the Nuclear Regulatory Commission as they pertain to the practice of nuclear pharmacy.

The pharmacist-in-charge of a nuclear pharmacy must be a qualified nuclear pharmacist. All personnel performing task radiopharmaceuticals and ancillary drugs must be under the direct supervision of a qualified nuclear pharmacist.

(B) Revocation of the radioactive materials license from the Department of Health and Environmental Control voids the be returned to the board within ten days.

(C) Copies of all regulatory inspection reports must be made available upon request for board inspection.

(D) The nuclear pharmacist-in-charge shall notify the Board of Pharmacy by letter of the outcome of any hearings that a state or federal laws or regulations governing radioactive materials. Notification must be within thirty days of the date of

(E) Space and equipment must be adequate to the scope of services required and provided. All nuclear pharmacy facili preparations/dispensing area, a radioactive material shipping/receiving area, and a radioactive waste decay area. Airflo efficiency in accordance with federal standards by a qualified technician and must be recertified each time the hood is n the hood and shall state the date certification was granted. Prefilters must be changed in accordance with manufacturer date and initials. Documentation must be retained for two years.

(F) For purposes of this section, "qualified nuclear pharmacist" means a pharmacist who holds a current license issued is either certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or meets minimal standards of tra material, as specified by the Nuclear Regulatory Commission.

HISTORY: 1998 Act No. 366, Section 1.

Tennessee

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-06
NUCLEAR PHARMACY PRACTICE SITES

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1140-06-.01 APPLICABILITY.

The provisions of this Chapter are in addition to, and not in substitution for, other applicable laws and rules administered by the board, the State Board of Radiological Health.

Authority: *T.C.A. § 63-10-504(b)(1).* ***Administrative History:*** *Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-06-.02 GENERAL REQUIREMENTS.

(1) A nuclear pharmacy practice site shall contain adequate space, commensurate with the scope of services required and provided. The board may, upon request, exempt a nuclear pharmacy practice site handling radioactive drugs exclusively from the minimum space requirements for pharmacy practice sites.

(2) The compounding and dispensing area for radioactive drugs shall be separate from the compounding and dispensing area for non-radioactive drugs, and shall be secured from unauthorized personnel.

(3) All pharmacy practice sites handling radiopharmaceuticals shall provide adequate radioactive storage and product decay area, preferably separate from and exclusive of the hot laboratory and the compounding, dispensing, quality assurance, and office areas.

A nuclear pharmacy practice site shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(5) A pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with *T.C.A. 68-202-206.* A nuclear pharmacy practice site may also furnish radiopharmaceuticals for office use to authorized practitioners for individual patient use.

(6) In addition to any labeling requirements of the board for non-radioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

(a) the standard radiation symbol;
(b) the words "Caution - Radioactive Material";
(c) the radionuclide;
(d) the chemical form;
(e) the amount of radioactive material contained, in millicuries or microcuries;
(f) if a liquid, the volume;
(g) the calibration time for the amount of radioactivity contained;
(h) the expiration time; and
(i) the name, address, and telephone number of the nuclear pharmacy practice site.

(Rule 1140-06-.02, continued)

(7) The immediate container shall be labeled with:

(a) the standard radiation symbol;
(b) the words "Caution - Radioactive Material";
(c) the name of the drug; and
(d) the medical or prescription order number.

(8) The amount of radioactivity shall be determined by radiometric methods for each product immediately prior to dispensing.

(9) A nuclear pharmacy practice site shall conduct and keep proper records of appropriate internal test assessments on all radiopharmaceuticals, with interpretation of the resulting data to determine suitability for use in humans.

(10) A nuclear pharmacy practice site shall conduct authentication of product history by identifying and keeping proper records of the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

Authority: *T.C.A. § 63-10-404(4),(11),(16),(28), § 63-10-504(b)(1), § 63-10-504(b)(1),(2), § 63-10-504(j).* ***Administrative History:*** *Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-06-.03 LIBRARY.

Each nuclear pharmacy practice site shall maintain an adequate reference library (printed or electronic) consistent with its scope of practice. The reference library shall include a current edition of the Tennessee Pharmacy Laws issued by the Tennessee Board of Pharmacy and may include current material regarding the technical, clinical, and professional components of the practice of pharmacy, with particular emphasis in the area in which the pharmacy specializes.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.*

1140-06-.04 EQUIPMENT.

Each nuclear pharmacy practice site shall contain at least the following equipment:

(1) Vertical laminar flow hood;
(2) Dose calibrator;
(3) Refrigerator;
(4) Room monitor;
(5) Portable survey meter;
(6) Single or multiple channel scintillation counter;
(7) Microscope;
(8) Radio chemical exhaust hood and filter system, only if required for licensing by the State Board of Radiological Health.
(9) Such other equipment as may be required by the State Board of Radiological Health.

Authority: *T.C.A. § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998*

Texas

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TITLE 22 EXAMINING BOARDS
PART 15 TEXAS STATE BOARD OF PHARMACY
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TITLE 22	EXAMINING BOARDS
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SUBCHAPTER C	NUCLEAR PHARMACY (CLASS B)
RULE §291.51	**Purpose**

The purpose of this subchapter is to provide standards for the preparation, labeling, and distribution of compounded radiopharmaceuticals by licensed nuclear pharmacies, pursuant to a radioactive prescription drug order. The intent of this subchapter is to establish a minimum acceptable level of pharmaceutical care to the patient so that the patient's health is protected while contributing to positive patient outcomes. The board has determined that this subchapter is necessary to protect the health and welfare of the citizens of this state.

Source Note: The provisions of this §291.51 adopted to be effective March 19, 1998, 23 TexReg 2815; amended to be effective September 14, 2010, 35 TexReg 8357

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RULE §291.52	**Definitions**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set forth in the Act, §551.003.

(1) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(2) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug order or radioactive prescription drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Subchapter A, Chapter 562 of the Act.

(3) ACPE--Accreditation Council for Pharmacy Education.

(4) Administer--The direct application of a prescription drug and/or radiopharmaceutical, by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(5) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:

(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);

(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and

(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than

3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).

(6) Ancillary supplies--Supplies necessary for the administration of compounded sterile radiopharmaceuticals.

(7) Aseptic processing--The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(8) Authentication of product history--Identifying the purchasing source, the intermediate handling, and the ultimate disposition of any component of a radioactive drug.

(9) Authorized nuclear pharmacist--A pharmacist who:

(A) has completed the specialized training requirements specified by this subchapter for the preparation and distribution of radiopharmaceuticals; and

(B) is named on a Texas radioactive material license, issued by the Texas Department of State Health Services, Radiation Control Program.

(10) Authorized user--Any individual named on a Texas radioactive material license, issued by the Texas Department of State Health Services, Radiation Control Program.

(11) Automated compounding or drug dispensing device--An automated device that compounds, measures, counts, packages, and/or labels a specified quantity of dosage units for a designated drug product.

(12) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.

(13) Board--The Texas State Board of Pharmacy.

(14) Clean room or controlled area--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(15) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(16) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Act.

(17) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(18) Critical site--Sterile ingredients of compounded sterile preparations and locations on devices and components used to prepare, package, and transfer compounded sterile preparations that provide opportunity for exposure to contamination.

(19) Dangerous drug--A drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(20) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).

(21) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device, radiopharmaceutical, or controlled substance from one person to another, whether or not for a consideration.

(22) Designated agent--

(A) an individual, including a licensed nurse, physician assistant, or pharmacist:

(i) who is designated by a practitioner and authorized to communicate a prescription drug order to a pharmacist; and

(ii) for whom the practitioner assumes legal responsibility;

(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom a practitioner communicates a prescription drug order; or

(C) a registered nurse or physician assistant authorized by a practitioner to administer a prescription drug order for a dangerous drug under Subchapter B, Chapter 157 (Occupations Code).

(23) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or

other similar or related articles, including any component parts or accessory that is required under federal or state law to be ordered or prescribed by a practitioner.

(24) Diagnostic prescription drug order--A radioactive prescription drug order issued for a diagnostic purpose.

(25) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device, or a radiopharmaceutical in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(26) Dispensing pharmacist--The authorized nuclear pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

(27) Distribute--The delivering of a prescription drug or device, or a radiopharmaceutical other than by administering or dispensing.

(28) Electronic radioactive prescription drug order--A radioactive prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).

(29) Internal test assessment--Validation of tests for quality control necessary to insure the integrity of the test.

(30) Nuclear pharmacy technique--The mechanical ability required to perform the nonjudgmental, technical aspects of preparing and dispensing radiopharmaceuticals.

(31) Original prescription--The:

(A) original written radioactive prescription drug orders; or

(B) original verbal or electronic radioactive prescription drug orders maintained either manually or electronically by the pharmacist.

(32) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(33) Pharmacy technician--An individual whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(34) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(35) Process validation--Documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

(36) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile radiopharmaceuticals lead to preparations that meet predetermined standards of quality.

(37) Radiopharmaceutical--A prescription drug or device that exhibits spontaneous disintegration of unstable nuclei with the emission of a nuclear particle(s) or photon(s), including any nonradioactive reagent kit or nuclide generator that is intended to be used in preparation of any such substance.

(38) Radioactive drug quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final radiopharmaceutical prepared meets predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility and the interpretation of the resulting data in order to determine the feasibility for use in humans and animals including internal test assessment, authentication of product history, and the keeping of mandatory records.

(39) Radioactive drug service--The act of distributing radiopharmaceuticals; the participation in radiopharmaceutical selection and the performance of radiopharmaceutical drug reviews.

(40) Radioactive prescription drug order--An order from a practitioner or a practitioner's designated agent for a radiopharmaceutical to be dispensed.

(41) Sterile radiopharmaceutical--A dosage form of a radiopharmaceutical free from living micro-organisms.

(42) Therapeutic prescription drug order--A radioactive prescription drug order issued for a specific patient for a therapeutic purpose.

(43) Ultimate user--A person who has obtained and possesses a prescription drug or radiopharmaceutical for administration to a patient by a practitioner.

Source Note: The provisions of this §291.52 adopted to be effective March 19, 1998, 23 TexReg 2815; amended to be effective September 16, 1999, 24 TexReg 7259; amended to be effective June 1, 2002, 27 TexReg 1781; amended to be effective March 4, 2004, 29 TexReg 1999; amended to be effective June 6, 2004, 29 TexReg 5362; amended to be effective September 14, 2010, 35 TexReg 8357

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SUBCHAPTER C	NUCLEAR PHARMACY (CLASS B)
RULE §291.53	**Personnel**

(a) Pharmacists-in-Charge.

(1) General.

(A) Every nuclear pharmacy shall have an authorized nuclear pharmacist designated on the nuclear pharmacy license as the pharmacist-in-charge who shall be responsible for a nuclear pharmacy's compliance with laws and regulations, both state and federal, pertaining to the practice of nuclear pharmacy.

(B) The nuclear pharmacy pharmacist-in-charge shall see that directives from the board are communicated to the owner(s), management, other pharmacists, and interns of the nuclear pharmacy.

(C) Each Class B pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(i) more than one Class B pharmacy, if the additional Class B pharmacies are not open to provide pharmacy services simultaneously; or

(ii) up to two Class B pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy.

(2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(A) ensuring that radiopharmaceuticals are dispensed and delivered safely and accurately as prescribed;

(B) developing a system to assure that all pharmacy personnel responsible for compounding and/or supervising the compounding of radiopharmaceuticals within the pharmacy receive appropriate education and training and competency evaluation;

(C) determining that all pharmacists involved in compounding sterile radiopharmaceuticals obtain continuing education appropriate for the type of compounding done by the pharmacist;

(D) supervising a system to assure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including radiopharmaceuticals, components used in the compounding of radiopharmaceuticals, and drug delivery devices;

(E) assuring that the equipment used in compounding is properly maintained;

(F) developing a system for the disposal and distribution of drugs from the Class B pharmacy;

(G) developing a system for bulk compounding or batch preparation of radiopharmaceuticals;

(H) developing a system for the compounding, sterility assurance, and quality control of sterile radiopharmaceuticals;

(I) maintaining records of all transactions of the Class B pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials including radiopharmaceuticals, required by applicable state and federal laws and rules;

(J) developing a system to assure the maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(K) assuring that the pharmacy has a system to dispose of radioactive and cytotoxic waste in a manner so as not to endanger the public health; and

(L) legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy.

(b) Owner. The owner of a Class B pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(1) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the Class B pharmacy;

(2) establishment of policies and procedures for the security of the prescription department including the maintenance of effective controls against the theft or diversion of prescription drugs;

(3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(4) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(5) establishment of policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(c) Authorized nuclear pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by a sufficient number of additional authorized nuclear pharmacists as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(B) All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of an authorized nuclear pharmacist. General qualifications for an authorized nuclear pharmacist are the following. A pharmacist shall:

(i) meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Texas Regulations for Control of Radiation of the Radiation Control Program, Texas Department of State Health Services;

(ii) be a pharmacist licensed by the board to practice pharmacy in Texas; and

(iii) submit to the board either:

(I) written certification that he or she has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(II) written certification signed by a preceptor authorized nuclear pharmacist that he or she has achieved a level of competency sufficient to independently operate as an authorized nuclear pharmacist and has satisfactorily completed 700 hours in a structured educational program consisting of both:

(-a-) 200 hours of didactic training in a program accepted by the Radiation Control Program, Texas Department of State Health Services in the following areas:

(-1-) radiation physics and instrumentation;

(-2-) radiation protection;

(-3-) mathematics pertaining to the use and measurement of radioactivity;

(-4-) radiation biology; and

(-5-) chemistry of radioactive material for medical use; and

(-b-) 500 hours of supervised practical experience in a nuclear pharmacy involving the following:

(-1-) shipping, receiving, and performing related radiation surveys;

(-2-) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(-3-) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(-4-) using administrative controls to avoid adverse medical events in the administration of radioactive material; and

(-5-) using procedures to prevent or minimize contamination and using proper decontamination procedures.

(C) The board may issue a letter of notification that the evidence submitted by the pharmacist meets

the requirements of subparagraph (B)(i) - (iii) of this paragraph and has been accepted by the board and that, based thereon, the pharmacist is recognized as an authorized nuclear pharmacist.

(D) Authorized nuclear pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for delegating nuclear pharmacy techniques and additional duties, other than those listed in paragraph (2) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each authorized nuclear pharmacist:

(i) shall verify the accuracy of all acts, tasks, or functions performed by pharmacy technicians and pharmacy technician trainees; and

(ii) shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(E) All authorized nuclear pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(F) The dispensing pharmacist shall ensure that the drug is dispensed and delivered safely and accurately as prescribed.

(2) Special requirements for compounding.

(A) Non-sterile preparations. All pharmacists engaged in compounding non-sterile radiopharmaceuticals shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(B) Sterile Preparations. All pharmacists engaged in compounding sterile radiopharmaceuticals shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(3) Duties. Duties which may only be performed by an authorized nuclear pharmacist are as follows:

(A) receiving verbal therapeutic prescription drug orders and reducing these orders to writing, either manually or electronically;

(B) receiving verbal, diagnostic prescription drug orders in instances where patient specificity is required for patient safety (e.g., radiolabeled blood products, radiolabeled antibodies) and reducing these orders to writing, either manually or electronically;

(C) interpreting and evaluating radioactive prescription drug orders;

(D) selection of drug products; and

(E) performing the final check of the dispensed prescription before delivery to the patient to ensure that the radioactive prescription drug order has been dispensed accurately as prescribed.

(d) Pharmacy Technicians and Pharmacy Technician Trainees.

(1) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy

Technician Trainee Training).

(2) Special requirements for compounding.

(A) Non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile radiopharmaceuticals shall meet the training requirements specified in §291.131 of this title.

(B) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile radiopharmaceuticals shall meet the training requirements specified in §291.133 of this title.

(3) Duties.

(A) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in subsection (c)(3) of this section.

(B) An authorized nuclear pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nuclear pharmacy technique which is associated with the preparation and distribution of radiopharmaceuticals provided:

(i) an authorized nuclear pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(ii) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist.

(4) Ratio of authorized nuclear pharmacist to pharmacy technicians and pharmacy technician trainees.

(A) The ratio of authorized nuclear pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and is trained in the handling of radioactive materials.

(B) The ratio of authorized nuclear pharmacists to pharmacy technician trainees may not exceed 1:2.

(e) Special education, training, and evaluation requirements for pharmacy personnel compounding or responsible for the direct supervision of pharmacy personnel compounding sterile radiopharmaceuticals. All pharmacy personnel preparing sterile radiopharmaceuticals shall meet the training requirements specified in §291.133 of this title.

Source Note: The provisions of this §291.53 adopted to be effective March 19, 1998, 23 TexReg 2815; amended to be effective September 16, 1999, 24 TexReg 7259; amended to be effective September 12, 2001, 26 TexReg 6920; amended to be effective March 4, 2004, 29 TexReg 1999; amended to be effective June 6, 2004, 29 TexReg 5362; amended to be effective September 14, 2010, 35 TexReg 8357; amended to be effective June 7, 2012, 37 TexReg 4047

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SUBCHAPTER C	NUCLEAR PHARMACY (CLASS B)
RULE §291.54	**Operational Standards**

(a) Licensing requirements.

(1) It is unlawful for a person to provide radioactive drug services unless such provision is performed by a person licensed to act as an authorized nuclear pharmacist, as defined by the board, or is a person acting under the direct supervision of an authorized nuclear pharmacist acting in accordance with the Act and its rules, and the regulations of the Texas Department of State Health Services, Radiation Control Program. Subsection (a) of this section does not apply to:

(A) a licensed practitioner or his or her designated agent for administration to his or her patient, provided no person may receive, possess, use, transfer, own, acquire, or dispose of radiopharmaceuticals except as authorized in a specific or a general license as provided in accordance with the requirements of the Texas Department of State Health Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1, Subchapter F, §289.252 relating to Licensing of Radioactive Material, or the Act;

(B) institutions and/or facilities with nuclear medicine services operated by practitioners and who are licensed by the Texas Department of State Health Services, Radiation Control Program, to prescribe, administer, and dispense radioactive materials (drugs and/or devices).

(2) An applicant for a Class B pharmacy shall provide evidence to the board of the possession of a Texas Department of State Health Services radioactive material license or proof of application for a radioactive material license.

(3) A Class B pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(4) A Class B pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(5) A Class B pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title.

(6) A Class B pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title.

(7) A Class B pharmacy shall notify the board in writing within ten days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(8) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

(10) A Class B pharmacy, licensed under the provisions of the Act, §560.051(a)(2), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §291.31 of this title (relating to Definitions); §291.32 of this title (relating to Personnel); §291.33 of this title (relating to Operational Standards); §291.34 of this title (relating to Records); and §291.35 of this title (relating to Official Prescription Requirements), to the extent such rules are applicable to the operation of the pharmacy.

(11) A Class B (nuclear) pharmacy engaged in the compounding of non-sterile non-radioactive preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(12) A Class B (nuclear) pharmacy engaged in the compounding of sterile non-radioactive preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(b) Risk levels for compounded sterile radiopharmaceuticals. Risk Levels for sterile compounded radiopharmaceuticals shall be as listed below.

(1) Low-risk level compounded sterile radiopharmaceuticals.

(A) Low-risk level compounded sterile radiopharmaceuticals are those compounded under all of the following conditions.

(i) The compounded sterile preparations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.

(ii) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are performed promptly and attentively.

(iii) Manipulations are limited to aseptically opening ampuls, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products.

(iv) For a low-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following periods: before administration, 48 hours at controlled room temperature, for not more than 14 days if stored in cold temperatures, and for 45 days if stored in a frozen state at minus 20 degrees Celsius or colder). For delayed activation device systems, the storage period begins when the device is activated.

(B) Examples of low-risk compounding include radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multidose container.

(2) Medium-risk level compounded sterile radiopharmaceuticals.

(A) Medium-risk level compounded sterile radiopharmaceuticals are those compounded aseptically under low-risk conditions and one or more of the of the following conditions exists.

(i) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile radiopharmaceuticals that will be administered either to multiple patients or to one patient on multiple occasions.

(ii) The compounding process includes complex aseptic manipulations other than the single-volume transfer.

(iii) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing.

(iv) The sterile compounded radiopharmaceuticals do not contain broad-spectrum bacteriostatic substances, and they are administered over several days.

(v) For a medium-risk preparation, in the absence of passing sterility test, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature for not more than 7 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees or colder.

(B) Examples of medium-risk compounding include the following.

(i) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

(ii) Filling of reservoirs of injection and infusion devices with multiple sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed.

(iii) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit).

(iv) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.

(3) High-risk level compounded sterile radiopharmaceuticals.

(A) High-risk level compounded sterile radiopharmaceuticals are those compounded under any of the following conditions.

(i) Non-sterile ingredients, including manufactured products are incorporated, or a non-sterile device is employed before terminal sterilization.

(ii) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.

(iii) Non-sterile preparations are exposed no more than 6 hours before being sterilized.

(iv) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

(v) For a high-risk preparation, in the absence of passing sterility test, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 24 hours at controlled room temperature for not more than 3 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees or colder.

(B) Examples of high-risk compounding include the following.

(i) Dissolving non-sterile bulk drug and nutrient powders to make solutions, which will be terminally sterilized.

(ii) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.

(iii) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.

(iv) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

(c) Environment.

(1) Special requirements for the compounding of sterile radiopharmaceuticals. When the pharmacy compounds sterile radiopharmaceuticals, the following is applicable.

(A) Low and Medium Risk Preparations.

(i) The pharmacy shall have a designated controlled area for the compounding of sterile radiopharmaceuticals that is functionally separate from areas for the preparation of non-sterile radiopharmaceuticals and is constructed to minimize the opportunities for particulate and microbial contamination. This controlled area for the preparation of sterile radiopharmaceuticals shall:

(I) have a controlled environment that is aseptic or contains an aseptic environmental control device(s). If the aseptic environmental control device is located within the controlled area, the controlled area must extend a minimum of six feet from the device and clearly marked to identify the separation between the controlled and non-controlled area;

(II) be clean, well lighted, and of sufficient size to support sterile compounding activities;

(III) be used only for the compounding of sterile radiopharmaceuticals;

(IV) be designed to avoid outside traffic and airflow;

(V) be designed such that hand sanitizing and gowning occurs outside the controlled area but accessible without use of the hands of the compounding personnel;

(VI) have non-porous and washable floors or floor covering to enable regular disinfection;

(VII) be ventilated in a manner not interfering with aseptic environmental control conditions;

(VIII) have walls, ceilings, and fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, and nonshedding (acoustical ceiling tiles that are coated with an acrylic paint are acceptable);

(IX) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning; and

(X) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles may not be brought into the controlled area.

(ii) The pharmacy shall prepare sterile radiopharmaceuticals in a primary engineering control device, such as a vertical air flow hood, which is capable of maintaining at least ISO Class 5 conditions during normal activity.

(I) The primary engineering control shall:

(-a-) be located in the buffer area or room and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(-b-) be certified by an independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for operational efficiency at least every six months and when it is relocated, in accordance with the manufacturer's specifications; and

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TITLE 22	EXAMINING BOARDS
PART 15	TEXAS STATE BOARD OF PHARMACY
CHAPTER 291	PHARMACIES
SUBCHAPTER C	NUCLEAR PHARMACY (CLASS B)
RULE §291.55	**Records**

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under this section shall be:

(A) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format it specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

(3) Records of controlled substances, other than original prescription drug orders, listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subsection, "readily retrievable" means that the controlled substances shall be asterisked, red-lined, or in some other manner readily identifiable apart from all other items appearing on the record.

(4) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(A) the records maintained in the alternative system contain all of the information required on the manual record; and

(B) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(b) Prescriptions.

(1) Professional responsibility. Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any radioactive prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a radioactive prescription drug order, he/she shall verify the

order with the practitioner prior to dispensing.

(2) Verbal radioactive prescription drug orders.

(A) Only an authorized nuclear pharmacist or a pharmacist-intern under the direct supervision of an authorized nuclear pharmacist may receive from a practitioner or a practitioner's designated agent:

(i) a verbal therapeutic prescription drug order; or

(ii) a verbal diagnostic prescription drug order in instances where patient specificity is required for patient safety (e.g., radiolabeled blood products, radiolabeled antibodies).

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to communicate prescriptions verbally for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(C) A pharmacist may not dispense a verbal radioactive prescription drug order for a dangerous drug or a controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(3) Radioactive prescription drug orders issued by practitioners in another state.

(A) Dangerous drug prescription orders. A pharmacist may dispense a radioactive prescription drug order for dangerous drugs issued by practitioners in a state other than Texas in the same manner as radioactive prescription drug orders for dangerous drugs issued by practitioners in Texas are dispensed.

(B) Controlled substance prescription drug orders. A pharmacist may dispense radioactive prescription drug orders for controlled substances in Schedule III, IV, or V issued by a practitioner in another state provided:

(i) the radioactive prescription drug order is written, oral, or telephonically or electronically communicated prescription as allowed by the DEA issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number, and who may legally prescribe Schedule III, IV, or V controlled substances in such other state;

(ii) the radioactive prescription drug order is not dispensed more than six months from the initial date of issuance.

(4) Radioactive prescription drug orders issued by practitioners in the United Mexican States or the Dominion of Canada.

(A) Controlled substance prescription drug orders. A pharmacist may not dispense a radioactive prescription drug order for a Schedule II, III, IV, or V controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States.

(B) Dangerous drug prescription drug orders. A pharmacist may dispense a radioactive prescription drug order for a dangerous drug issued by a person licensed in the Dominion of Canada or the United

Mexican States as a physician, dentist, veterinarian, or podiatrist provided the radioactive prescription drug order is an original written prescription.

(C) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled substance may be dispensed without a written prescription drug order of a practitioner on a official prescription form as required by the Texas Controlled Substances Act, §481.075.

(5) Electronic radioactive prescription drug orders. For the purpose of this paragraph, electronic radioactive prescription drug orders shall be considered the same as verbal radioactive prescription drug orders.

(A) An electronic radioactive prescription drug order may be transmitted by a practitioner or a practitioner's designated agent:

(i) directly to a pharmacy; or

(ii) through the use of a data communication device provided:

(I) the confidential prescription information is not altered during transmission; and

(II) confidential patient information is not accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to electronically transmit prescriptions for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(C) A pharmacist may not dispense an electronic radioactive prescription drug order for a:

(i) Schedule II controlled substance except as authorized for faxed prescriptions in §481.074, Health and Safety Code; or

(ii) dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(6) Original prescription drug order records.

(A) Original prescriptions shall be maintained and readily retrievable by the pharmacy and remain accessible for a period of two years from the date of filling.

(B) If an original prescription drug order is changed, such prescription order shall be invalid and of no further force and effect; if additional drugs are to be dispensed, a new prescription drug order with a new and separate number is required.

(C) Original prescriptions shall be maintained in one of the following formats:

(i) in three separate files as follows:

(I) prescriptions for controlled substances listed in Schedule II;

(II) prescriptions for controlled substances listed in Schedule III - V; and

(III) prescriptions for dangerous drugs and nonprescription drugs; or

(ii) within a patient medication record system provided that original prescriptions for controlled substances are maintained separate from original prescriptions for noncontrolled substances and prescriptions for Schedule II controlled substances are maintained separate from all other original prescriptions.

(D) Original prescription records other than prescriptions for Schedule II controlled substances may be stored on microfilm, microfiche, or other system which is capable of producing a direct image of the original prescription record, e.g., digitalized imaging system. If original prescription records are stored in a direct imaging system, the following is applicable.

(i) The original prescription records must be maintained and readily retrievable as specified in subparagraph (C) of this paragraph.

(ii) The pharmacy must provide immediate access to equipment necessary to render the records easily readable.

(7) Prescription drug order information.

(A) All original radioactive prescription drug orders shall bear:

(i) name of the patient, if applicable at the time of the order;

(ii) name of the institution;

(iii) name, and if for a controlled substance, the address and DEA registration number of the practitioner;

(iv) name of the radiopharmaceutical;

(v) amount of radioactive material contained in millicuries (mCi), microcuries (uCi), or bequerels (Bq) and the corresponding time that applies to this activity, if different than the requested calibration date and time;

(vi) date and time of calibration; and

(vii) date of issuance.

(B) At the time of dispensing, a pharmacist is responsible for the addition of the following information to the original prescription:

(i) unique identification number of the prescription drug order;

(ii) initials or identification code of the person who compounded the sterile radiopharmaceutical and the pharmacist who checked and released the product unless maintained in a readily retrievable format;

(iii) name, quantity, lot number, and expiration date of each product used in compounding the sterile radiopharmaceutical; and

(iv) date of dispensing, if different from the date of issuance.

(8) Refills. A radioactive prescription drug order must be filled from an original prescription which may not be refilled.

(c) Policy and procedure manual.

(1) All nuclear pharmacies shall maintain a policy and procedure manual. The nuclear pharmacy policy and procedure manual is a compilation of written policy and procedure statements.

(2) A technical operations manual governing all nuclear pharmacy functions shall be prepared. It shall be continually revised to reflect changes in techniques, organizations, etc. All pharmacy personnel shall be familiar with the contents of the manual.

(3) The nuclear pharmacy policies and procedures manual shall be prepared by the pharmacist-in-charge with input from the affected personnel and from other involved staff and committees to govern procurement, preparation, distribution, storage, disposal, and control of all drugs used and the need for policies and procedures relative to procurement of multisource items, inventory, investigational drugs, and new drug applications.

(d) Other records. Other records to be maintained by a pharmacy:

(1) a permanent log of the initials or identification codes which will identify each dispensing pharmacist by name (the initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes shall not be used);

(2) copy 3 of DEA order form (DEA 222) which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;

(3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);

(4) suppliers' invoices of controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(5) suppliers' credit memos for controlled substances and dangerous drugs;

(6) a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements);

(7) hard-copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(8) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(9) a hard copy of any notification required by the Texas Pharmacy Act or these sections, including, but not limited to, the following:

(A) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

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administration facility and the consulting pharmacist of the supplying pharmacy;

(c) a copy of the approved list of contents shall be conspicuously posted on or near the kit;

(d) the emergency kit shall be used only for bona fide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner;

(e) records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the facility and the pharmacy;

(f) the pharmacy shall be responsible for ensuring proper storage, security and accountability of the emergency kit and shall ensure that:

(i) the emergency kit is stored in a locked area and is locked itself; and

(ii) emergency kit drugs are accessible only to licensed physicians, physician assistants and nurses employed by the facility;

(g) the contents of the emergency kit, the approved list of contents and all related records shall be made freely available and open for inspection to appropriate representatives of the Division and the Utah Department of Health.

R156-17b-614d. Operating Standards - Class B - Nuclear Pharmacy.

In accordance with Subsection 58-17b-601(1), the operating standards for a Class B pharmacy designated as a nuclear pharmacy shall have the following:

(1) A nuclear pharmacy shall have the following:

(a) have applied for or possess a current Utah Radioactive Materials License; and

(b) adequate space and equipment commensurate with the scope of services required and provided.

(2) Nuclear pharmacies shall only dispense radiopharmaceuticals that comply with acceptable standards of quality assurance.

(3) Nuclear pharmacies shall maintain a library commensurate with the level of radiopharmaceutical service to be provided.

(4) A licensed Utah pharmacist shall be immediately available on the premises at all times when the facility is open or available to engage in the practice of pharmacy.

(5) In addition to Utah licensure, the pharmacist shall have classroom and laboratory training and experience as required by the Utah Radiation Control Rules.

(6) This rule does not prohibit:

(a) a licensed pharmacy intern or technician from acting under the direct supervision of an approved preceptor who meets the requirements to supervise a nuclear pharmacy; or

(b) a Utah Radioactive Materials license from possessing and using radiopharmaceuticals for medical use.

(7) A hospital nuclear medicine department or an office of a physician/surgeon, osteopathic physician/surgeon, veterinarian, pediatric physician or dentist that has a current Utah Radioactive Materials License does not require licensure as a Class B pharmacy.

(8) A nuclear pharmacy preparing sterile compounds must follow the USP-NF Chapter 797 Compound for sterile preparations.

(9) A nuclear pharmacy preparing medications for a specific person shall be licensed as a Class B - nuclear pharmacy if located in Utah, and as a Class D pharmacy if located outside of Utah.

R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer in Utah.

In accordance with Subsections 58-17b-102(48) and 58-17b-601(1), the operating standards for Class C pharmacies designated as pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensees includes the following:

(1) Every pharmaceutical wholesaler or manufacturer that engages in the wholesale distribution and manufacturing of drugs or medical devices located in this state shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

(2) Manufacturers distributing only their own FDA-approved prescription drugs or co-licensed product shall satisfy this requirement by registering their establishment

Vermont

Administrative Rules Vermont Board of Pharmacy
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(effective October 1, 2009)

Part 1 General Information

Part 2 Requirements for Pharmacist Licensure

Part 3 Continuing Pharmacy Education

Part 4 Pharmacy Interns

(a) Routine performance of prospective drug use review and patient monitoring functions by a pharmacist;

(b) Patient monitoring plans that include written outcome measures and systems for routing patient assessment (examples include infection rates, rehospitalization rates, and the incidence of adverse drug reactions);

(c) Documentation of patient training as required by Section 12.14 above; and

(d) Appropriate collaboration with other health care professionals.

Part 13 Licensing of Investigative and Research Projects

13.1 Licenses Required Licensing of Investigative and Research Projects is required by 26 V.S.A. § 2061(5). A legitimate institution or entity which possess prescription drugs in the course of conducting research or investigation shall apply to the Board for a license. The Board may issue a license when it determines that:

(a) The entity requesting the license is a legitimate research entity, recognized by state or national licensing or accreditation organizations approved by the Board;

(b) The entity explains with its application;

(1) where and how regulated drugs used for research or investigation will be stored, secured, and accounted for,

(2) who will be responsible for ensuring compliance with the requirements of this rule and;

(c) The Board can conclude that the regulated drugs can be handled in a manner consistent with these rules.

13.2 Conditions The Board may set reasonable conditions on licenses granted under this section.
The license holder will notify the Board within 5 working days if there is a change in the person responsible for compliance.

13.3 Exemptions Medical facilities such as clinics and physicians' offices which are otherwise legally entitled to possess prescription drugs or are otherwise licensed by this Board are not required to be licensed under this Part 13 of the rules.

Part 14 Nuclear/Radiologic Pharmacy

14.1 Purpose and Scope The practice of nuclear/radiologic pharmacy is a specialty of pharmacy practice regulated by the Board. Nuclear/radiologic pharmacy practice refers to 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 and other drugs.

14.2 Definitions
(a) "Authentication of product history" means, but is not limited to, identifying the purchasing source,

the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

(b) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(c) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services or, as provided in Rule 14.3 below, the appropriate area of any institutional facility.

(d) "Qualified licensed professional" means a non-pharmacist individual (such as a physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and dispense radiopharmaceuticals as defined by the Board.

(e) "Qualified nuclear pharmacist" means a currently licensed pharmacist in Vermont who is certified as a nuclear pharmacist by a certification board recognized by the Board, or who meets the following standards:

(1) Minimum standards of training for "authorized user status" of radioactive material, as defined by the Vermont Department of Health (VDH).

(2) Completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a program approved by the Board, with emphasis on the following areas:

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics of radioactivity;
(D) Radiation biology; and
(E) Radiopharmaceutical chemistry.

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

(f) "Radiopharmaceutical quality assurance" means, but is not limited to, 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.

(g) "Radiopharmaceutical service" means, but shall not be limited to, the procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping, and disposal of radiopoharmaceuticals and other drugs.

(h) "Radiopharmaceuticals" are radioactive drugs as defined by the FDA.

14.3 General Requirements for Pharmacies Providing Radio-Pharmaceutical Services

(a) A license to operate a pharmacy providing radio-pharmaceutical services shall be issued only to a qualified nuclear pharmacist.

(b) All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist.

(c) A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy and shall be in personal attendance at all times that the pharmacy is open for business.

(d) In emergency situations when a qualified nuclear pharmacist is not present, designated qualified licensed professionals may have access to the licensed area. These individuals may prepare single doses of radio-pharmaceuticals for the immediate emergency, and must document such activities.

14.4 Physical Requirements Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in Vermont or as otherwise defined by the Board.

14.5 Security The nuclear pharmacy area shall be secured from unauthorized personnel.

14.6 Records Nuclear pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with the requirements of the Vermont Department of Health.

14.7 Radioactive Storage All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the Board and the Vermont Department of Health before approval of the certification to practice nuclear pharmacy.

14.8 Prescriptions Radiopharmaceuticals are to be dispensed only upon a prescription drug order from a practitioner authorized to possess, use, and administer radiopharmaceuticals.

14.9 Permit Prerequisites The permit to operate a nuclear pharmacy is conditioned upon an approved Vermont Department of Health (VDH) or Nuclear Regulatory Commission (NRC) license. Copies of the VDH or NRC inspection reports shall be made available upon request for Board inspection.

14.10 Other Requirements All nuclear/radiologic pharmacies shall also adhere to the rules for pharmaceutical care as they pertain to the practice of nuclear pharmacy.

Part 15 Drug Outlet Closure

15.1 Voluntary Surrender of Drug Outlet License The Board may accept a license to operate a drug outlet that has been surrendered voluntarily, if:

(a) The licensee submits, in writing, a signed statement setting forth the reasons the license is being surrendered; and

(b) All prescription legend drugs are properly disposed of under these rules; and

(c) The Board does not have cause for disciplinary action under statutes and rules governing the Board.

15.2 Termination Of License To Operate A Drug Outlet Unless a temporary license has been applied for within 5 business days of the following, a license to operate a drug outlet is immediately terminated:

(a) If a sole proprietorship: death of owner, change of location, change in ownership, or change in business name.

(b) If a partnership: death of a partner, change of location, change in partners or other change in ownership, change in business name, or other factors as provided in statutes governing partnerships.

(c) If a corporation: change in location, or change in corporate name or charter.

Virginia

THE PHARMACY ACT AND THE DRUG CONTROL ACT WITH RELATED STATUTES

COMMONWEALTH OF VIRGINIA

Department of Health Professions
VIRGINIA BOARD OF PHARMACY

(804) 367-4456
(804) 527-4472 *fax*
pharmbd@dhp.virginia.gov *email*
www.dhp.virginia.gov *web page*

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3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.

If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

(1970, c. 650, § 54-524.67; 1972, c. 798; 1976, c. 614; 1977, c. 302; 1983, cc. 395, 612; 1988, c. 765; 1996, c. 408; 2003, c. 511.)

§ 54.1-3410.1. Requirements for radiopharmaceuticals.

A. A pharmacist who is authorized by the Board and acting in good faith, may sell and dispense radiopharmaceuticals pursuant to the order of a physician who is authorized by state or federal law to possess and administer radiopharmaceuticals for the treatment or diagnosis of disease.

B. When an authorized nuclear pharmacist dispenses a radioactive medical material, he shall assure that the outer container (shield) of the radiopharmaceutical shall bear the following information:

1. The name and address of the nuclear pharmacy;

2. The name of the prescriber (authorized user);

3. The date of dispensing;

4. The serial number assigned to the radiopharmaceutical order;

5. The standard radiation symbol;

6. The name of the diagnostic procedure;

7. The words "Caution: Radioactive Material";

8. The name of the radionuclide;

9. The amount of radioactivity and the calibration date and time;

10. The expiration date and time;

11. In the case of a diagnostic radiopharmaceutical, the patient's name or the words "Per Physician's Order"; and

12. In the case of a therapeutic radiopharmaceutical, the patient's name.

C. Orders for radiopharmaceuticals, whether written or verbal, shall include at least the following information:

1. The name of the institution or facility and the name of the person transmitting the order;

2. The date that the radiopharmaceutical will be needed and the calibration time;

3. The name or generally recognized and accepted abbreviation of the radiopharmaceutical;

4. The dose or activity of the radiopharmaceutical at the time of calibration; and

5. In the case of a therapeutic radiopharmaceutical or a radiopharmaceutical blood product, the name of the patient shall be obtained prior to dispensing.

(2000, c. 861.)

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to

Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF PHARMACY

Title of Regulations: 18 VAC 110-20-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Revised Date: December 22, 2011

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1464

Phone: 804-367-4456
Fax: 804-527-4472

email: pharmbd@dhp.virginia.gov

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug which has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18VAC110-20-210. Disposal of drugs by pharmacies.

If a PIC wishes to dispose of unwanted drugs, he shall use one of the following procedures:

1. Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or

2. Destroy the drugs by burning in an incinerator, or other board-approved method, in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through V drugs are to be destroyed, the following procedures shall apply:

a. At least 14 days prior to the destruction date, the PIC shall provide a written notice to the board office; the notice shall state the following:

(1) Date, time, manner, and place of destruction.

(2) The names of the pharmacists who will witness the destruction process.

b. If the destruction date is to be changed or the destruction does not occur, a new notice shall be provided to the board office as set forth above in subdivision 2 of this section.

c. The actual destruction shall be witnessed by the PIC and another pharmacist not employed by the pharmacy.

d. The DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the pharmacy with other inventory records.

Part V. Nuclear Pharmacies

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

A. Nuclear pharmacies shall comply with standards and requirements of the Nuclear Regulatory Commission (NRC) and the Virginia Department of Health related to the staffing and operation of the facility.

B. Radiopharmaceuticals are to be dispensed only upon an order from a prescriber authorized to possess, use and administer radiopharmaceuticals.

1. Orders shall originate at an institution or healthcare facility licensed to receive and possess radiopharmaceuticals, and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions.

2. Orders for radiopharmaceuticals may be transmitted orally, by fax, or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature, but must include the name of the agent.

C. The immediate outside container of a radioactive drug to be dispensed shall also be labeled in accordance with requirements of § 54.1-3410.1 B of the Code of Virginia.

D. The immediate inner container shall be labeled with: (i) the standard radiation symbol; (ii) the words "Caution--Radioactive Material"; and (iii) the serial number assigned to the order.

E. Nuclear pharmacies may redistribute approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

18VAC110-20-230. (Repealed.)

Part VI. Drug Inventory and Records

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

A. Each pharmacy shall maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy.

3. All executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

Washington

Last Update: 1/25/93

Chapter 246-903 WAC
Nuclear pharmacies and pharmacists

Complete Chapter

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Beginning of Chapter << 246-903-001 >> 246-903-010

WAC 246-903-001 No agency filings affecting this section since 2003

Purpose and scope.

(1) No person may lawfully provide radiopharmaceutical services unless he or she is a nuclear pharmacist, or is performing radiopharmaceutical services under the supervision of a nuclear pharmacist, and is acting in accordance with the state board of pharmacy and state radiation control agency regulations.

(2) These regulations shall not apply to anyone who is an "authorized practitioner" as that term is defined in section 2 of these regulations.

(3) The requirements imposed by these nuclear pharmacy regulations shall apply in addition to, and not in place of, any other requirements contained in regulations of the state board of pharmacy, the state radiation control agency, or any other state or federal agency.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-903-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-010, filed 2/1/79.]

No agency filings affecting this section since 2003

WAC 246-903-010 Definitions.

(1) A "nuclear pharmacy" is a class A pharmacy providing radiopharmaceutical services.

(2) "Nuclear pharmacist" means a licensed pharmacist who has submitted evidence to the board of pharmacy that he or she meets the requirements of WAC 246-903-030 of these regulations regarding training, education, and experience, and who has received notification by letter from the board of pharmacy that, based on the evidence submitted, he or she is recognized by the board of pharmacy as qualified to provide radiopharmaceutical services.

(3) "Radiopharmaceutical service" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(4) A "radiopharmaceutical" is any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on 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.

(6) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

(7) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

(8) "Authorized practitioner" means a practitioner duly authorized by law to possess, use, and administer radiopharmaceuticals.

(9) "Accepted professional standards" are those set forth in the *Nuclear Pharmacy Practice Standards* published by the American Pharmaceutical Association, Board of Pharmaceutical Specialties, adopted on March 18, 1986.

[Statutory Authority: RCW 18.64.005. 93-04-016 (Order 329B), § 246-903-010, filed 1/25/93, effective 2/25/93; 92-12-035 (Order 277B), § 246-903-010, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-903-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-020, filed 2/1/79.]

WAC 246-903-020 No agency filings affecting this section since 2003

Nuclear pharmacies.

(1) A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

(2) Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel. A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy and the state radiation control agency before approval of the license.

(3) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted professional standards.

(4) The board recognizes that the preparation of nuclear pharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(5) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the state board of pharmacy, the state radiation control agency and other state and federal agencies.

(6) For nuclear pharmacies handling radiopharmaceuticals exclusively, the state board of pharmacy may waive regulations pertaining to the pharmacy permits for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(7) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(8) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(9) In addition to any labeling requirements of the state board of pharmacy for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: (a) Standard radiation symbol; (b) the words "caution-radioactive material"; (c) the name of the radiopharmaceutical; (d) the amount of radioactive material contained, in millicuries or microcuries; (e) if a liquid, the volume in milliliters; (f) the requested calibration time for the amount of radioactivity contained; (g) expiration data, if applicable; and (h) specific concentration of radioactivity.

(10) The immediate container shall be labeled with: (a) The standard radiation symbol; (b) the words "caution-radioactive material"; (c) the name of the nuclear pharmacy; (d) the prescription number; (e) the name of the radiopharmaceutical; (f) the date; and (g) the amount of radioactive material contained in millicuries or microcuries.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) Nuclear pharmacies may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have the current revisions of state laws and regulations of the state board of pharmacy and state radiation control agency.

(14) The nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided. A detailed library listing shall be submitted to the state board of pharmacy and state radiation control agency before approval of the license.

[Statutory Authority: RCW 18.64.005. 93-04-016 (Order 329B), § 246-903-020, filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-903-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-030, filed 2/1/79.]

WAC 246-903-030 No agency filings affecting this section since 2003

Nuclear pharmacists.

In order for a pharmacist to qualify under these regulations as a nuclear pharmacist, he or she must:

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the state radiation control agency; and,

(2) Be a pharmacist licensed to practice in Washington; and,

(3) Submit to the board of pharmacy either:

(a) Certification that he or she has completed a minimum of 6 months on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services, or

(b) Certification that he or she has completed a nuclear pharmacy training program in an accredited college of pharmacy or

(c) That upon application to the board in affidavit form, and upon the furnishing of such other information as the board may require, the board may grant partial or equivalent credit for education and experience gained in programs not sponsored by an accredited college of pharmacy, if, in the opinion of the board, the education and experience gained by participants in these programs would provide the same level of competence as participation in a program at an accredited college of pharmacy; and

(4) Receive a letter of notification from the board of pharmacy that the evidence submitted that the pharmacist meets the requirements of subsections 1, 2, and 3 above has been accepted by the board and that, based thereon, the pharmacist is recognized by the board as a nuclear pharmacist.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-903-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-040, filed 2/1/79.]

WAC 246-903-040 No agency filings affecting this section since 2003

Minimum equipment requirements.

(1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the state board of pharmacy and radiation control agency before approval of the license.

(2) The state board of pharmacy may, for good cause shown, waive regulations pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-903-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-050, filed 2/1/79.]

West Virginia

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

2011 JUN 29 AM 11:18

SERIES 1
LICENSURE AND PRACTICE OF PHARMACY

§15-1-1. General.

1.1. Scope. -- This rule provides definitions of many terms and establishes general provisions for Board operation; establishes internship requirements; provides the requirements for application as a pharmacist, including examination requirements, renewals, and reinstatement of lapsed licenses; establishes the qualifications for obtaining a license by reciprocity, including requirements for a foreign pharmacy graduates; establishes proceedings for disciplinary action; establishes how drugs may be transferred and the restrictions on refilling and transferring of prescription orders, including establishing communications requirements for the manual and electronic prescribing and dispensing of prescription drugs, specifically providing for E-prescribing and Electronic Data Intermediaries; establishes how drugs and devices may be returned; states the requirements for drug product selection and substitution; establishes the requirements for pharmacy permits, including the minimum requirements, security, and professional work environment; states the required equipment, facilities, and record systems required by a pharmacy; establishes the requirements for a permit to conduct sterile pharmaceutical compounding; establishes licensure and control of nuclear pharmacies; establishes the sanitary requirements in a pharmacy; establishes rules of professional conduct for pharmacists; establishes the duties and responsibilities of a pharmacist-in-charge; establishes the manner of issuance of a prescription; states different labeling requirements; establishes the requirements and responsibilities of a consultant pharmacist; establishes different types of specialized dispensing systems, including the use of emergency kits; states the requirement for places that need to obtain a controlled substance permit, including the fees for such permit.

1.2 Authority -- W. Va. Code §§30-5-12C(d), 30-5-14, and 30-5-19.

1.3 Filing date -- June 28, 2011.

1.4 Effective date -- July 1, 2011.

§15-1-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings:

2.1.1. "Act" or "Uniform Controlled Substance Act" means to West Virginia Code § 60A-1-1, et seq.

2.1.2. "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means.

2.1.3 "Automated pharmacy system" means mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage,

"clean" anteroom adjoining the buffer room according to United States Pharmacopeia standards.

4. The compounding area shall be large enough to allow working room for all personnel to be in the room at one time without interference with each other.
5. The buffer room must contain at least one certified airflow hood, vented if necessary;

b. At least the following equipment shall be available and shall be maintained in working order:

1. Properly certified airflow hood;
2. Adequate refrigerator and freezer space;
3. A sink and wash area in the anteroom as provided for in this section; and
4. Appropriate waste containers for:

A. Used needles and syringes;
B. All cytotic waste including disposable apparel used in its preparation;

c. Minimum supplies on hand shall include, but not be limited to:

1. Cloves, masks, and disposable gowns;
2. Disposable syringes and needles in necessary sizes;
3. Disinfectant cleaning material for equipment surfaces;
4. Disposable towels;
5. Liquid bactericidal cleanser for hand washing; and
6. Spill kits for cytotoxic agent spills;

d. Minimum reference works required in a pharmacy with a Sterile Pharmaceutical Compounding permit are:

1. A current edition of the three volume set of the USP-DI with supplements, or referenced texts designated by the Board;
2. Handbook of Injectable Drugs published by the American Society of Hospital Pharmacists, or its equivalent.

§ 15-1-17. Licensure and Control of Nuclear Pharmacies.

17.1. General Requirements.

17.1.1. A pharmacy providing radiopharmaceutical services, and compounding or mixing prescription orders for radiopharmaceuticals shall obtain a Nuclear Pharmacy license from the Board. The license will be issued after satisfactory inspection of the completed facilities. The license will be issued only when the pharmacist-in-charge is a qualified nuclear pharmacist and the pharmacy has been approved by the appropriate federal agency.

17.1.2. Pharmacies providing regular pharmaceutical care in addition to

radiopharmaceutical services shall comply with all sections of this rule applicable to pharmacies in general.

17.2. Space.

17.2.1. The nuclear pharmacy area shall be separate from all other pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel.

17.2.2. A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and product decay area which meets the requirements of the appropriate federal agency.

17.3. Dispensing and labeling.

17.3.1. A prescription order for a radiopharmaceutical shall be dispensed in a package that is properly labeled.. A pharmacy may furnish radiopharmaceuticals only to practitioners for administration to patients and for the occasional transfer to another pharmacist.

17.3.2. In addition to any label requirements of the Board for nonradioactive drugs, the immediate outside container of a radiopharmaceutical to be dispensed shall also be labeled with:

a. the standard radiation symbol;
b. The words "CAUTION-Radioactive Material";
c. the name of the radio nucleotide;
d. the chemical form;
e. The amount of radioactive material contained in millicuries or microcuries;
f. The volume in milliliters, if the material is a liquid;
g. The requested calibration time for the amount of radioactivity contained; and
h. The practitioner's name and the assigned lot number.

17.3.3. The immediate inner container shall be labeled with:

a. The standard radiation symbol;
b. The words "CAUTION-Radioactive Material"; and
c. The prescription number

17.3.4. The amount of radioactivity shall be determined by radiometric methods for each dose immediately prior to dispensing.

17.4. Distribution – Nuclear pharmacies may distribute approved radioactive drugs to any receiving pharmacy if the receiving pharmacy does not process the radioactive drugs in any manner nor violate or change the product packaging except that a licensed pharmacist may divide the product into individual doses.

§ 15-1-18. Sanitary Regulation of Pharmacies.

18.1. The pharmacist-in-charge of a pharmacy shall maintain the prescription room and equipment in the prescription room in a clean and orderly condition and in good operating order at all times.