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 33.1-10. It is also unlawful for any person to provide radiopharmaceutical services unless that person is a pharmacist meeting the qualifications of 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, state board of pharmacy regulations, and the North Dakota radiological health rules in article 33.1-10, 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 a radioactive material license on which the person is an authorized user, as required by the state department of health pursuant to article 33.1-10. 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 state department of health.

History: Effective August 1, 1983; amended effective October 1, 2012.
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 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 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 nuclear 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 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 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 nuclear 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 nuclear 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 pharmacies providing radiopharmaceutical services shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.

4. Nuclear 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 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 request from a licensee 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 radiopharmaceutical may be provided only to a facility licensed under article 33.1-10, 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, and determining the current activity and then the dose is available to be administered to a 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 milliliters; and

   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. 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; amended effective October 1, 2012.
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 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. Hold a current, active license to practice pharmacy in this state.

3. Have 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 with emphasis in the following areas:

   a. Radiation physics and instrumentation.

   b. Radiation protection.

   c. Mathematics pertaining to the use and measurement of readioactivity.

   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-emitting 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. 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 state board of pharmacy.

5. Submit evidence 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; amended effective October 1, 2012.
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 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.

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 33.1-10.

5. Nuclear Medicine: The Requisites - by Thrall and Ziessman.

6. Principles and Practice of Nuclear Medicine - by Early and Sodee.

7. Nuclear Pharmacy - by Chilton and Witcofski.

8. Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine - by Kowalski and Phelan.

The state 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 state board of pharmacy.

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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 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. Area radiation monitor which is stationary and away from other activity.

2. Dose calibrator and well counter.

3. Portable survey meter, capable of measuring up to two thousand mR/hr for determining 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-channel or multichannel scintillation counter.

8. Sink with hot and cold running water.

9. Wipe test counter capable of detecting 0.005 microcuries of the radionuclides in question.

10. Chromatographic equipment.

11. 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 or hemocytometer, or both.

15. ISO class 5 laminar flow-dispensing hood.

16. Forceps or tongs for remote handling of material.

17. Hotplate or heat block, or both.

18. Class II biosafety cabinet for handling blood samples for labeling.

19. Glassware.

20. Other equipment necessary for radiopharmaceutical services provided as required by the state board of pharmacy.

The state 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 state board of pharmacy.

History: Effective August 1, 1983; amended effective October 1, 2012.
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 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36