

**ARTICLE 61-05
RADIOPHARMACEUTICAL SERVICES**

Chapter
61-05-01 Radiopharmaceutical Services

**CHAPTER 61-05-01
RADIOPHARMACEUTICAL SERVICES**

Section
61-05-01-01 Purpose and Scope
61-05-01-02 Definitions
61-05-01-03 General Requirements for Pharmacies Providing Radiopharmaceutical Services
61-05-01-04 General Requirements for Pharmacists to Manage a Pharmacy Providing Radiopharmaceutical Services
61-05-01-05 Library
61-05-01-06 Minimum Equipment Requirements

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 Bland.~~
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 Radiosotope Methodology by Chase and Rabinwitz.~~
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 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, 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. ~~Fume~~ 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