

CHAPTER 16
NUCLEAR PHARMACY PRACTICE
[Prior to 12/14/88, see Pharmacy Examiners Board 657—8.8(155A)]

Chapter rescission date pursuant to Iowa Code section 17A.7: 1/1/28

657—16.1(155A) Purpose and scope. This chapter establishes the minimum standard for the practice of pharmacy relating to radioactive drugs. These rules apply to individuals authorized to receive, handle, transfer, dispense, or dispose of radioactive drugs pursuant to Iowa Code chapters 136C, 155A, and 455B, and rules of the board, the environmental protection commission, or the public health department. For pharmacies, these rules are in addition to other applicable chapters of rules of the board including, but not limited to, 657—Chapters 8 and 20.

[ARC 3525C, IAB 12/20/17, effective 1/24/18]

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.

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

“*Board*” means the Iowa board of pharmacy.

“*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.

“*Radioactive drug*” or “*radiopharmaceutical*” means a drug or device that contains a radioactive substance and is used to diagnose or treat disease.

“*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.

[ARC 3525C, IAB 12/20/17, effective 1/24/18]

657—16.3(155A) Training requirements for authorized nuclear pharmacist. An authorized nuclear pharmacist shall meet all requirements of the United States Nuclear Regulatory Commission pursuant to federal regulations.

[ARC 3525C, IAB 12/20/17, effective 1/24/18]

657—16.4(155A) General requirements for a pharmacy providing radiopharmaceutical services. A pharmacy providing radiopharmaceutical services shall obtain a limited use pharmacy license pursuant to rule 657—8.35(155A) prior to commencing provision of services in this state.

16.4(1) Authorized nuclear pharmacist. The pharmacist in charge shall be an authorized nuclear pharmacist and shall be responsible for, at a minimum, the requirements in rule 657—8.3(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of an authorized nuclear pharmacist. An authorized 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 drug 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, the public health department, and the environmental protection commission.

16.4(6) *Compliance.* Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs. Nuclear pharmacies shall comply with all standards identified in United States Pharmacopeia General Chapter 825.

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 a radiopharmaceutical prepared by a nuclear pharmacy shall be determined by radiometric methods immediately prior to dispensing.

16.4(11) *Redistribution.* When a nuclear pharmacy distributes to another entity radioactive drugs that are FDA-approved, commercially manufactured drug products, the pharmacy shall not process the radioactive drugs in any manner or violate the product packaging.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 3525C, IAB 12/20/17, effective 1/24/18; ARC 5352C, IAB 12/30/20, effective 2/3/21]

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. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice;
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.

[ARC 2196C, IAB 10/14/15, effective 11/18/15]

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

1. Appropriate primary engineering control device to comply with rule 657—16.8(155A);
2. Dose calibrator;
3. Single-channel scintillation counter;
4. Microscope;
5. Incubator, or access to one;
6. Radiation survey meter;
7. Other equipment necessary for the radiopharmaceutical services provided as required by the board.

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

[ARC 3525C, IAB 12/20/17, effective 1/24/18; ARC 5348C, IAB 12/30/20, effective 2/3/21]

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]

657—16.8(155A) Sterile radiopharmaceutical preparations and compounding. Sterile radiopharmaceutical preparations shall comply with federal laws and regulations for radiopharmaceuticals, including enforceable chapters of the United States Pharmacopeia (USP) and final guidance documents regarding sections of the Federal Food, Drug, and Cosmetic Act.

[ARC 3525C, IAB 12/20/17, effective 1/24/18]

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]

[Filed emergency 1/21/88—published 2/10/88, effective 1/22/88]

[Filed 3/29/88, Notice 2/10/88—published 4/20/88, effective 5/25/88]

[Filed 11/17/88, Notice 8/24/88—published 12/14/88, effective 1/18/89]

[Filed emergency 5/16/89—published 6/14/89, effective 5/17/89]

[Filed 3/19/90, Notice 1/10/90—published 4/18/90, effective 5/23/90]

[Filed 7/30/91, Notice 5/29/91—published 8/21/91, effective 9/25/91]

[Filed 3/21/94, Notice 10/13/93—published 4/13/94, effective 5/18/94]

[Filed 2/27/97, Notice 1/1/97—published 3/26/97, effective 4/30/97]

[Filed 9/8/99, Notice 6/2/99—published 10/6/99, effective 11/10/99]

[Filed 2/7/01, Notice 10/18/00—published 3/7/01, effective 4/11/01]

[Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02]

[Filed 6/2/05, Notice 3/16/05—published 6/22/05, effective 7/27/05]

[Filed ARC 8673B (Notice ARC 8380B, IAB 12/16/09), IAB 4/7/10, effective 6/1/10]

[Filed ARC 2196C (Notice ARC 2065C, IAB 7/22/15), IAB 10/14/15, effective 11/18/15]

[Filed ARC 3525C (Notice ARC 3228C, IAB 8/2/17), IAB 12/20/17, effective 1/24/18]

[Filed ARC 5348C (Notice ARC 5113C, IAB 7/29/20), IAB 12/30/20, effective 2/3/21]

[Filed ARC 5352C (Notice ARC 5194C, IAB 9/23/20), IAB 12/30/20, effective 2/3/21]