CHAPTER 16
NUCLEAR PHARMACY

[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 and the board of pharmacy examiners rules, and rules of the environmental protection commission with the exception of a medical practitioner 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 other applicable provisions of rules of the board of pharmacy examiners and the environmental protection commission or the public health department.

657—16.2(155A) Definitions.

16.2(1) A *"nuclear pharmacy"* is a pharmacy providing radiopharmaceutical services.

16.2(2) *"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.

16.2(3) *"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.

16.2(4) *"Internal test assessment"* means, but is not limited to, conducting those tests of a quality assurance necessary to ensure the integrity of the test.

16.2(5) *"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.

657—16.3(155A) General requirements for pharmacies providing radiopharmaceutical services.

16.3(1) The application for 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 personal supervision of a nuclear pharmacist. A nuclear pharmacist is responsible for all operations of the licensed area and shall be in personal attendance at all times that the pharmacy is open for business.

16.3(2) Nuclear pharmacies 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 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 area. A nuclear pharmacy handling radioactive drugs exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the board of pharmacy examiners. Detailed floor plans shall be submitted to the board of pharmacy examiners and the public health department before approval of the license.

16.3(3) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

16.3(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with the board of pharmacy examiners and the environmental protection commission.

16.3(5) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

16.3(6) Radioactive drugs are to 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.

16.3(7) In addition to any labeling requirements of the board of pharmacy examiners 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;
g. The requested calibration time for the amount of radioactivity contained.

16.3(8) 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.

16.3(9) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

16.3(10) Nuclear pharmacies may redistribute NDA-approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner or violate the product packaging.

657—16.4(155A) General requirements for nuclear pharmacists to obtain a nuclear pharmacy license. A qualified nuclear pharmacist shall:

1. Meet minimal standards of training for medical uses of radioactive material;
2. Be a currently licensed pharmacist in the state;
3. Have received a minimum of 90 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy;

4. Attain a minimum of 160 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;
5. Submit an affidavit of experience and training to the board of pharmacy examiners.

657—16.5(155A) Library. Each nuclear pharmacy shall have access to the following reference books. All books must be current editions or revisions. A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—1.3(17A,124,126,147,155A,205,272C).

1. United States Pharmacopoeia/National Formulary, with supplements;
2. State laws and regulations relating to pharmacy;
3. State rules or federal regulations governing the use of applicable radioactive materials.

657—16.6(155A) Minimum equipment requirements. A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—1.3(17A,124,126,147,155A,205,272C).

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

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

These rules are intended to implement Iowa Code sections 155A.4(2)*"f,"* 155A.13, 155A.28 and 155A.31.

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