RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-06
NUCLEAR PHARMACY PRACTICE SITES

TABLE OF CONTENTS

1140-06-.01	Applicability	1140-06-.03	Library
1140-06-.02	General Requirements	1140-06-.04	Equipment

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*