DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

OFFICE OF HEALTH SERVICES

BOARD OF PHARMACY

RADIOPHARMACEUTICALS

(By authority conferred on the board of pharmacy by section 16145 of Act No. 368 of the Public Acts of 1978, being S333.16145 of the Michigan Compiled Laws)

R 338.3001 Definitions.

Rule 1. As used in these rules:

(a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

(b) "Board" means the state board of pharmacy.

(c) "Internal test assessment" means conducting those tests of a quality assurance system necessary to insure the integrity of the test.

(d) "Radiopharmaceutical" means a pharmaceutical, biological, or drug which has a radioactive entity.

(e) "Radiopharmaceutical quality assurance" means 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.

(f) "Radiopharmaceutical service" means 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.

History: 1979 AC.

R 338.3002 Professional conduct regarding radiopharmaceuticals.

Rule 2. It is the professional responsibility of a pharmacist and a pharmacy to conduct the radiopharmaceutical area of a pharmacy in a manner which is consistent with pertinent state and federal laws and regulations.

History: 1979 AC.

R 338.3003 Dispensing radiopharmaceuticals; restrictions.

Rule 3. A radiopharmaceutical shall only be dispensed to a person having authority to possess such drugs. A radiopharmaceutical shall not be dispensed directly to a patient.

History: 1979 AC.

R 338.3004 Labeling of radiopharmaceuticals.

Rule 4. (1) The immediate container of radiopharmaceuticals shall be labeled with all of the following:

(a) The standard radiation symbol.

(b) The words "Caution--Radioactive Material."

(c) The name, address, and telephone number of the pharmacy.

(d) The prescription number.

(2) The immediate outer container (within which has been placed the immediate container) shall be labeled with all of the following:

(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 therein in millicuries or microcuries.

(f) If a liquid, the volume in milliliters.

(g) The requested calibration time for the amount of radioactivity contained therein.

(h) If a radiopharmaceutical is dispensed to a physician it shall be labeled "FOR PHYSICIAN USE ONLY."

History: 1979 AC.

R 338.3005 Requirements for pharmacist handling radiopharmaceuticals.

Rule 5. (1) The pharmacist directing radiopharmaceutical services shall develop, implement, supervise, and coordinate all of the services provided, which shall include at least the following: preparation, handling, storage, receiving, dispensing, disposition, radiopharmaceutical quality assurance, internal test assessment, authentication of product history, and pharmacology of radioactive drugs.

(2) A person performing tasks within the radiopharmaceutical area of a pharmacy shall be under the direct and effective supervision of a pharmacist, who shall be responsible for the adequacy and accuracy of the person's performance.

(3) A pharmacy directly or indirectly involved with radiopharmaceuticals shall adopt written policies and procedures containing an organizational description of authority and responsibilities associated with radiopharmaceuticals, which shall be updated as necessary. These policies and procedures shall be available to authorized representatives of the board.

History: 1979 AC.

R 338.3006 Housing of radiopharmaceutical area of pharmacy.

Rule 6. (1) All professional and technical equipment and supplies and radiopharmaceuticals shall be located in a suitable, well-lighted, and well-ventilated room or department having clean and sanitary surroundings.

(2) A pharmacy handling radiopharmaceuticals shall have an area for the compounding of radiopharmaceuticals. The area shall occupy not less than 300 square feet of space and shall include a prescription counter providing not less than 10 square feet of free working surface, excluding
hood space. If more than 1 pharmacist is on duty at any 1 time, the free working surface shall be increased by not less than 4 square feet for each additional pharmacist. The prescription counter shall be kept clean and free of all material not being currently used in the compounding and dispensing of radiopharmaceuticals. The space behind the prescription counter shall be sufficient to allow free movement within the area and shall be free of obstructions.

(3) A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying not less than 25 square feet of space, separate from, and exclusive of, the hot laboratory, compounding, dispensing, quality assurance, and office areas.

(4) A pharmacy handling radiopharmaceuticals shall be maintained in an area separate from areas where nonradioactive drugs are maintained.

History: 1979 AC.

R 338.3007 Professional and technical equipment and supplies for pharmacies handling radiopharmaceuticals.

Rule 7. (1) A pharmacy handling radiopharmaceuticals shall meet all of the requirements of a pharmacy except that, upon request by a pharmacy which handles only radiopharmaceuticals, the board may waive a requirement which it finds is not pertinent to the handling of radiopharmaceuticals.

(2) The following reference books are required in a pharmacy handling radiopharmaceuticals; all books shall be current editions or revisions:

(a) United States pharmacopeia, with supplements.

(b) National formulary, with supplements.

(c) Michigan laws relating to pharmacy.

(d) Michigan state department of public health, division of radiological health, ionizing radiation rules, being R 325.5001 to R 325.5511 of the Michigan Administrative Code.

(e) United States public health service radiological health handbook.

(3) The following technical equipment is required in a pharmacy handling radiopharmaceuticals:

(a) Fume hood.

(b) Laminar flow hood.

(c) Dose calibrator.

(d) Prescription balance, sensitive to 30 milligrams.

(e) Refrigerator.

(f) Scintillation counter.

(g) Adequate supplies, such as glassware, utensils, gloves, shields, and remote handling devices.

(h) Autoclave, or access to one.

(i) Pyrogen oven, or access to one.

(j) Miscroscope.

(k) Portable radiation detectors capable of detecting 0.005 microcuries of any radionuclide handled or stored.

(l) Typewriter.

(m) Any other equipment necessary for radiopharmaceutical quality control for the products compounded or dispensed.

History: 1979 AC.