**Section 1330.540 Nuclear Pharmacy Services**

a) Pharmacies that provide and/or offer for sale radiopharmaceuticals shall, in addition to any other requirements of the Act and this Part, comply with this Section.

b) Prior to issuance of a pharmacy license to practice as a nuclear pharmacy:

1) The pharmacy shall provide a copy of its Illinois Radioactive Material License issued by the Illinois Emergency Management Agency in accordance with the Radiation Protection Act [420 ILCS 40].

2) The Division shall conduct an on-site inspection of the facility.

c) The pharmacy shall have:

1) Space commensurate with the scope of services provided, but at least 300 square feet; and

2) A radioactive storage and product decay facility separate from and exclusive of the "hot" laboratory, compounding, dispensing, quality assurance and office areas.

d) Each nuclear pharmacy shall have the following equipment:

1) Laminar flow hood;

2) Fume hood – minimum of 30 inches in height, which shall be vented through a filter with a direct outlet to the outside;

3) Dose calibrator;

4) Refrigerator;

5) Class A prescription balance or a balance of greater sensitivity;

6) Single-channel or multi-channel gamma scintillation counter;

7) Microscope;

8) Low level, thin-window portable radiation survey meter;

9) Drawing station – lead glass and lead lined;

10) Syringe shields; and

11) Energy Compensated Geiger Mueller (GM) Probe or ion chamber.

e) Each nuclear pharmacy shall have the following reference texts available:

1) The current edition or revision of the United States Pharmacopoeia – Dispensing Information;

2) The current edition or revision of the United States Pharmacopoeia/National Formulary;

3) State and federal regulations governing the use of applicable radioactive material; and

4) U.S. Public Health Service Radiological Health Handbook.

f) Pharmacist-in-Charge

1) The pharmacist-in-charge for a nuclear pharmacy shall meet the requirements set forth in subsection (i). The responsibilities of the pharmacist-in-charge shall include:

A) Supervision of all the activities of all employees as they relate to the practice of nuclear pharmacy;

B) Establishment and supervision of the record keeping system for the purchase, acquisition, disposition, sale, delivery, possession, storage and safekeeping of radiopharmaceuticals; and

C) Establishment and maintenance of security provisions, which shall include the following:

i) There shall be no public access to the pharmacy hot lab/dispensing area; and

ii) In the absence of a nuclear pharmacist, all radiopharmaceuticals shall be locked and accessible only to a nuclear pharmacist or a pharmacy technician under direct supervision of the pharmacist; except, a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals may have access to radiopharmaceuticals in the absence of a nuclear pharmacist.

2) Within 30 days after the change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.

g) Dispensing Radiopharmaceuticals

1) A radiopharmaceutical shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

2) No radiopharmaceutical shall be dispensed in the absence of a nuclear pharmacist except, a licensed medical practitioner authorized to possess, use, dispense and administer radiopharmaceuticals may dispense in the absence of a nuclear pharmacist.

3) The amount of radioactivity in a preparation for dispensing shall be determined by radiometric methods for each individual preparation at the time of preparation, and calibrated for the anticipated time of administration.

h) Labeling Requirements

1) In addition to the labeling requirements of pharmaceuticals, as stipulated in the Act, the immediate outer container of a radioactive drug, diagnostic agent or device to be dispensed shall also be labeled to include:

A) The standard radiation symbol;

B) The words "Caution − Radioactive Material";

C) The name of the radionuclide;

D) The name of the chemical form;

E) The amount of radioactive material contained, in milliCuries or microCuries, in the container contents at the time of calibration;

F) If the container contents are in liquid form, the volume in milliliters;

G) The requested calibration time for the amount of radioactivity contained;

H) The prescription number; and

I) The name or initials of the nuclear pharmacist filling the prescription.

2) The immediate container shall be labeled with:

A) The standard radiation symbol;

B) The words "Caution − Radioactive Material";

C) The name and address of the pharmacy;

D) The prescription number;

E) Name of radionuclide; and

F) Name of chemical form.

i) Nuclear Pharmacist Requirements. A nuclear pharmacist who serves as the pharmacist-in-charge of a nuclear pharmacy and all other pharmacists employed in the pharmacy shall provide evidence to the Division of the following:

1) Licensure as a pharmacist in the State of Illinois; and

2) That he/she is named as an authorized user, or works under the supervision of a pharmacist who is named as an authorized user, on a commercial nuclear pharmacy license issued by the Illinois Emergency Management Agency (IEMA) or, when a nuclear pharmacist who works under a broad medical license at a university or research hospital has been approved as a user by that institution's radiation safety committee in accordance with conditions of the license issued by IEMA.

j) Nothing in this Part shall prohibit the operation of a nuclear medicine laboratory or any other department that is operated under the direct supervision of a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.