Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite 300, Des Plaines, IL 60016
320 W. Washington Street, 2nd Floor, Springfield, IL 62786

Email: fpr.drugcomplianceunit@illinois.gov

(Read this Page Carefully)

NUCLEAR PHARMACY

Pharmacy Self-Inspection Form

Illinois Law holds the Pharmacist-in-Charge (PIC) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy.

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. The inspection report also serves as a necessary document used by the Drug Compliance investigators during an inspection to evaluate a pharmacy's level of compliance. When a Drug Compliance investigator discovers an area of non-compliance, he or she may issue either a Deficiency Notice or a Notice of Non-Compliance. Both require a written response from the PIC. Identifying or correcting an area of non-compliance prior to a Drug Compliance investigator inspection may eliminate the receipt of a Deficiency Notice/Notice of Non-Compliance for that item.

Failure to complete this report by December 31st of each year may result in Disciplinary Action. (Section 1330.800)
Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. The annual self-inspection shall be conducted during the same month, annually, as determined by the pharmacy. Documentation of the self-inspection shall be maintained at the pharmacy for 5 years. The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.

NOTE: Neither the self-inspection nor a Drug Compliance investigator inspection evaluates your complete compliance with all Laws and Rules of the practice of pharmacy. Further, nothing herein shall constitute a waiver of IDFPR enforcement discretion or constitute compliance with all applicable Laws and Rules governing the practice of pharmacy. This report is not final agency action and is intended as guidance. This report is not intended, nor can it be relied upon to create any rights enforceable by any party in litigation or in any enforcement action brought by IDFPR.

STATE OF ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DRUG COMPLIANCE UNIT
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320 W. WASHINGTON STREET, 2ND FLOOR, SPRINGFIELD, IL 62786

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(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)

NUCLEAR PHARMACY

BUSINESS NAME	HOURS		DEA REGISTRATION NUMBER	EXPIRES	DATE OF INSPECTION
	M				
	T				
	W				
ADDRESS	TH		ICSA LICENSE NUMBER	EXPIRES	PHARMACY LICENSE NUMBER
	F				
	SAT				
	SUN				
CITY ZIP CODE	OTHER HOURS EXCEP		TELEPHONE ( )		

OWNERSHIP	OWNERS	TELEPHONE AFTER HOURS	PHARMACY E-MAIL ADDRESS
☐ Individual pharmacist ☐ Individual Non-pharmacist ☐ Partnership ☐ Corporation ☐ LLC	PERSON IN CHARGE	OWNER'S E-MAIL ADDRESS	COUNTY

NAME OF LICENSEE	LICENSE NUMBER
R Ph IN CHARGE	

If the Pharmacist in charge listed above is the PIC in other pharmacies, list here			
	NAME	ADDRESS	PHONE NUMBER
1.			
2.			

QUESTION	YES	NO	N/A	AUTHORITY
GENERAL				
The pharmacy's license is current and posted.				225 ILCS 85/15(5)
All required current licenses are posted in a conspicuous location in the pharmacy (pocket license or photocopy may be used when registrants are employed at multiple sites).				225 ILCS 85/15(5)
Pharmacy is compliant with Section 1330.540 of the Illinois Pharmacy Practice Act Rules, Nuclear Pharmacy Services.				68 Administrative Code Section 1330.540
The PIC has personally reviewed the licenses of all registrants and determined that they are current.				68 Administrative Code Section 1330.660
Registrants wear proper clean attire and have proper name tags and designations.				68 Administrative Code Section 1330.30(k)
All pharmacy technicians and certified pharmacy technicians have completed the required training/work experience set forth in the Act and Rules.				68 Administrative Code Section 1330.210
Current reference books and copy of laws and rules are maintained in hard copy or readily available in electronic data format. If preparing compounded sterile preparations, then pharmacy shall maintain references listed in Section 1330.640.				68 Administrative Code Section 1330.610(f), Section 1330.640, and Section 1330.500(h)

SECURITY, SANITATION AND STORAGE	YES	NO	N/A	AUTHORITY
Security provisions are provided for all drugs and devices within the pharmacy when pharmacist is on staff and during the absence of a pharmacist.				68 Administrative Code Section 1330.600 and 225 ILCS 85/15(1)(b)
Refrigerators for the exclusive use of medications are clean, defrosted and in working order maintaining proper temperature.				68 Administrative Code Section 1330.610(d)
Pharmacy is clean and sanitary.				68 Administrative Code Section 1330.630
Pharmacy must have a sink with hot and cold running water.				68 Administrative Code Section 1330.630(c)
Food and/or beverages are kept in designated areas away from dispensing activities and stored in refrigerators not used for medications.				68 Administrative Code Section 1330.630(e)
Pharmacy area shall not be used for storage of merchandise that interferes with the practice of pharmacy.				68 Administrative Code Section 1330.610(e)
The pharmacy area and all store rooms shall be well-lighted and properly ventilated.				68 Administrative Code Section 1330.610(c)
All dispensing and drug storage areas of the pharmacy are contiguous with connecting door.				68 Administrative Code Section 1330.610(b)
Expired medications are stored separately from active medication stock.				410 ILCS 620/14(b)

NUCLEAR PHARMACY REQUIREMENTS	YES	NO	N/A	AUTHORITY
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.				68 Administrative Code Section 1330.540(c)
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.				68 Administrative Code Section 1330.540(d)
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.				68 Administrative Code Section 1330.540(e)
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;				68 Administrative Code Section 1330.540(f)

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.				
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.				68 Administrative Code Section 1330.540(g)
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				68 Administrative Code Section 1330.540(i)

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.				
Every prescription dispensed shall be documented with the name, initials or other unique identifiers of the pharmacist and pharmacy technician if one is used.				68 Administrative Code Section 1330.500(c)
No prescription may be dispensed after 15 months from the date of the original issuance of the prescription by the prescriber.				68 Administrative Code Section 1330.500(c)(1)
All records are maintained for 5 years and are readily retrievable.				225 ILCS 85/18
All sterile compounded medications are prepared in compliance with Section 1330.640. **If preparing compounded sterile preparations, the Sterile Compounding Self-Inspection Report must be filled out in addition to this Report.**				68 Administrative Code Section 1330.640

LABELING	**YES**	**NO**	**N/A**	**AUTHORITY**
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.				68 Administrative Code Section 1330.540(h)(1)
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;				68 Administrative Code Section 1330.540(h)(2)

E. Name of radionuclide; and F. Name of chemical form.				

DO NOT SEND ANY PART OF THIS REPORT TO THE DEPARTMENT!
KEEP IN THE PHARMACY FOR DRUG COMPLIANCE INVESTIGATOR'S REVIEW.
COPIES SENT TO THE DEPARTMENT WILL BE DISCARDED.

I hereby certify that I have verified that this pharmacy is in compliance with all laws and rules related to the practice of pharmacy in the State of Illinois and the answers marked on this report are true and correct to the best of my knowledge.

PIC NAME: _____ LICENSE NUMBER: _____

PIC SIGNATURE: _____ DATE: _____