



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV365 - Nuclear Pharmacy**



File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

Additional Information

Business Operation Hours

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Registered Pharmacist / Intern / Tech

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ACS Manager

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Optional Information

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Basic License Data - PSD

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License Relations

RX DPT MGR/COR/POR

	License #
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INV 365 - Nuclear Pharmacy

Nuclear Pharmacy Requirements

Current nuclear pharmacy permit. [465.0193, F.S.]	
Licensed nuclear pharmacist personally supervising all production. [64B16-28.901(1), F.A.C.]	
Secured radioactive storage and decay area. [64B16-28.901(4), F.A.C.]	
Compliance with all applicable laws and regulations of federal and state agencies for procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals. [64B16-28.901(5), F.A.C.]	
Pharmacy technicians and interns properly identified and supervised. [64B16-27.100 (2) F.A.C.] [64B16-27.4001 F.A.C.] [64B16-27.410 F.A.C.] [64B16-26.400(4) F.A.C.] [64B16-27.420 F.A.C.]	
Radiopharmaceuticals are distributed only upon a prescription from an authorized medical practitioner or his agent. [64B16-28.901(6), F.A.C.]	
Transfers of radioactive materials by nuclear pharmacist is in accordance with all applicable laws and regulations. [64B16-28.901(7), F.A.C.]	
Each prescription contains name of authorized user or agent, date of distribution, time of administration, name of procedure, name of radiopharmaceutical, dose or quantity, serial # assigned to the order, any special instructions and the initials of the person who received the order. [64B16-28.901(8), F.A.C.]	
Oral prescriptions for radiopharmaceuticals are immediately reduced to writing. [64B16-28.901(8), F.A.C.]	
Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.110, F.A.C.]	
The immediate inner container label of a radiopharmaceutical to be distributed has standard radiation symbol, "Caution Radioactive Material," radionuclide, chemical form, and the prescription number of the radiopharmaceutical. [64B16-28.901(10), F.A.C.]	
Area for storage, compounding, distribution and disposal of radiopharmaceuticals is adequate to separate them from areas that contain non-radioactive medicinal drugs. [64B16-28.902(1)(a), F.A.C.]	
The hot lab storage area and compounding and dispensing area contain a minimum of 150 square feet. [64B16-28.902(1)(b), F.A.C.]	
Minimum equipment: fume hood with an air sampler, shielded radiation containment drawing station, dose calibrator, well scintillation counters, area rate meters, Geiger-Mueller (GM) survey meters, refrigerator, microscope, syringe shields, personnel radiation detection devices. [64B16-28.902(2), F.A.C.]	
Minimum supplies: syringes and vials, disposable gloves and protective lab coats, appropriate supplies to perform thin layer chromatography, lead transport shields for syringes and vials, DOT type 7A transport containers for shipping radioactive materials. [64B16-28.902(3), F.A.C.]	

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CQI Policy and Procedures and proof of quarterly meetings protected under [766.101, F.S.] [64B16-27.300, F.A.C.]	
Licensed nuclear pharmacist in charge of pharmacy. [465.0193, F.S.]	
Nuclear pharmacy area secured from access by unauthorized personnel. [64B16-28.901(2), F.A.C.]	
Each nuclear pharmacist maintains accurate records of the acquisition, inventory, distribution and disposal of all radiopharmaceuticals. [64B16-28.901 (3), F.A.C.]	
Pharmacy technicians may only receive diagnostic orders. [64B16-27.420(3), F.A.C.]	
All orders for a therapeutic or blood-product radiopharmaceutical contain the patient's name prior to dispensing and must be received by the pharmacist only. [64B16-27.420(3), F.A.C.] [64B16-28.901(8), F.A.C.]	
All registered pharmacy technicians wear identification badge with name and "Registered Pharmacy Technician". [64B16-27.420(4), F.A.C.]	
Policy and procedure available showing utilization of pharmacy technician. [64B16-27.440, F.A.C.]	
Minimum current references: [10 CFR - FL], [49 CFR - DOT], [USP/NF, USP - DI], [404, F.S.], [465, F.S.] [893, F.S.], [64B16, F.A.C.], [64E-5, F.A.C.], [64B16-28.902(4), F.A.C.]	
In addition to other labeling requirements, the immediate outer container shield of the name of the radiopharmaceutical is labeled with standard radioactive symbol and words "Caution Radioactive Material," name of procedure, serial number, radionuclide and chemical form, amount of radioactivity and calibration date, the expiration date and time, the volume or weight, if a gas, the number of ampules or vials, molybdenum 99 content and the name of the patient or the words "Physicians use only" [64B16-28.901(9), F.A.C.]	

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
Central Fill and originating pharmacy shall each be identified on the prescription container label.	
The word "central fill" appears on the face of the original prescription and the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal. May be recorded electronically for non-controlled substances.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Pharmacy Ships Medicinal Drugs to Patients

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature:

Representative:

Date:

Date: