



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES**



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NUCLEAR PHARMACY

File # _____

ROUTINE
 CHANGE LOC
 NEW
 CURRENTLY NOT OPERATING
 CHANGE OWNER

Insp # _____

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT				PERMIT NUMBER				DATE OF INSPECTION									
DOING BUSINESS AS				DEA NUMBER				NUCLEAR PHARMICIST/MANAGER									
STREET ADDRESS				TELEPHONE #		EXT.											
CITY		COUNTY		STATE/ZIP				LICENSE #									
PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN				LICENSE #					
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1.									
Open								2.									
Close								3.									
								SATISFACTORY		YES		NO					
1 Current nuclear pharmacy permit. [465.0193, F.S.]								<input type="checkbox"/>		<input type="checkbox"/>		16 Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.110, F.A.C.]		<input type="checkbox"/>		<input type="checkbox"/>	
2 Licensed nuclear pharmacist in charge of pharmacy. [465.0193, F.S.]								<input type="checkbox"/>		<input type="checkbox"/>							
3 Licensed nuclear pharmacist personally supervising all production. [64B16-28.901(1), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		17 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.]		<input type="checkbox"/>		<input type="checkbox"/>	
4 Nuclear pharmacy area secured from access by unauthorized personnel. [64B16-28.901(2), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>							
5 Each nuclear pharmacist maintains accurate records of the acquisition, inventory, distribution and disposal of all radiopharmaceuticals. [64B16-28.901 (3), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>							
6 Secured radioactive storage and decay area. [64B16-28.901(4), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		18 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.]		<input type="checkbox"/>		<input type="checkbox"/>	
7 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.]								<input type="checkbox"/>		<input type="checkbox"/>							
8 Pharmacy technicians may only receive diagnostic orders. [64B16-27.420(3), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		19 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.]		<input type="checkbox"/>		<input type="checkbox"/>	
9 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(4), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		20 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.]		<input type="checkbox"/>		<input type="checkbox"/>	
10 All registered pharmacy technicians wear identification badge with name and "Registered Pharmacy Technician". [64B16-27.420(4), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		21 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.]		<input type="checkbox"/>		<input type="checkbox"/>	
11 Policy and procedure available showing utilization of pharmacy technician. [64B16-27.440, F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		22 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.]		<input type="checkbox"/>		<input type="checkbox"/>	
12 Radiopharmaceuticals are distributed only upon a prescription from an authorized medical practitioner or his agent. [64B16-28.901(6), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>							
13 Transfers of radioactive materials by nuclear pharmacist is in accordance with all applicable laws and regulations. [64B16-28.901(7), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		23 CQI Policy and Procedures and proof of quarterly meetings protected under [766.101, F.S.] [64B16-27.300, F.A.C.]		<input type="checkbox"/>		<input type="checkbox"/>	
14 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.]								<input type="checkbox"/>		<input type="checkbox"/>							
15 Oral prescriptions for radiopharmaceuticals are immediately reduced to writing. [64B16-28.901(8), F.A.C.]								<input type="checkbox"/>		<input type="checkbox"/>		24 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.]		<input type="checkbox"/>		<input type="checkbox"/>	
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.

PRINT NAME _____

ID _____

Institutional Representative
INV 365 Revised 03/11, 01/07, 06/02

Date _____

Investigator/Sr. Pharmacist Signature _____

Save