### Additional Information

#### Business Operation Hours

#### Registered Pharmacist / Intern / Tech

<table>
<thead>
<tr>
<th>License #</th>
<th>Licensee Name</th>
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| ACS Manager

#### Optional Information

#### Basic License Data - PSD

#### License Relations

#### Pharmacy Affiliate

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<th>License #</th>
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#### Rx DPT MGR/CO/POR

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#### Special Sterile Compounding

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### INV 365 - Nuclear Pharmacy

#### Nuclear Pharmacy Requirements

- Current nuclear pharmacy permit. [465.0193, F.S.]
- The Prescription Department Manager is a Licensed Nuclear Pharmacist. [465.0193 F.S.][64B16-28.901(1) F.A.C.]
- Licensed nuclear pharmacist personally supervising all production. [64B16-28.901(1), F.A.C.]
- Pharmacy area secured from access by unauthorized personnel, [64B16-28.901(2), F.A.C.]
- Pharmacy maintains accurate records of the acquisition, inventory, distribution and disposal of all radiopharmaceuticals. [64B1628.901 (3), 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 may only receive diagnostic orders, [64B16-27.420(1)(h), 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(2)(b), F.A.C.]

Written policy and procedure manual regarding the number of technician positions, their utilization and on-going training and documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2)(a) F.A.C., 64B1627.410(2)(b) F.A.C.]

Pharmacy technicians and interns properly identified and supervised. [64B16-27.100(3) & (4) F.A.C., 64B16-27.4001 F.A.C., 64B16-27.410 F.A.C.]

[64B16-27.400(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.]

In addition to other labeling requirements, the immediate outer container shield 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.]

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.]

CQI Policy and Procedures and proof of quarterly meetings protected under [766.101, F.S.] [64B16-27.300, F.A.C.]

Current references as required by rule: [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.]

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. I have received a copy of the Licensee Bill of Rights.