STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

NUCLEAR PHARMACY

Florida HEALTH

WWW.DOH.STATE.FL.US

File # 6825

Insp # 123200

ROUTINE ☒ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

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

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
ANAZAOHEALTH CORP		16308		12/5/2013
DOING BUSINESS AS		DEA NUMBER		NUCLEAR PHARMICISTMANAGER
STREET ADDRESS 5710 HOOVER BLVD		TELEPHONE # (813) 882-4500	EXT.	ARLINDA OANH CHAI
CITY TAMPA	COUNTY 39	STATE/ZIP 33634		LICENSE # 399

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	6:30	6:30	6:30	6:30	6:30	X	X
Close	5	5	5	5	5		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. See attached
2.
3.

	SATISFACTORY	YES	NO
1	Current nuclear pharmacy permit. [465.0193, F.S.]	☒	☐
2	Licensed nuclear pharmacist in charge of pharmacy. [465.0193, F.S.]	☒	☐
3	Licensed nuclear pharmacist personally supervising all production. [64B16-28.901(1), F.A.C.]	☒	☐
4	Nuclear pharmacy area secured from access by unauthorized personnel. [64B16-28.901(2), F.A.C.]	☒	☐
5	Each nuclear pharmacist maintains accurate records of the acquisition, inventory, distribution and disposal of all radiopharmaceuticals. [64B16-28.901 (3), F.A.C.]	☒	☐
6	Secured radioactive storage and decay area. [64B16-28.901(4), F.A.C.]	☒	☐
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.]	☒	☐
8	Pharmacy technicians may only receive diagnostic orders. [64B16-27.420(3), F.A.C.]	☒	☐
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(3), F.A.C.] [64B16-28.901(6)(i), F.A.C.]	☒	☐
10	All registered pharmacy technicians wear identification badge with name and "Registered Pharmacy Technician". [64B16-27.420(4), F.A.C.]	☒	☐
11	Policy and procedure available showing utilization of pharmacy technician. [64B16-27.440, F.A.C.]	☒	☐
12	Radiopharmaceuticals are distributed only upon a prescription from an authorized medical practitioner or his agent. [64B16-28.901(6),F.A.C.]	☒	☐
13	Transfers of radioactive materials by nuclear pharmacist is in accordance with all applicable laws and regulations. [64B16-28.901(7), F.A.C.]	☒	☐
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.]	☒	☐
15	Oral prescriptions for radiopharmaceuticals are immediately reduced to writing. [64B16-28.901(8), F.A.C.]	☒	☐

	SATISFACTORY	YES	NO
16	Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.110, F.A.C.]	☒	☐
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.]	☒	☐
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.]	☒	☐
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.]	☒	☐
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.]	☒	☐
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.]	☒	☐
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.]	☒	☐
23	CQI Policy and Procedures and proof of quarterly meetings protected under [766.101,F.S.] [64B16-27.300, F.A.C.]	☒	☐
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.]	☒	☐

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.

PRINT NAME Arlinda Chai

Institutional Representative

12-05-2013
Date

Investigator/Sr. Pharmacist Signature

ID oi129

INV 365 Revised 06/12, 12/11, 03/11, 01/07, 06/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

Florida HEALTH

WWW.DOH.STATE.FL.US

Standards of Practice for Compounding Sterile Preparations (CSPs)

ROUTINE X | CHANGE LOC | NEW | CURRENTLY NOT OPERATING | CHANGE OWNER

File # 6825

Insp # 123200

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

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
ANAZAOHEALTH CORP		16308		12/5/2013
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 5710 HOOVER BLVD		TELEPHONE # (813) 882-4500	EXT.	ARLINDA OANH CHAI
CITY TAMPA	COUNTY 39	STATE/ZIP 33634		PRESCRIPTION DEPARTMENT MANAGER LICENSE # 399

COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE	COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE
See attached			

		SATISFACTORY	N/A	YES	NO
High-Risk Level CSPs					
1	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i)4.]			X	
2	Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannually). [64B16-27.797(1)(i),F.A.C.]			X	
3	High risk sterile compounded preparations greater than 25 units have antimicrobial testing prior to dispensing [64B16-27.797(7)(a)3., F.A.C.]			X	
Medium and Low-Risk Level CSPs					
4	Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified in rule. [64B16-27.797(1)(n)4.; (o)4.]			X	
5	Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 months. [64B16-27.797(1)(n), F.A.C.]			X	
Barrier Isolator or Compounding Environment					
6	All sterile compounds prepared in barrier isolator which has been certified as ISO 5 by independent contractor. [64B16-27.797(5)(e), F.A.C.]	X			
7	Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for medium and low-risk.			X	
	a) Anteroom/Ante area maintained within ISO class 8 [64B16-27.797(1)(a), F.A.C.]			X	
	b) Buffer area (clean room) maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(a), F.A.C.]			X	
	c) Laminar Air Flow Hood(s) or class100 ISO room maintained within ISO class 5 [64B16-27.797(1)(k), F.A.C.]			X	
8	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]			X	
Antineoplastic Drugs (Cytotoxins)					
9	Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.]	X			
10	All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.]	X			
11	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]	X			
General Requirements					
12	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]			X	
13	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]			X	
14	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]			X	
15	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]			X	
16	Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), F.A.C.]			X	
17	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]			X	
18	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]			X	
19	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation and protective apparel for cytotoxins. [64B16-27.797(5)(6), F.A.C.]			X	
20	Documented on-going quality assurance program with audits at regular planned intervals. [64B16-27.797(7), F.A.C.]			X	
21	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]			X	
22	Compounding records properly maintained [64B16-28.140(4), F.A.C.]			X	
23	Quantity of compounded drug is reasonable considering the intended use and nature of the practitioner's practice [64B16-27.700(3)(b), F.A.C.]			X	

Remarks: Medrep certified anteroom, clean rooms and LAFWS 6-13 AND 6-14-2013

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.

PRINT NAME OF RECIPIENT Arlinda Chai

Institutional Representative

12-05-2013
Date

Investigator/Sr. Pharmacist Signature

ID 01129

INV 797 Revised 12/12, 12/11 Created 8/11