DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FLORIDA DISTRICT OFFICE 555 WINDERLEY PLACE, SUITE 200 MAITLAND, FL 32751-7140 (407) 475-4700 Industry Information: www fda.gov/oc/industry	3/19-23/2018
	FEI NUMBER 3010421557

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Warren C. Gray, President

FIRM NAME	STREET ADDRESS
West Coast Nuclear Pharmacy, LLC	3906 Cragmont Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Tampa, FL 33619	Nuclear Pharmacy

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production without adequate product evaluation and remedial action.

Specifically, your surface sampling of the ISO 5 laminar flow hood (b) (4) identified the presence of Bacillus spp. on 1/8/2018, and the environmental monitoring procedures did not require additional action such as the sanitization of this hood with a sporicidal agent to remove this spore forming bacteria. You continued sterile radiopharmaceutical drug preparations in this hood. You prepared (b) (4) mixed kits of radiopharmaceuticals such as sestamibi Tc99m lot K-20180321-035 from 1/18/2018 to 3/22/2018.

Observation 2
Poor aseptic practices were observed during aseptic preparations.

Specifically, on 3/21/2018 we observed the (b) (4) preparation of sodium pertechnetate TcO4 lot E-20180321-018 and kit preparation of sestamibi Tc99m lot K-20180321-035 which are used to prepare patient doses of sestamibi Tc99m lot K-20180321-035. During these operations we observed the following:
A. Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves. Personnel failed to disinfect or change gloves frequently enough to prevent contamination. Sterile gloves worn by employees came in direct contact with non-sterile objects such as the buffer room door, lead pigs, vials, syringes, (b) (4) wipes, computer key boards and mouse, labels, label printers, and (b) (4) .

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Joanne E. King -S Christos G. Tsingelis -S	Joanne E. King, Investigator Christos G. Tsingelis, Investigator	03/23/2018

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These gloves were then used to perform radiopharmaceutical preparations in the laminar flow hoods (b) (4)

B. Personnel were observed to be moving rapidly in the vicinity of open sterile units or instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 area.
Employees were observed moving quickly in front of the ISO 5 Hood (b) (4) drug preparation area while preparing patient doses of sestamibi Tc99m for injection. These movements included passing single patient doses in lead pigs through sliding glass doors to the non-controlled room while wearing sterile gloves and then returning to the ISO 5 environment without sanitizing the gloves and to continue drawing patient doses.

Observation 3

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, media fills were not performed that simulate the kit preparation of sestamibi Tc99m which are used to prepare patient doses of sestamibi Tc99m pre-filled syringes.

Observation 4

The facility design was observed to allow the influx of poor quality air into a higher classified area.

Specifically, the pass through (b) (4) windows located in between the buffer room ISO 7 and the unclassified room are not properly sealed to prevent the mixture of classified and unclassified air. In addition, these pass through windows directly open to the ISO 7 areas that are located in front of your ISO 5 laminar flow hoods (b) (4)

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Observation 5

Post (b) (4) (b) (4) testing to the sterilizing (b) (4) was not performed.

Specifically, you do not perform sterilizing (b) (4) (b) (4) tests on the (b) (4) which are located (b) (4) your (b) (4) generators such as generator (b) (4) used to produce the (b) (4) preparation of sodium pertechnetate TcO4 lot E-20180321-018 on 3/21/2018. These generators use (b) (4) for an (b) (4) up to (b) (4) for (b) (4) days.

Observation 6

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area [aseptic processing areas] are not sterile.

Specifically on 3/21/2018, we observed that employees were using non-sterile (b) (4) on lint-free wipes to wipe down the walls and (b) (4) surfaces in laminar flow hoods (b) (4)

Observation 7

The scheduled use of (b) (4) whole room surface disinfection system is (b) (4) rather than when spore forming organisms are identified through environmental monitoring.

Specifically, Bacillus spp. was recovered by surface samples taken from the ISO 5 (b) (4) surface area located in the (b) (4) air flow laminar flow hood (b) (4) This hood was not treated with an anti-sporicidal as a preventative and corrective action to this objectionable organism.

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