DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	01/05/2015 - 01/09/2015
	FEI NUMBER 3008364285

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joe Huber, RPh, BCNP, Pharmacy Manager

FIRM NAME	STREET ADDRESS
Triad Isotopes Inc.	712 Westport Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kansas City, MO 64111-3130	Producer of Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

For the aseptic processing of over [redacted] sterile injectable radiopharmaceutical drug products such as Technetium-99m sestamibi, Tachnetium-99 medronate, Tachnetium-99 mebrofenin, Iodine I-131 Sodium Chloride and Mertiade (MAG-3) Tc-99m (e.g. Lot-20150106-004 compounded and shipped to (b) (4) on (b) (4)):

OBSERVATION 1

Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically, your firm is aseptically manipulating sterile ingredients and sterile components during the processing of sterile injectable radiopharmaceuticals in an ISO 5 laminar flow hood. Your firm lacks adequate data to support that the following conditions are not compromising the sterility of your injectable drug products.

Your operators put on non-sterile gloves and non-sterile forearm covers, in an unclassified area that is not supplied by HEPA filtered air, they spray their gloves with (b) (4) and then begin to aseptically process sterile drug products and sterile components in the ISO 5 laminar flow hood.

OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically:

1. Your firm lacks adequate environmental monitoring data to support that your aseptic manipulation of sterile drugs and sterile components in the ISO-5 hoods does not compromise the sterility of injectable drug products. You are performing these operations (b) (4) and you are currently monitoring:

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Russell Glapion, Investigator James G. Flahive, Investigator	01/09/2015

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A. Viable organisms in your ISO-5 hoods, (b) (4) [redacted]. Since you missed your testing schedule in 9/2014, your most recent assessment was on 3/15/2014.

B. Operator gloved finger tips, (b) (4) [redacted].

2. Your ISO 5 laminar flow hoods used to process sterile drug products are deficient. The inside working area of your hoods were modified to accommodate (b) (4) permanently mounted (b) (4) [redacted] that are below the HEPA filters and above and to the left and right of the critical ISO 5 working area where sterile drugs and sterile components are processed. The improper installation of the (b) (4) [redacted] equipment compromised the original design and effectiveness of the unidirectional airflow and created a condition of disrepair that precludes the proper cleaning and sanitization of the hood. More specifically:

A. The original overhead covers inside your hoods were removed, apparently to allow for the installation of an electric outlet just below the HEPA filters, centered on the back inside wall of the hood. Your (b) (4) [redacted] are plugged into that outlet. This modification created insanitary conditions above the critical ISO 5 work areas. In addition to the suspended power cords, in one of your hood the two overhead florescent light bulbs are completely exposed and in the other hood they were partially covered by two parts of a broken, waffle-style white plastic grate.

B. The loosely fitting plastic covers designed to protect the (b) (4) [redacted] from the sanitizing agents controls is not of appropriate design to facilitate cleaning.

C. There are no magnehellic gauges installed on your (b) (4) primary ISO 5 laminar flow hoods to allow you to evaluate whether the hoods are operating properly on a (b) (4) basis.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, you use annual media fills to simulate the processing of sterile injectable drug products in an ISO 5 Laminar flow hood and to evaluate the aseptic technique used by the operators. Your personnel are following an improperly worded procedure and their filled media challenge samples are being incubated for (b) (4) [redacted] at approximately (b) (4) [redacted]. These temperatures are below the optimum temperature range (25 C and 35 C) for promoting microbial growth. This can result in false negatives for no detected microbial growth and incorrect conclusions about the ability of your operators to aseptically process sterile drug products.

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OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

For example:

A. You are not complying with your procedure No:11.a.05.797, Version 3, effective 2/11/2014, in that signature approvals for verifying equipment cleaning logs are missing on all your records dating back to at least 2/2014.

B. Your vast array of on-line corporate procedures have not been differentiated to site specific procedures, so that all of your personnel can clearly identify and understand what procedures are applicable to their responsibilities. One (b) (4) QC personnel questioned could not identify what or where they could find procedures specifically related to their job function.

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