DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food & Drug Administration 555 Winderley Place #200 Maitland, FL 32751 Phone: (407) 475-4700	12/1-23/2009
	FEI NUMBER 3004483463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jacob J. Beckel, CEO

FIRM NAME	STREET ADDRESS
AnazaoHealth Corporation	5710 Hoover Blvd.
CITY, STATE AND ZIP CODE Tampa, FL 33634	TYPE OF ESTABLISHMENT INSPECTED Pharmacy

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

1. There is no designated Quality Control Unit for the Nuclear Pharmacy.

2. There is a lack of separate or defined areas or other control systems for the firm's operations as are necessary to prevent contamination during the course of aseptic processing. Specifically,

A. During the processing of I123MIBG batch I123MIBG091202V in the Nuclear Pharmacy the partially stoppered vials that were (b) (4) filled in an ISO5 hood in Room (b) (4) were (b) (4) a (b) (4) from an ISO7 area of this room. The (b) (4) was observed to be (b) (4) (b) (4) same ISO7 area prior to (b) (4). Additionally, a tray was observed to have been taken from Room (b) (4) (ISO7) through a vestibule (Room (b) (4) to Room (b) (4) (ISO7) where it was filled with (b) (4) and brought back through the vestibule into Room (b) (4) where the contents were (b) (4) the (b) (4). In addition:

i. The (b) (4) (b) (4) is not sterilized prior to use.

ii. There is no (b) (4) of the (b) (4) used to (b) (4) which is used to (b) (4) (b) (4).

B. Items routinely introduced into the ISO5 hoods of Rooms (b) (4) (vial filling area) and (b) (4) ((b) (4) area) of the Nuclear Pharmacy are not rendered sterile prior to introduction into these hoods, including but not limited to forceps, coated paper liners, non-woven sponges used for cleaning, oven mitts used to transfer materials into the hood, and a pen.

C. As observed during the processing of I123MIBG batch I123MIBG091202V in the Nuclear Pharmacy all items necessary for performing the (b) (4) were not present within the (b) (4) (b) (4) Hood (ISO5) located in Room (b) (4) at the initiation of (b) (4) The pharmacist was observed to remove (b) (6) hands from the ISO5 Hood several times, in order to obtain articles on shelving located across the room (ISO7) needed for (b) (4) activities and was subsequently observed introducing these articles into the ISO5 Hood without sterilizing the articles and without spraying (b) (4) onto (b) (6) gloves before resuming activities within the (b) (4) (b) (4) Hood (ISO5).

D. During the (b) (4) vial filling operation of I123MIBG batch I123MIBG091202V in the Nuclear Pharmacy, the pharmacy technician performing the filling was observed to use (b) (6) gloved fingers to (b) (4).

E. During the (b) (4) filling (b) (4) operation of I123MIBG batch I123MIBG091202V in the Nuclear Pharmacy the Pharmacist and

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	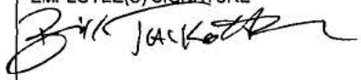	Bill Tackett Jr., Investigator /Kristy A. Zielny, Investigator/Mihaly S. Ligmond, Investigator/Mark Sassaman, Senior Chemist/Meghan Murphy, Investigator/Leslie A. Cartmil, Investigator	12/23/09

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Pharmacy Technician were observed to move between Rooms (b)(4) and (b)(4) (ISO7 areas) to other unclassified areas and back without re-gowning although re-gloving was observed when within Room (b)(4) and (b)(4) (ISO7 areas).

F. For the Nuclear Pharmacy there is no defined area where gowning for aseptic operations is performed. Laboratory coats are donned in a distribution area and gloving routinely occurs within Rooms (b)(4) and (b)(4) (ISO7 areas).

G. The floors of Room (b)(4) as well as the working surface of the (b)(4) (b)(4) Hood (ISO5 hood) are not easily cleanable in that the floor coating was observed to be chipped and the working surface of the ISO5 hood was observed to be covered with a white covering which was not smooth. In addition tacky mats were observed within Rooms (b)(4) and (b)(4) (ISO7 areas).

H. (b)(4) used in the (b)(4) of radiopharmaceutical products and non-radiopharmaceutical products in the Nuclear and Pain Management Pharmacies are not (b)(4). Additionally, product specific validation of the (b)(4) has not been performed.

I. The monitoring of the differential pressures between Rooms (b)(4) (b)(4) and the adjacent vestibule (Room (b)(4) is inadequate in that the differential pressures are only measured every (b)(4). There is no assurance that differential pressures are adequate on each day of (b)(4) aseptic filling. In addition, there are no pressure gauges for Rooms (b)(4) and (b)(4).

J. While cleaning the (b)(4) (b)(4) Hood (ISO5 hood) after (b)(4) operations had been completed for I123MBIG batch I123MIBG091202V, the forceps (within a lead container) and the non-woven sponges were placed on top of a waste container outside of the hood in an ISO7 area. The non-woven sponges were then used to clean the interior of the (b)(4) (b)(4) Hood (ISO5) and the forceps would be replaced into the hood without sterilization.

K. There are no validation studies to support the cleaning practices used in the Nuclear Pharmacy.

3. Personnel engaged in the making of radiopharmaceuticals in the Nuclear Pharmacy failed to wear appropriate protective apparel to protect the drug product from contamination. Specifically, during the (b)(4) and/or filling of I123MBIG batch I123MIBG091202V the following was observed:

A. The pharmacy technician who performed (b)(4) aseptic filling operations within an ISO5 hood located within room (b)(4) (ISO7) was observed to be inadequately gowned. Specifically, the pharmacy technician was observed with exposed facial hair, and exposed skin at

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the wrist and forearm during processing. Additionally, the cloth laboratory coat worn by this technician appeared soiled.

B. The pharmacy technician was observed entering and exiting Room (b) (4) (ISO7) without gloves while the pharmacist performed (b) (4) (b) (4) within the (b) (4) (b) (4) Hood (ISO5) located within room (b) (4)

C. The pharmacy technician was observed within Room (b) (4) (ISO7) without gloves manipulating a portable audio player just prior to filling.

D. While preparing empty sterile vials in an ISO5 hood in Room (b) (4) for the aseptic filling operation, the pharmacy technician was observed to remove (b) (6) hands from the hood and place an ear bud (for the portable audio player) into (b) (6) ear with (b) (6) gloved hand and then resume preparation within the ISO5 hood.

E. The pharmacy technician was observed to place a meter within the ISO5 hood adjacent to the (b) (4) in Room (b) (4) pick up a bottle of sanitizer, enter settings on the (b) (4) and turn off the light to the ISO5 hood with bare hands.

F. An additional employee was observed entering Room (b) (4) during (b) (4) at which time (b) (6) was observed to remove (b) (6) gloves within the ISO7 area.

4. Gowning practices in the Nuclear Pharmacy are inappropriate for the aseptic processing of radiopharmaceuticals intended to be sterile. Specifically,

A. There is no gowning qualification.

B. The pharmacist and/or pharmacy technician performing the (b) (4) and (b) (4) aseptic filling of I123MBIG batch I123MIBG091202V were observed with only the following gowning: street clothes and shoes under the following: shoe covers, lab coat, face mask, hair net and gloves. The pharmacist also had sleeve coverings but used powdered gloves. None of these garments are rendered sterile prior to use. Gloves are routinely removed within the ISO7 areas within rooms (b) (4) and (b) (4) which are used for filling and (b) (4) respectively.

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5. Media fill procedures are inadequate or not always followed. Specifically,

A. The media fills conducted to support the aseptic filling of I123MIBG and I131MIBG in the Nuclear Pharmacy are incomplete in that no simulation of the (b) (4) to the (b) (4) located in the ISO7 area of Room (b) (4) have been performed.

B. The media fill procedures for the Nuclear Pharmacy and the Pain Management Pharmacy consider positive leaking vials that may be found post incubation as a "No Test" and therefore would not be counted as a media positive.

C. Media fill documentation from both the Nuclear and Pain Management Pharmacies contains no documentation as to the specific interventions conducted during the fill.

D. Media fill failures are not investigated. For example, Pain Management Pharmacy employee (b) (6) failed media fills performed on (b) (4) . No investigation was performed into these failures to determine root cause and product impact. As per the firm's own Pain Management Pharmacy media fill procedure, an investigation into a failed media fill is required.

E. Growth promotion testing of media filled units is not performed post incubation.

F. No media fills have been performed to support the filling of (b) (4) Sodium Chloride.

6. The sterility and endotoxin testing performed for I123MIBG does not represent the final filled containers in that the sterility test sample is taken from the (b) (4) (b) (4) (b) (4) (b) (4)(b) (4)

7. The following dispensed radiopharmaceutical batches failed to meet finished product sterility specifications and no investigation was documented regarding these failures:

A. I123 MIBG lot I123MIBG090317 prepared on 3/17/09

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B. In-ProstaScint lot IN111PROST090429AL prepared on 4/29/09

C. In-ProstaScint lot IN111PROST090521OE prepared on 5/21/09

8. No finished product endotoxin testing results were recorded for the following dispensed radiopharmaceutical batches:

A. I123 MIBG lot I123MIBG090107 prepared 1/7/09

B. I123 MIBG lot I123MIBG090105 prepared 1/5/09

C. I123 MIBG lot I123MIBG090112 prepared 1/12/09

D. I123 MIBG lot I123 MIBG081016M prepared 10/16/08

E. I123 MIBG lot I123MIBG090225F prepared 2/25/09

F. In addition, no endotoxin testing was performed on In-ProstaScint lot IN111PROST090526OE as no (b) (4) were available.

9. Finished product sterility testing results were not recorded for the following dispensed radiopharmaceutical batches:

A. I123 MIBG lot I123MIBG081015-V2 (TSB results)

B. In-Oxine batches 090408, 091808, 092508, 100908, 101608, 102308 ((b)(4) day (b) (4) results) and 111308 (b) (4) and ((b)(4) day (b) (4) results)

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10. Environmental monitoring practices are inadequate. Specifically,

A. No non-viable particulate air monitoring is performed within any of the ISO5 Hoods with the exception of (b) (4) certification.

B. No viable air sampling is performed in the Nuclear Pharmacy ISO5 hoods under dynamic conditions.

C. There is no monitoring of personnel performing activities in the Nuclear Pharmacy ISO5 and ISO7 areas.

D. Growth promotion is not performed in the Nuclear Pharmacy or the Pain Management Pharmacy for media used for environmental monitoring activities.

E. The settling plates used for air monitoring of rooms in the Nuclear Pharmacy may be placed in locations (b) (4) such as on (b) (4) and there is no map with specific locations identified as to where to place air monitoring settling plates.

F. No investigations were conducted into environmental monitoring excursions for samples taken in the Nuclear Pharmacy on (b) (4) in Room (b) (4) (Room (b) (4) Room (b) (4) (Room (b) (4) and Room (b) (4) (Room (b) (4) or for excursions for samples taken on (b) (4) in Room (b) (4) (Room (b) (4) Processing operations occurred in these rooms during the time periods represented by these samples.

G. No investigations were conducted into environmental monitoring excursions in the Pain Management Pharmacy for samples taken in the ISO5 Hood #(b)(on (b) (4), ISO5 Hood #(b)(on (b) (4), and ISO5 Hood #(b) on approximately (b) (4) Processing operations occurred in these rooms during the time periods represented by these samples.

11. There are no written procedures designed to assure that correct labels, labeling and packaging materials are used for drug products. There is insufficient and inconsistent identification of the drug product with a lot or control number that permits determination of the history of the preparation and control of the batch. Specifically, batch numbers are recorded incorrectly on the record for sterility and endotoxin (LAL) testing, within batch records and on labels applied to product vials/units. For example,

A. The following batch numbers were identified in the record for sterility and endotoxin (LAL) testing: In-Oxine 090408, 091108, 091808, 092508, 100908, 101608, 102308 and 111308. As it was explained during the inspection and as appearing on the corresponding compounding records, batch numbers appear as follows (b) (4). The above

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numbers were recorded as "(b) (4)".

B. The documentation corresponding to the In-Oxine identified in the record for sterility and endotoxin (LAL) testing as In-Oxine 090408 revealed the following: The compounding sheet has INOX080908 recorded as the Lot #, the compounded date was not documented, the label attached indicates Lot # INOX090408DH (with an expiration date of 09/13/08), and the Sample ID entered for the endotoxin test is INOXIN0908. Dispensing records indicate INOX090408DH was dispensed on 9/4/08.

C. No compounding sheets could be located for batches identified as In-Oxine 091108, INPROST090506 and I123MIBG090125 in the record for sterility and endotoxin (LAL) testing.

D. The documentation corresponding to the In-Oxine lots identified in the record for sterility and endotoxin (LAL) testing as INOX092508 and INOX111308 revealed that the compounding sheets contained no documentation of the lot number and no sample label was attached in order to show how the individual units were identified.

E. The documentation corresponding to the In-Oxine identified in the record for sterility and endotoxin (LAL) testing as INOX100908 revealed that the compounding sheet documents no lot number or compounding date and the label attached indicates the units were identified as INOX081009.

F. Batches of I-123MIBG prepared on 1/12/09 and 12/1/09 were both identified as I123MIBG091201 on their respective compounding sheets. No labels were attached to either of these compounding sheets and therefore it is not possible to tell if the individual units of the lot produced on 1/12/09 had been labeled with the correct lot number.

12. The firm has not demonstrated that product container/closure systems are suitable to protect the dosage form throughout its shelf life. Specifically, no container/closure or shipping validation has been performed for any of the products produced in the Nuclear and Pain Management Pharmacies.

13. Firms handling of complaints is inadequate as follows:

A. Firm's complaint handling SOP/Work Instruction titled "Maintenance of Account Issues (WI 3027)" fails to have who issued the

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document and who approved the document.

B. The complaint SOP/Work Instruction (WI 3027) fails to include when a complaint should be investigated, and to determine if a complaint represents a serious or unexpected adverse drug experience.

C. Written records of all complaints were not maintained in that the following complaint ID#s from the 2008-09 list of complaints were not found:

1) (b) (4) (Patient had reaction) 2) (b) (4) (Diltiazem batch bad) 3) (b) (4) (Mold growth on labels) 4) (b) (4) (Wrong dose)

5) (b) (4) (Lost contents of Oxine due to high pressure in vial) 6) (b) (4) (Wrong Medication) 7) (b) (4) (Syringe precipitated).

The following observations (14-18) pertain to the nuclear pharmacy:

14. The firm has inadequate controls for production of radiopharmaceuticals in the following areas: (A) controls associated with acceptance of raw materials into production, (B) in-process controls, and (C) controls over release of finished drug product.

A. Personnel (b) (6) indicated that raw materials, including active pharmaceutical ingredients and/or final intermediates, are (b) (4). The COA for MIBG (b) (4), supplied by (b) (4), includes a (b) (4) which reads, (b) (4)

B. You synthesize (b) (4) (b) (4) by the (b) (4) (b) (4) (b) (4) but have no in-process controls in place which assure (b) (4) The potential consequence is (b) (4) (b) (4) (b) (4) resulting in off-target biodistribution and poor or unusable image quality.

15. Compounding sheets are inadequate. The majority of records do not include a pre-printed master template with spaces to enter measured values; there are no clear directions for technicians to follow; there is no secondary check system or place for primary and secondary technicians/supervisors to enter initials or signatures. In some cases, pages are missing from records kept on file.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print orType)*	DATE ISSUED
		Bill Tackett Jr., Investigator /Kristy A. Zielny, Investigator/Mihaly S. Ligmond, Investigator/Mark Sassaman, Senior Chemist/Meghan Murphy, Investigator/Leslie A. Cartmil, Investigator	12/23/09

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food & Drug Administration 555 Winderley Place #200 Maitland, FL 32751 Phone: (407) 475-4700	12/1-23/2009
	FEI NUMBER 3004483463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jacob J. Beckel, CEO

FIRM NAME	STREET ADDRESS
AnazaoHealth Corporation	5710 Hoover Blvd.
CITY, STATE AND ZIP CODE Tampa, FL 33634	TYPE OF ESTABLISHMENT INSPECTED Pharmacy

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:

A. There are no signatures or initials for the release of a 2009 lot of Sulfur Colloid and the compounding sheet contains only a hand-written list of components and four one-phrase, hand-written entries as a procedure. The total number of vials produced is entered once as (b) (4) and a second time as (b) (4)

B. The compounding sheet for Mebrofenin produced on 14 AUG 2009 is missing the last page. The compounding sheet for the Mebrofenin kits produced on 07 JUL 2009 does not include the (b) (4) (b) (4) used, does not include the number of kits produced, and does not indicate the number of vials sent out for testing. There is no indication that bacterial endotoxin or sterility tests were actually performed.

C. A compounding sheet for Sulfur Colloid, examined 02 DEC 2009, was found to be dated 12/13/09.

16. Expired chemicals are used in production. Records show (b) (4) used in Mebrofenin kits produced after 14 AUG 2009 expired on 11 AUG 2009.

17. Expiration dating is not supported by appropriate stability testing; no stability program is in place. Personnel refer to retained samples, which are periodically tested as evidence of stability, however no records of this testing are maintained. For example, (b) (4) kits have not been release tested or evaluated for stability; these include discontinued or soon-to-be discontinued products such as Mebrofenin and RBC.

As discussed with personnel, (b) (4) of nonradioactive kits resulted in (b) (4) There are no data available showing they are suitable for distribution. It was observed that distribution stock included more than (b) (4) vials of Mebrofenin which were being (b) (4)

18. The firm has no protocol for sampling batches for sterility testing. Records provided by the firm demonstrate at times (b) (4) is thought to be sufficient; at other times (b) (4) may be sent out for sterility assessments with no correlation to any requirements.

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