

January 6, 2008

To: United States Nuclear Regulatory Commission
Region IV
612 East Lamar BLVD, Suite 400
Arlington, Texas 76011-4125

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DNMS

From: Advanced Isotopes of Idaho
4968 Rainbow Lane
Chubbuck, Idaho 83202

Subject: NRC Inspection Report 030-37048/2008-001 and Notice of Violation

Dear Sir,

This letter is in response to an inspection conducted on December 4, 2008, in which two violations were identified. The violations and Advanced Isotopes of Idaho's response are described below.

- A. License Condition 20 of Advanced Isotopes of Idaho's NRC license states in part that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures in the license application dated September 21, 2005.

Page 4, Section 2.4.2.c.i of the Policy & Procedure Manual of the application dated September 21, 2005, states in part that, "Upon leaving the restricted area, personnel should monitor their hands, feet and clothing."

Contrary to the above, on December 4, 2008, personnel of Advanced Isotopes of Idaho failed to monitor their hands, feet and clothing upon leaving the restricted area. Specifically, personnel handling syringes and ammo boxes containing radioactive material failed to use the hand and foot survey meter stationed next to the restricted area exit to check for contamination before exiting the restricted area.

Advanced Isotopes of Idaho Response;

It is unfortunate that although initial and ongoing training occur regarding monitoring when leaving the restricted area, lapses in memory still occur, especially during an NRC inspection.

Re-training of Page 4, Section 2.4.2.c.i of the Advanced Isotopes of Idaho's Policy & Procedure Manual, specifically when leaving the restricted area, personnel should monitor their hands, feet and clothing. This training was directed at pharmacists and pharmacy technicians, and was conducted by the Radiation Safety Officer. Documentation is available for review. Frequency of re-training will increase from yearly to quarterly, with appropriate documentation.

- B. License Condition 20 of Advanced Isotopes of Idaho's NRC license states in part that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures in the license application dated September 21, 2005.

Page 45, Section 5.E.1 of the Policy & Procedure Manual of the application dated September 21, 2005, states in part that, "Individuals who routinely work compounding iodine capsules or diluting I-131 must have a thyroid bioassay performed weekly."

Contrary to the above, between September 18 and December 4, 2008, individuals working with I-131 capsules failed to have a thyroid bioassay performed weekly. Specifically, between September 18 and December 4, 2008, 13 diagnostic capsules containing I-131 were prepared, but not thyroid bioassays were performed.

Advanced Isotopes of Idaho Response;

This is an obvious lapse in our commitment to follow the Policy and Procedure manual. There is no explanation for this lapse of judgment. During an interview with Cathy Heyneman R.Ph, ANP and Nicki Chopski R.Ph, ANP, the violation and severity of the lack of bioassays over almost 3 months was discussed. Both Cathy and Nicki realize the lapse in judgment. Recommitment was made to our bioassay program. Please see attached "Recommitment To Bioassay". Previously, the RSO would review the performed bioassays once per year and generate a synopsis report. Advanced Isotopes of Idaho commits to a weekly review of individual bioassay's correlated with diagnostic and therapeutic I-131 capsule preparation by the RSO. If non-adherence to the weekly bioassay program described above is observed, it will be immediately brought to the attention of the infracting pharmacist. Consistent infractions will be discussed with the owners of Advanced Isotopes of Idaho, and disciplinary actions will be developed.

On December 4, 2008 the Bioassay described on Page 45, Section 5.E.1 of the Policy & Procedure Manual of the application dated September 21, 2005 was re-initiated and performed by Nicki Chopski R.Ph. Subsequent bioassays were performed on 12-5-08, 12-10-08, 12-17-08, 12-23-08, 12-24-08, 12-31-08 and 1-5-09 by Nicki Chopski, Cathy Heyneman R.Ph and Adam Anderson, and continue current to date.

If you have any questions regarding this response, do not hesitate to contact me at (208) 406-2543 or e-mail me at nukemdude@gmail.com.

Sincerely,



Troy Curnutt, RSO
Advanced Isotopes of Idaho
4968 Rainbow lane
Chubbuck Idaho 83201

Recommitment to Bioassay Program

December 4, 2008

We will follow the Bioassay procedure as described in our Policy and Procedure Manual, Page 45, Section 5 E.1 as described below;

E. Procedures for handling radioiodine

1. Thyroid bioassay

All individuals who handle open forms of radioactive iodine will be required to have a thyroid bioassay performed. Individuals who routinely work compounding iodine capsules or diluting I-131 must have a thyroid bioassay performed weekly. I-125 will not be handled in an open form, thus making thyroid I-125 bioassay unnecessary.

2. In vivo thyroid bioassay procedure:

- a. With a known I-131 source, peak the analyzer by adjusting the amplifier gain until the peak of the source is at channel 364. (This procedure is performed by the RSO weekly)
- b. Set the window to read all counts between 30 and 428 KeV.
- c. Obtain a background count for 1 minute.
- d. Place capsule or rod source in a thyroid neck phantom and center on detector face and obtain counts for 1 minute.
- e. Calculate net standard counts by subtracting background.
- f. Place the detector against the neck over the thyroid and obtain counts.
- g. Calculate net thyroid counts by subtracting background.
- h. Calculate thyroid activity via:
$$\frac{\text{Net neck cpm}}{\text{Net std cpm}} \times \mu\text{Ci of standard} = \mu\text{Ci in thyroid}$$
- i. Action limit is 0.04 μCi as per NRC regulation guide 8.20.
- j. Minimum detectable activity (MDA) is a measurement of instrument sensitivity. It must be proven that the instrument can detect the action limit of 0.04 μCi . The following formula will be used to determine MDA:

$$\text{MDA} = \frac{3.3 \times \text{square root of } (2 \times \text{Bkg} \times \text{Tb})}{\text{CF}}$$

Where Bkg = background counting rate, Tb = background counting time, and CF = calibration factor (cpm of std/activity of std)

- k. Only equipment with an MDA of less than 0.04 μCi will be used to perform bioassays. (This procedure is performed by the RSO weekly, and documentation is found directly behind the meter and probe)

Cathy Heyneman 12/5/08
Cathy Heyneman, RPh. Date

Nicki Chopski 12/4/08
Nicki Chopski, RPh. Date

Troy Curnutt 12-4-08
Troy Curnutt, RSO Date