January 6, 2008

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

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;

In 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.

IE07

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 12-5-8, 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:

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

      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, RPh. 12/5/08
Date

Nicki Chopski, RPh. 12/4/08
Date

Troy Curnutt, RSO 12-4-08
Date

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

December 23, 2008

Advanced Isotopes of Idaho
Attn: Troy Curnutt, RT(N)
President, Radiation Safety Officer
4968 Rainbow Lane
Chubbuck, Idaho 83202

SUBJECT: NRC INSPECTION REPORT 030-37048/2008-001 AND NOTICE OF VIOLATION

Dear Mr. Curnutt:

This refers to the unannounced inspection conducted on December 4, 2008, at the Chubbuck, Idaho, facility. This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspector discussed the preliminary inspection findings with you, by phone, at the conclusion of the onsite portion of the inspection. The inspector received follow-up electronic mail and facsimile correspondence during the week of December 8, 2008. The inspector conducted a final exit briefing telephonically with you on December 9, 2008.

Based on the results of the inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail. The violations involved: (1) the failure to perform adequate surveys when exiting the restricted area; and (2) the failure to perform bioassays in a timely manner. The violations are being cited in the Notice because they were identified by the NRC during the inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC's Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your

response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Should you have any questions concerning this inspection, please contact Mr. Jason M. Razo at (817) 276-6589 or the undersigned at (817) 860-8130.

Sincerely,

G. Michael Vasquez, Acting Chief
Nuclear Materials Safety Branch A

Docket: 030-37048
License: 11-29216-01MD

Enclosures:
1. Notice of Violation
2. Information Notice 96-28

cc w/Enclosure 1:
Idaho Radiation Control Program Director

NOTICE OF VIOLATION

Advanced Isotopes of Idaho
Chubbuck, Idaho

Docket 030-37048
License 11-29216-01MD

During an NRC inspection conducted on December 4, 2008, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed 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.

This is a Severity Level IV violation (Supplement IV).

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 no thyroid bioassays were performed.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Advanced Isotopes of Idaho is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for

disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at www.nrc.gov/reading-rm/pdr.html or www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days.

Dated this 23rd day of December 2008

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600)[1] 60 FR 34381, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VII.B.1 of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence. In some cases, such violations are documented on Form 591 (for materials licensees)

[1]Copies of NUREG-1600 can be obtained by calling the contacts listed at the end of the Information Notice.

which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions. The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

   - Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

- Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

- Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an auditable record and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Elizabeth Q. Ten Eyck, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Donald A. Cool, Director
Division of Industrial
and Medical Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Nader L. Mamish, OE
(301) 415-2740
Internet:nlm@nrc.gov

Daniel J. Holody, RI
(610) 337-5312
Internet:djh@nrc.gov

Bruno Uryc, Jr., RII
(404) 331-5505
Internet:bxu@nrc.gov

Bruce L. Burgess, RIII
(708) 829-9666
Internet:blb@nrc.gov

Gary F. Sanborn, RIV
(817) 860-8222
Internet:gfs@nrc.gov

Advanced Isotopes of Idaho
4968 Radinbow Lane
Chubbuck, Idaho 83202

U.S. Nuclear Regulatory Commission
Region IV
612 E. Lamar BLVD, Suite 400
Arlington, Texas 76011-4125

REPLY TO A NOTICE OF VIOLATION

Copy Sent to the above address