



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

November 9, 2016

Mr. Steve Laflin, President
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: NRC INSPECTION REPORT 030-35486/2016-001; AND NOTICE OF VIOLATION

Dear Mr. Laflin:

This letter refers to the routine, unannounced inspection conducted during July 12-13, 2016, at your facility in Idaho Falls, Idaho. This inspection examined activities conducted under your license as they relate to safety and compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of selected procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. The inspection also reviewed your corrective actions related to the Notice of Violation and Special Inspection Report 030-35486/2015-001 (EA-16-006) dated June 3, 2016 (ML16155A285). The preliminary inspection findings were discussed with Mr. John Miller of your staff at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you and Mr. Miller on November 2, 2016.

Based on the results of this inspection, the NRC has determined that one or more violation(s) of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy which can be found at the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The security related violation(s) are cited in the enclosed non-public Notice of Violation (Notice) because they were identified by the NRC during the inspection.

You are required to respond to this letter and must follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC website at: <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. Information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

This letter's Enclosure contains Security-Related Information.
When separated from the Enclosure, this letter is decontrolled.

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The Enclosed Notice contains Security-Related Information under 10 CFR 2.390(d)(1), and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in the enclosure will not be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Document Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If Security-Related Information is necessary to provide an acceptable response, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1). In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response.

During the inspection, your corrective actions related to the Notice of Violation and Special Inspection Report 030-35486/2015-001 (EA-16-006) dated June 3, 2016, were reviewed. The NRC's review of these corrective actions was discussed in detail with you during the November 2, 2016, telephonic exit meeting. The following is a summary of our review and provides the current status of the violations.

In the June 3, 2016, Notice, the first two violations were categorized as a Severity Level III problem. These violations were closely interconnected and not separate regulatory breakdowns. The violations involved 10 CFR 33.13(c)(3) and License Condition 24 of NRC License 11-27680-01MD, Amendment 26. Based on the inspection observations, you have taken a number of corrective actions to address the violations, including, but not limited to: the revision of existing administrative procedures, the development of new administrative procedures, and providing training to applicable staff and supervisors regarding the new or revised procedures. As noted in your Predecisional Enforcement Conference presentation, the changes to the ALARA Committee review process must be sustainable in the long term. The inspection revealed examples of procedural changes that appear to have warranted full ALARA Committee review, but were not presented to the full ALARA Committee. The decision-making process for not presenting the items to the full ALARA Committee was not documented. This was discussed with the Radiation Safety Officer at the conclusion of the onsite inspection. Following the inspection, the licensee made changes to its Document Change Request Form to better address the requirements of License Condition 24 of NRC License 11-27680-01MD, Amendment 26, and to better document its decision-making processes. This and other actions taken should help you be more effective in addressing underlying issues that were identified in both the NRC's and your causal analysis of the overexposure event. The NRC needs to observe sustained performance such that there will not be a recurrence of the same issues that led to the violations occurring. As a result, these two violations, which were categorized as a Severity Level III problem, cannot be closed at this time. We will review your additional corrective actions during a future inspection. If you wish to provide information related to the additional corrective actions that were put in place after the July 12-13, 2016, inspection, you may provide that in your response to the Notice or through a separate correspondence.

The third Severity Level III violation in the June 3, 2016, Notice, was related to License Condition 25 of NRC License 11-27680-01MD, Amendment 26, regarding the failure to follow procedures and stop work when an electronic dosimeter alarmed. Your corrective actions were reviewed during the inspection. These included: revisions to your radiation work permit process and updating certain job position descriptions and training materials for those jobs. You also reviewed and established methods for determining appropriate electronic dosimeter alarm set points based on expected radiation levels for specific work tasks. Training was conducted for

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appropriate staff for actions to take in response to a radiation area alarm. The inspection noted that on February 29, 2016, a situation occurred during a source transfer that resulted in an electronic dosimeter alarming. In this case, licensee personnel immediately stopped work and took appropriate actions to address the alarm. Based on this and other information gathered during the inspection, it appears that your corrective actions to address the violation have been effective. This violation is considered closed.

The fourth Severity Level III violation in the June 3, 2016, Notice, was related to 10 CFR 20.1201(a)(1), for a failure to control the occupational dose to an individual to the annual limits of 5 rem total effective dose equivalent. The licensee's corrective actions included: the performance of its own dose assessment and an independent dose assessment, properly completing the individual's NRC Form 5, "Occupational Dose Record for a Monitoring Period" for calendar year 2015, and providing the completed NRC Form 5 to the individual. Additionally, there have been no recurrences of any personnel exposures in excess of NRC regulatory limit. This violation is considered closed.

If you have any questions concerning this matter, please contact Janine F. Katanic, PhD, CHP, of my staff at 817-200-1151 or the undersigned at 817-200-1191.

Sincerely,

/RA/

Ray L. Kellar, P.E., Chief
Nuclear Materials Safety Branch A
Division of Nuclear Materials Safety

License No.: 11-27680-01MD
Docket No.: 030-35486

Enclosure:
Notice of Violation (Notice)

cc w/ Enclosure:
State of Idaho Radiation Control Program Director

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If you have any questions concerning this matter, please contact Janine F. Katanic, PhD, CHP, of my staff at 817-200-1151 or the undersigned at 817-200-1191.

Sincerely,

/RA/

Ray L. Kellar, P.E., Chief
Nuclear Materials Safety Branch A
Division of Nuclear Materials Safety

License No.: 11-27680-01MD

Docket No.: 030-35486

Enclosure:
Notice of Violation (Notice)

cc w/ Enclosure:
State of Idaho Radiation Control Program Director

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ADAMS ACCESSION NUMBER – PUBLIC LETTER: ML16312A384

ADAMS ACCESSION NUMBER – NON-PUBLIC LETTER W/Enclosure: ML16312A374

Cover Letter (w/o Enclosure) X SUNSI Review by: JFK		ADAMS X Yes <input type="checkbox"/> No	X Publicly Available <input type="checkbox"/> Non-Publicly Available	X Non-Sensitive <input type="checkbox"/> Sensitive	Keyword: N/A
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