



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

June 3, 2016

EA-16-006
EN-51331

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

SUBJECT: NOTICE OF VIOLATION AND NRC SPECIAL INSPECTION
REPORT 030-35486/2015-001

Dear Mr. Laffin:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) special inspection that was conducted on August 21-22, and September 14-16, 2015, at your facility in Idaho Falls, Idaho, with continued in-office review through February 19, 2016. The inspection was conducted in response to a reportable event (Event Notification 51331) that occurred on August 20, 2015, involving a personnel radiation exposure that exceeded the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201(a)(1). The significance of the issues leading up to the overexposure event and the need for lasting and effective corrective actions were discussed with you during an exit meeting on February 19, 2016. The results of the inspection and details regarding the apparent violations were provided in NRC Inspection Report 030-35486/2015-001, dated March 18, 2016, Agencywide Documents Access and Management System (ADAMS) ML16028A493.

On May 3, 2016, a predecisional enforcement conference was conducted in the NRC Region IV office with you and another member of your staff to discuss the apparent violations, their significance, root causes, and your corrective actions. The predecisional enforcement conference summary, including the information you presented during the conference, is documented in ADAMS (ML16132A250).

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that four violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

Specifically, the violations involved the failures to: (1) establish appropriate administrative procedures that assured the completion of safety evaluations of proposed uses of byproduct material and the review, approval, and recording by the radiation safety committee to assure safe operations; (2) obtain prior Commission approval for activities that had not been documented, reviewed, and approved by the as low as reasonably achievable (ALARA) safety committee; (3) stop work when an unsafe condition existed and an electronic dosimeter alarmed; and (4) control the occupational dose to an individual adult to the limits specified in 10 CFR 20.1201(a)(1).

The causes of the above violations include: the failure to provide a sufficient level of oversight of the implementation and approval responsibilities of your ALARA committee, the lack of mechanical barriers in the design of the transfer cask to prevent the removal of the source drawer, and the lack of formal instructions to control and implement safe radiological work activities while performing a cask-to-cask source transfer that resulted in the exposure of one of your technicians to radiation in excess of regulatory limits (overexposure event).

The NRC categorized the violations in accordance with the NRC Enforcement Policy. The first two violations contributed to the overexposure event. These violations were the result of a common cause of inadequate management oversight and are characterized as a Severity Level III problem. The third violation involved the failure to stop work when an individual's electronic dosimeter alarmed. A potential consequence is associated with this violation, in that, the failure to stop work when an electronic dosimeter alarms may cause unnecessary exposure to the individual wearing the dosimeter and other employees working in the area. This violation was characterized as a Severity Level III violation. The fourth violation was the overexposure event. Based on the cumulative annual total effective dose equivalent for the individual, the violation was characterized as a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last 2 years or the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC considered the information you provided in your letters dated September 17, 2015 (ML15273A053), and October 1, 2015 (ML15279A453), as well as the information you provided during the predecisional enforcement conference on May 3, 2016.

Your corrective actions included: (1) implementation of physical safety precautions for the equipment and casks; (2) modifications and changes to procedures that incorporated additional safety measures when handling the equipment and casks; (3) updating position descriptions and on-the-job training qualification documents to incorporate specific requirements for handling the equipment, casks, and significant quantities of radioactive material; (4) performing training on the new and revised procedures; and (5) incorporating specific thresholds in procedures for when a full ALARA committee review was required for specific procedures, designs, equipment, and processes. In addition, during the predecisional enforcement conference, you informed the NRC that the significant lessons learned from the event have been shared with the industry at the Eastern Idaho Health Physics Society and you have proposed to present the same at the Health Physics Society Annual Meeting.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III violations constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in your letters dated September 17 and October 1, 2015, as well as the information you provided during the

S. Laflin

- 3 -

predecisional enforcement conference on May 3, 2016. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's ADAMS, accessible from the NRC 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.

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 information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the basis for your claim, (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.) The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

If you have any questions concerning this matter, please contact Mr. Ray Kellar of my staff at 817-200-1191.

Sincerely,

/RA/

Kriss M. Kennedy
Deputy Regional Administrator

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

Enclosure:
Notice of Violation

cc: Mark Dietrich, Administrator
Technical Services Division
Idaho Department of Environmental
Quality
1410 North Hilton
Boise, ID 83706

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Kriss M. Kennedy
Deputy Regional Administrator

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Notice of Violation

cc: Mark Dietrich, Administrator
Technical Services Division
Idaho Department of Environmental
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1410 North Hilton
Boise, ID 83706

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Letter to Mr. Steve Laflin from Mr. Kriss M. Kennedy, dated June 3, 2016.

SUBJECT: NOTICE OF VIOLATION AND NRC SPECIAL INSPECTION
REPORT 030 35486/2015-001

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NOTICE OF VIOLATION

International Isotopes, Inc.
Idaho Falls, Idaho

Docket: 030-35486
License: 11-27680-01MD
EA-16-006

During an NRC inspection conducted between August 21, 2015, and February 19, 2016, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 33.13(c)(3) requires, in part, that the licensee establish appropriate administrative procedures to assure completion of safety evaluations of proposed uses of byproduct material; and the review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prior to use of the byproduct material.

The licensee established the following two administrative procedures to implement 10 CFR 33.13:

- 1) Licensee Policy Document, PD-RSP-001, "Radiation Safety Manual," Revision C, dated August 24, 2010, and
- 2) Licensee Operating Procedure, OP-QMS-011, "Product Development and Design Control," Revision B, dated April 18, 2012.

Contrary to the above, as of August 20, 2015, the licensee failed to establish appropriate administrative procedures to assure completion of safety evaluations of proposed uses of byproduct material; and the review, approval and recording by the radiation safety committee of the safety evaluation prior to the use of the byproduct material.

Specifically, the licensee developed and designed a shielded cask (MLC cask) for transferring a 3,664 curie cobalt-60 source to another cask in air without the review, approval, and recording by the radiation safety committee (ALARA committee). The licensee's Policy Document PD-RSP-001 and Operating Procedure OP-QMS-011 did not contain specific criteria that would ensure licensee personnel would take the development and design of the MLC cask to the ALARA committee. As a result, there was no procedure, training, and limited risk management oversight of the source transfer using the MLC cask, which contributed in an over-exposure event on August 20, 2015.

- B. NRC License 11-27680-01 MD, Amendment 26, License Condition 24, requires, in part, that the licensee is authorized to make program changes and changes to procedures without prior Commission approval as long as the proposed revision is documented, reviewed, and approved by the licensee's ALARA committee in accordance with established procedures prior to implementation.

Enclosure

Contrary to the above, as of August 20, 2015, the licensee failed to obtain prior Commission approval for activities that had not been documented in a procedure, reviewed and approved by the licensee's ALARA committee. Specifically, the licensee failed to generate a procedure for conducting a source transfer using the MLC cask. Since the licensee did not obtain review and approval through the licensee's ALARA committee for a procedure or instruction, then the licensee was required to obtain prior Commission approval for this specific, non-routine use of byproduct material.

This is a Severity Level III problem (Section 6.3).

- C. NRC License 11-27680-01 MD, Amendment 26, License Condition 25, states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents submitted to the NRC. License Condition 25, Item D, identifies Procedure OP-RSP-001, "Radiological Work Permit," Revision B, was submitted to the NRC on August 25, 2010 (ML102500683).

Licensee Procedure OP-RSP-001, "Radiological Work Permit," Revision B, Section 7.4.3, requires, in part, that the radiation safety officer, health physics technicians, or radiological workers are required to stop work whenever an unsafe condition exists or an electronic dosimeter alarms.

Contrary to the above, on August 20, 2015, licensee personnel failed to stop work when an electronic dosimeter alarmed. Specifically, a radiological worker's electronic dosimeter alarmed and the individual did not stop work but continued to assist with the source transfer. The other radiological workers, as well as the health physics technician, also continued to work after they heard a high radiation area alarm (indicating an unsafe condition existed), as well as the electronic dosimeter alarm.

This is a Severity Level III violation (Section 6.3).

- D. 10 CFR 20.1201(a)(1) requires, in part, that licensees shall control the occupational dose to individual adults to an annual limit of 5 rems for the total effective dose equivalent.

Contrary to the above, on August 20, 2015, the licensee failed to control the occupational dose to an individual adult to an annual limit of 5 rems for the total effective dose equivalent. Specifically, during the process of performing a source transfer, an individual received 5.62 rem deep dose equivalent on August 20, 2015. The licensee subsequently summed the previous exposures for calendar year 2015 and determined the cumulative annual total effective dose equivalent for the individual was 8.06 rem.

This is a Severity Level III violation (Section 6.7).

The NRC has concluded that the information regarding the reasons for the violations, the corrective actions taken and planned to take to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in the letters dated September 17, 2015 (ML15273A053), and October 1, 2015 (ML15279A453), as well as the information you provided during the predecisional enforcement conference on May 3, 2016.

However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-16-006", and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, U.S., Nuclear Regulatory Commission, Region IV, 1600 E. Lamar Blvd., Arlington, TX 76011-4511.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you are required to post this Notice within 2 working days of receipt.

Dated this 3rd day of June 2016