



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

October 20, 2020

EA-20-073

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

SUBJECT: NOTICE OF VIOLATION AND EXERCISE OF ENFORCEMENT DISCRETION,
NRC INSPECTION REPORT 030-35486/2020-001

Dear Mr. Laflin:

This letter refers to the inspection conducted on February 25-28, 2020, at your facility in Idaho Falls, Idaho, with in-office review through May 20, 2020. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. A final exit briefing was conducted telephonically with you and your radiation safety officer on June 3, 2020, and the details regarding the two violations were provided in NRC Inspection Report 030-35486/2020-001, dated June 22, 2020, NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML20170A868.

On August 4, 2020, a predecisional enforcement conference was conducted with you and members of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that two 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. The violations involved: (A) the failure to have appropriate administrative procedures that assured the completion of safety evaluations to analyze the adequacy of equipment, the training and experience of users, and operating procedures to mitigate the risk of contamination release; and (B) the inappropriate approval of procedures by your radiation safety committee that decreased the effectiveness of the radiation safety program and changed the conditions of your NRC license.

The NRC considers the violations described above to be significant because the inadequate procedures, which your staff developed and approved in NRC jurisdiction, inappropriately allowed the use of a mobile hot cell and power tool for removing a sealed source from its source holder. Use of a mobile hot cell for this type of application is contrary to your NRC license and directly contributed to a significant contamination event at the University of Washington's Harborview Medical Center on May 2, 2019. While there were no overexposures during the

May 2, 2019, event, the NRC determined that the inappropriate use of a mobile hot cell and power tool to remove a sealed source from its source holder could have resulted in significant safety consequences. Specifically, the NRC determined that because the cesium-137 sealed source that was inadvertently breached contained a large amount of activity relative to the regulatory limits (either public or occupational) for inhalation dose, one or more personnel overexposures could have occurred under only slightly different circumstances. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level II problem. The Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$24,000 is considered for a Severity Level II problem.

In accordance with the civil penalty assessment process described in Section 2.3.4 of the NRC Enforcement Policy, the NRC considered whether credit is warranted for *Identification* and *Corrective Action* for violations characterized at Severity Level II. The NRC has determined that *Identification* credit is not warranted because the violations were revealed through the cesium-137 source breach event that occurred at the University of Washington's Harborview Medical Center on May 2, 2019. The NRC determined that credit is warranted for *Corrective Action* because: (1) you immediately suspended all field work operations to include not only self-shielded irradiator servicing/removal, but also field work for resourcing teletherapy and gamma knife devices worldwide; (2) you submitted a license amendment on April 20, 2020, requesting removal of the authorization for all field service activities from your license; and (3) on May 21, 2020, the NRC issued Amendment 39 to remove all field service activities from your license.

Normally for a Severity Level II problem, without credit for *Identification*, the NRC would assess a base civil penalty in the amount of \$24,000. However, in recognition of your significant actions to terminate all field service activities and remove them from your license, and in consultation with the Director, Office of Enforcement, I have been authorized to exercise enforcement discretion, in accordance with Section 3.6 of the NRC Enforcement Policy, and refrain from proposing the base civil penalty of \$24,000. In addition, issuance of this Notice constitutes an escalated enforcement action that may subject you to increased inspection in the future.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you should provide it in your response to the Notice. 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 and Procedure," a copy of this letter, the enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or in 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 or proprietary information so that it can be made available to the public without redaction. 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 Ms. Patricia Silva of my staff, at 817-200-1455.

Sincerely,

Scott A. Morris
Regional Administrator

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

Enclosure:
Notice of Violation

cc w/enc.:

Mark Dietrich
Radiation Control Program Director
Idaho Department of Environmental Quality
1410 North Hilton Drive
Boise, ID 83706

Mikel Elsen, Director
Office of Radiation Protection
Washington Department of Health
243 Israel Road, SE
P.O. Box 47827
Olympia, WA 98504

NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-35486/2020-001 - DATED OCTOBER 20, 2020

DISTRIBUTION:

RidsOeMailCenter Resource;
 RidsSecyMailCenter Resource;
 RidsEdoMailCenter Resource;
 RidsOiMailCenter Resource;
 SMorris, RA
 JMonninger, DRA
 MMuessle, DNMS
 LHowell, DNMS
 PSilva, DNMS
 JLThompson, DNMS
 RErickson, DNMS
 JCook, DNMS
 MBurgess, NMSS

RidsNmssOd Resource;
 RidsOcaMailCenter Resource;
 EDO_Managers;
 RidsRgn1MailCenter Resource;
 BMaier, ORA
 JGroom, ORA
 JKramer, ORA
 PJayroe, ORA
 JWeaver, ORA
 VDricks, ORA
 RSun, NMSS
 DCylkowski, ORA
 KWilliams, NMSS

RidsOgcMailCenter Resource;
 RidsOigMailCenter Resource;
 RidsOcfoMailCenter Resource;
 RidsRgn3MailCenter Resource;
 GWilson, OE
 FPeduzzi, OE
 JPeralta, OE
 PSnyder, OE
 AMoreno, CA
 JWeil, CA
 RSkokowski, OEDO
 R4DNMS_MLIB

S:\RAS\ACES\ENFORCEMENT_EA CASES - OPEN\INIS EA-20-073\Final Action\NOV_EA-20-073_International_Isotopes.docx

Cvr Ltr & Encl: ADAMS ACCESSION NUMBER: **ML20294A080**

SUNSI Review: JGK ADAMS: Non-Publicly Available Non-Sensitive Keyword: By:
 Yes No Publicly Available Sensitive

OFFICE	SES:ACES	C:MLIB	TL:ACES	RC	OE	NMSS
NAME	JKramer	PSilva	JGroom	DCylkowski	GWilson	KWilliams
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	09/28/20	09/28/20	09/28/20	10/01/20	10/02/20	10/06/20
OFFICE	D:DNMS	RA				
NAME	MMuessle	SMorris				
SIGNATURE	/RA/ E	/RA/ E				
DATE	10/15/20	10/20/20				

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

International Isotopes, Inc.
Idaho Falls, Idaho

Docket No. 030-35486
License No. 11-27680-01MD
EA-20-073

During an NRC inspection conducted from February 25-28, 2020, two 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)(ii) requires, in part, that the licensee establish appropriate administrative procedures to assure completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of equipment, training and experience of the user, and the operating or handling procedures.

Contrary to the above, from May 4, 2017, to May 2, 2019, the licensee failed to establish appropriate administrative procedures to assure completion of safety evaluations of proposed uses of byproduct material which took into consideration such matters as the adequacy of equipment, training and experience of the users, and the operating or handling procedures.

Specifically, the licensee developed procedure, OP-SRC-040, "JL Shepherd Model Mark 1 Series Irradiator Source Unloading," Revision A, effective May 4, 2017, and procedure OP-SRC-040, "JL Shepherd Model Mark 1 and 143 Series Irradiator Source Unloading," Revision B, effective April 29, 2019, without performing an adequate safety evaluation to analyze the adequacy of equipment, the training and experience of users, and operating procedures to mitigate the risk of contamination release. The procedure instructed staff to cut the irradiator's source holder within a mobile hot cell using a power tool to remove the sealed sources, and failed to identify the potential safety and engineering controls required if a source were to be breached during removal, as occurred during the contamination event on May 2, 2019, in Seattle, Washington.

- B. NRC License 11-27680-01MD, Amendment 31 Condition 24(b) and Amendments 32-35 Condition 23(b) state, in part, that the licensee is authorized to make program changes and changes to procedures without prior NRC approval, as long as the revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the radiation safety program.

NRC License 11-27680-01MD, Amendments 31-35 Condition 16 states that sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee except as specifically authorized by this license.

Contrary to the above, from May 4, 2017, to May 2, 2019, the licensee failed to obtain prior NRC approval for changes to procedures that changed license conditions and decreased the effectiveness of the radiation safety program. Specifically, Step 7.4.3 of licensee procedures OP-SRC-040, "JL Shepherd Model Mark 1 Series Irradiator Source Unloading," Revision A, effective May 4, 2017, and OP-SRC-040, "JL Shepherd Model Mark 1 and 143 Series Irradiator Source Unloading," Revision B, effective April 29, 2019, instructed users to carefully cut the aluminum tube just below the pin if the pin cannot be

Enclosure

removed, an activity not in accordance with License Condition 16 (the license only authorized the use of the mobile hot cell for the removal of the source holder from the irradiator). Further, the instructions to cut the source holder increased the probability of contamination release without corresponding engineering or process controls to mitigate the potential consequences, thereby increasing the risk of performing licensed activities and decreasing the effectiveness of the radiation safety program as implemented at temporary job sites and resulted in the contamination event on May 2, 2019, in Seattle, Washington.

This is a Severity Level II problem (NRC Enforcement Policy Section 6.3.b.1).

Pursuant to the provisions of 10 CFR 2.201, International Isotopes, Inc. 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, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, and emailed to R4Enforcement@nrc.gov 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; EA-20-073" 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; 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, the NRC may issue an order or a demand for information requiring you to explain why your 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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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>. To the extent possible, your response should not include any personal privacy or proprietary 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 are required to post this Notice within 2 working days of receipt.

Dated this 20th day of October 2020