



International Isotopes Inc.

October 28, 2020

U.S. Nuclear Regulatory Commission,
ATTN: Document Control Desk,
Washington, DC 20555-0001

R4Enforcement@nrc.gov

Subject: Reply to a Notice of Violation; EA-20-073
Docket No. 030-35486

Dear Sir or Ma'am,

The purpose of this letter is to provide International Isotopes Inc.'s (INIS) written response to the notice of violation (NOV), EA-20-073 dated October 20, 2020. We appreciate the acknowledgment of the corrective and preventive actions that we took to prevent recurrence of such an event.

We have reviewed the EA-20-073 NOV's that were provided in the October 20th letter and find them to be accurate and do not dispute NRC's findings and conclusions.

While amending our license to remove the authorization for field service work will prevent recurrence of an event associated with source handling work in the field, we took the further step of curtailing all cobalt-60 source manufacturing and handling activities at our facility pending the internal review and risk assessment of those procedures. We have also contracted with a third party radiation safety consultant to act as an independent reviewer to support INIS ALARA committee reviews and evaluations on an "as needed" basis. In the course of conducting these additional reviews we identified additional areas for improvement in the radiation safety program. All corrective actions resulting from those observations have been completed. A summary of the corrective and preventive actions that have been identified to prevent recurrence, are provided in Attachment 1: Corrective (CAR) and Preventative (PAR) Actions Table.

Please contact me if you have any questions or require additional information on the corrective and preventative actions that we have taken.

Sincerely,

Steve Laflin, President and C.E.O.

STL-2020-07

Enclosure: Attachment 1: Corrective (CAR) and Preventative (PAR) Actions Table

Copy

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| Corrective Action | CAR/PAR | Status |
|--|--------------|----------|
| 1. Corporate decision to cease field service operations. Request to remove field service authorizations from NRC license 11-27680-01MD submitted to NRC. | CAR-SRC-028 | Complete |
| 2. Limit Co-60 source production activities to only those activities that have been evaluated by ALARA committee. Prioritize reviews based on upcoming Co60 source manufacturing campaigns and other activities. | CAR-SRC-028 | Complete |
| 3. Review OP-QMS-012 Rev C Failure Mode Effects Analysis Procedure and Form F-243, Failure Mode and Effects Analysis (FMEA) Form against ISO 30001:2018 Risk Management – Guidelines | CAR-SRC-028 | Complete |
| 4. Reevaluate and revise as necessary Failure Mode and Effects Analysis (F-243) for Co-60 products to include process steps that could affect the safety of the employee, public or environment. | CAR -SRC-028 | Complete |
| 5. Revised PD-RSP-001, Radiation Safety Manual by: <ul style="list-style-type: none"> a) Clearly identifying the make-up of the ALARA Committee, including Independent Radiation Safety Consultant b) Adding clarification to the public dose evaluation c) Adding section on Authorized Users | CAR -SRC-031 | Complete |
| 6. Developed Form F-542 Authorized User Approval to document review and approval of authorized users. | CAR -SRC-031 | Complete |
| 7. CPM review on-the-job training checklists for hot cell technicians to ensure all necessary training skills are included. | CAR -SRC-031 | Complete |
| 8. Review Health and Safety Manual, update Safety Culture policy statement accordingly, and ensure safety messages are communicated to employees on a regular basis. | CAR-SRC-027 | Complete |
| 9. Review annual employee safety training and verify it is complete and adequate. | CAR-SRC-027 | Complete |
| 10. Revised Document Change Form F-77 by: <ul style="list-style-type: none"> a) Including an evaluation of the change to consider if there is an increase in the probability or severity of any radiological or safety event impacting personnel, facility or the environment/public. b) Requiring ALARA Chairman to perform first evaluation of the change, c) Including a block for requiring Risk Assessment of the change | CAR -SRC-028 | Complete |
| 11. Revised OP-ADM-002, Document Change Procedure to incorporate changes to F-77 | CAR -SRC-028 | Complete |
| 12. Consolidated Forms F-527 ALARA Committee Evaluation Form and F-267 ALARA Committee Review Form. Made F-267 obsolete. | CAR -SRC-028 | Complete |

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| 13. | Revise OP-QMS-021 to specify that training is to be documented and how to document training that may not include a certification upon completion. | PAR-SRC-003 | Complete |
| 14. | RSO to add the specific dates and attendees of applicable training in the report review table and all future vendor training will be provided to QA and retained in employee training records. | PAR-SRC-003 | Complete |
| 15. | Revise OP-QMS-021 to specify that training is to be documented and how to document training that may not include a certification upon completion. | PAR-SRC-003 | Complete |
| 16. | Review and revise RWPs to remove 1.0 DAC or provide clarification that indicates contamination hold point will limit airborne level. | CAR-SRC-029 | Complete |
| 17. | RSO to review NRC/DOE/OSHA incident reports and develop lessons learned from real events similar or related to INIS operations and incorporate these into regular safety meetings and training as appropriate. | PAR-SRC-002 | Complete |
| 18. | Review all INIS procedures and forms to identify those procedures and forms that are only administrative in nature or do not have any safety consequences. | CAR -SRC-028 | Complete |