

International Isotopes Inc.
Presentation to
U.S. Nuclear Regulatory Commission
Pre-Enforcement Meeting

August 4, 2020

I³ US NRC Notice of Violation

Two Violations were cited

1. Failure to have appropriate administrative procedures to ensure completion of safety evaluations

INIS does not dispute violation #1

2. Licensee approved procedures that decreased the effectiveness of the radiation safety program

INIS requests NRC's consideration of the company's interpretation of permitted license activities in regard to violation #2

I³ Washington DOH Notice of Violation

Two Violations were cited

1. Failure to obtain a radioactive air emissions license
2. Failure to control the release

I³ Interrelationship of the Violations Cited

NRC Cited Violation #1 - - Failure to have appropriate administrative procedures to ensure completion of safety evaluations

Contributed to ...

NRC Cited Violation #2 -- Licensee approved procedures that decreased the effectiveness of the radiation safety program

And also resulted in...

WA DOH Violation #1 – INIS Failure to obtain a radioactive air emissions license

I³ Violation #1 Root Cause Discussion

An Adequate risk assessment and ALARA review of OP-SRC-040 had not been completed

- Initial MHC process was thoroughly reviewed by management

- Revisions and new procedures did not adequately consider all risks

Some explanation is worthwhile to understand why this occurred

Explanation is not intended to be an excuse for our actions

INIS attended training at SWRI

SWRI trained on methods of source removal from source holders

- Hammering roll pins discouraged
- Drilling roll pins discouraged
- Grinding roll pin was the recommended method

Assumed cutting would be done at a “safe” distance from the source

The INIS process did not provide adequate visual clarity in the MHC

The INIS hardware did not adequately secure the source in position

A proper risk assessment for adopting this method was not completed

The NRC inspection report states...

"The inspectors determined that INIS was not authorized by the NRC to remove the sealed source from its holder in the field using the MHC."

"It was further determined that INIS approved this procedure for cutting the source holder in the MHC without NRC's approval..."

The changes violated license conditions 16 and 23

I³ The Evolution of INIS's Source Recovery Process

Initial development of the INIS Mobile Hot Cell (MHC) ~2013

Six years of safe operations

- 16 different locations

- 1,180 sources safely removed

- Initial license listed 6 specific devices, Amendment 26 August 2014 added any device so long as evaluated using INIS design control procedures.

All source recovery operations have involved the removal of a source(s) from the source holder, either cage/basket, drawer, or tube.

Document titled "Utilizing Mobile Hot Cell" submitted with license amendment request, Amendment 25

Procedure lists compatible Gamma cell units

- GC-10
- GC-40
- GC-100
- GC-200
- GC-220

Every one of these units contains sources within a basket, cage, or holder

I³ OP-SRC-024 Dated 6/28/13

International Isotopes Inc.

TITLE: Utilizing the INIS Mobile Hot Cell	Number: OP-SRC-024	Revision: B
		Effective Date: 6/14/2017

7.6.1 Remove source(s) from the device in accordance with manufactures instructions.
Document source removal in the table below:

Device Model/Serial No.:	Source Make	Source Model	Source Serial No.
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
12.			

Removed By: _____
Print name/signature _____ date _____

Use additional Sheets as Necessary

7.6.2 If necessary place source(s) in source canister (may be shielded) prior to loading into the transport package or shield cask.

7.6.3 Replace the device with the transport package or shield cask at the bottom of the MHC as applicable.

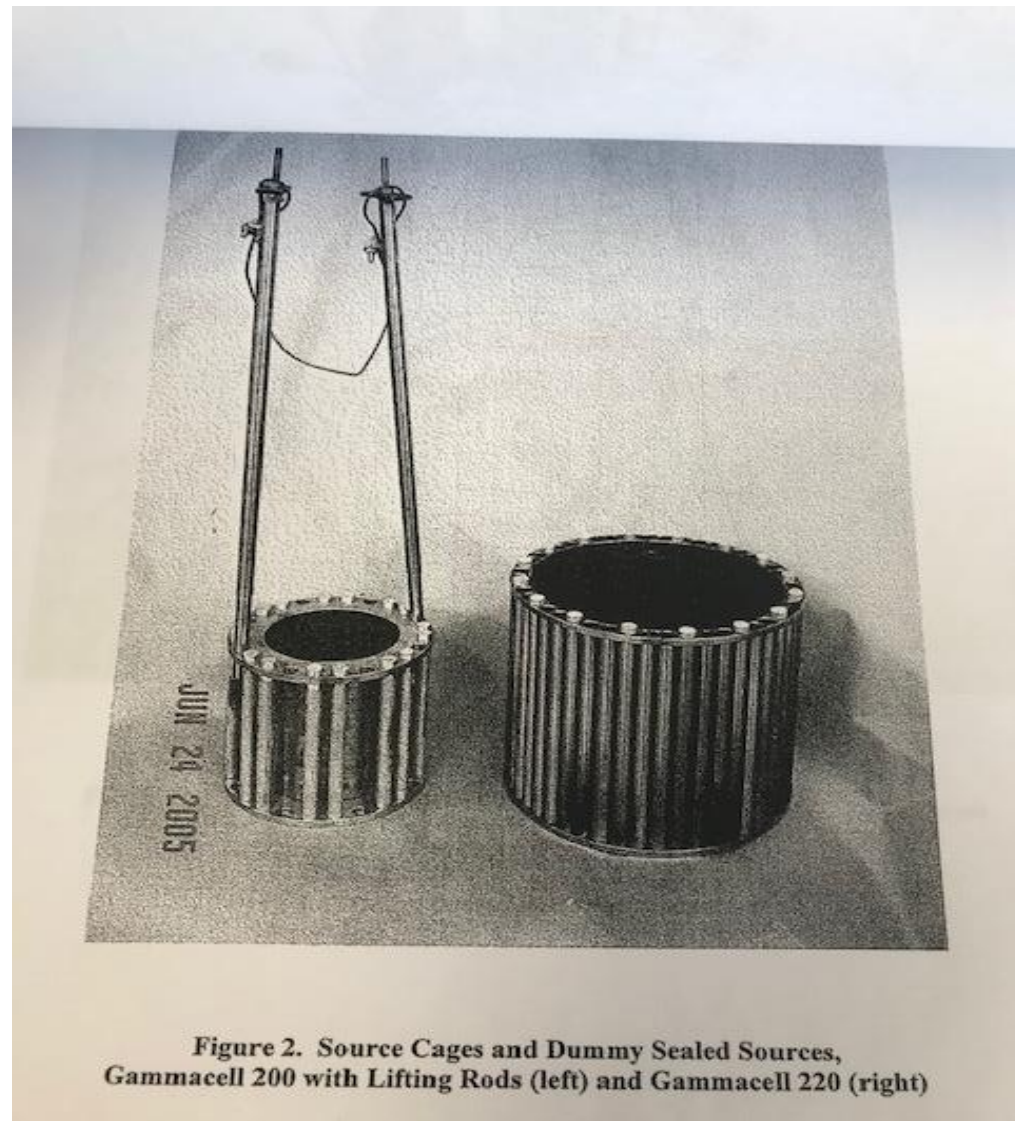
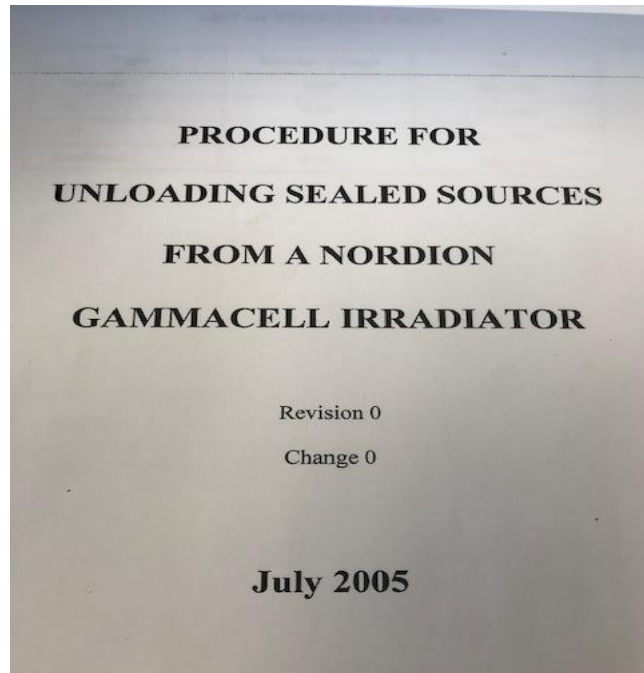
7.6.4 Transfer source canister into the transport package or shield cask .

7.6.5 Place shield plug over the transport package or shield cask this may be completed in the cell or as the transport package or shield cask is being removed from beneath the MHC if radiation levels are acceptable.

7.6.6 Place lid on transport package or shield cask in accordance with cask handling instructions.

OP-SRC-024 Obsolete

I³ GC Manufactures Instructions Manual



I³ INIS's Understanding of the NRC license

Condition 16 states "Sealed sources or detector cells containing licensed material shall not be opened or source removed from source holders by the licensee ***except as specifically authorized by this license.***"[emphasis added]

INIS has always considered that the specific authorization to perform that work on this device is contained within license condition 6.L which does specifically address the JLS model 6810 source (which includes the holder)

INIS believed that the accompanying description of Authorized Use contained in 9.L(i) which states "Pre-shipment activities such as preparing the contents for loading..." and 9.L.(iii) and 9.L.(iv) which allows transfer between devices not listed provided compatibility has been evaluated

Performing a transfer of the 6810 source from the device into a transportation package is not possible without removing the source from the holder and that was known in advance and considered in the work planning.

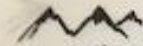
I³ OP-SRC-026 Dated 5/6/14



International Isotopes Inc.

TITLE:	Number:	Revision
JL Shepherd Model 109 Irradiator Shipping & Source Unloading	OP-SRC-026	C
		Effective Date:
		9/26/2018

- 7.7.15 Carefully but quickly position the shield under the Mobile Hot Cell, remove the security plate and raise scissor lift until the shield is mated to the bottom of the cell. The top of the shield is 14" in diameter and should penetrate into the 15" bottom transfer hole of the Mobile Hot Cell 1".
- 7.7.16 To remove the first lead ring, insert a 3/8"-16 or 1/2"-13 threaded rod into the 2 threaded holes and tighten.
- 7.7.17 Raise the lead ring weighing approximately 55 lbs. with the in cell winch system and place the ring in a corner of the cell.
- 7.7.18 Remove the second ring in the same manner but using 1/4"-20 threaded rod. The second plug weighs approximately 10 lbs. Place this ring in a corner of the cell also.
- 7.7.19 If the source cage and source are not visible, then there may be an additional stainless steel ring that will need to be removed. To remove the stainless steel ring, use a 1/4"-20 threaded rod and remove the ring in the same manner as the above steps.
- 7.7.20 Once the source cage and sources are visible, use the 1/4"-20 threaded rod to remove the source cage.
- 7.7.21 Insert the 1/4"-20 threaded rod into the 2 holes on opposite sides of the cage. It may be hard to identify the holes as corrosion may obscure them.
- 7.7.22 Secure the rods into the source cage and raise the source cage into the cell. If the cage is stuck inside the shield, contact the RSO or designee for further instruction.
- 7.7.23 Once the cage is safely loaded into the Mobile Hot Cell, place the lid over the transfer port hole. The sources may now be removed from the source cage.
- 7.7.24 If the sources are stuck inside the source cage because of corrosion, a hammer and punch may be used to tap out the source. The source cage bottom has holes at approximately 1/4" in diameter. Also, the RSO or designee may direct the FST to use a solution of 10% Phosphoric acid concentration to be applied to the source until it is removable.
- 7.7.25 Place the unloaded sources into the in-cell storage cage as they are extracted from the source cage.



International Isotopes Inc.

TITLE:	Number:	Revision
JL Shepherd Model Mark 1 and 143 Series Irradiator Source Unloading	OP-SRC-040	B
Effective Date:		
04/29/2019		

7.3.17 If contamination results indicate a source may be leaking then replace the plug and return device into a safe and secure storage configuration.

7.3.18 If using the bottom load method, complete the next two steps and then continue with 7.4.

7.3.19 Cover the access hole for the source tube with a plug and place the in-cell port cover over the port hole.

7.3.20 Lower the lifting cable to allow for enough slack to move the source tube to a staging area in the mobile hot cell, and then remove the lifting hook.

7.4 Remove Source(s) from Source Tube

7.4.1 The aluminum source tube is threaded onto the end of the tungsten plug and prevented from back threading with a pin.

7.4.2 If there is no visible oxidation it might be possible to force the pin out of the hole with a drill bit die and hammer. An alternative method is to grind the aluminum tube and roll pin in the area of the pin hole. Grind enough of the aluminum and roll pin so that the tube can be removed from the tungsten plug.

7.4.3 If the pin cannot be removed then carefully cut the aluminum tube just below the pin.

7.4.4 Unthread the source tube from the tungsten plug.

NOTE: The source(s) will be positioned inside the source tube with spacers and/or tubes of various lengths.

7.4.5 Slowly remove the contents of the source tube onto a tray.

7.4.6 Perform a contamination survey on the contents of the source tube. Record results below:

Results: _____ RSO Signature: _____

7.4.7 If contamination results indicate a source may be leaking, then place the contents of the source tube, including the source(s), into the INIS-SF-OE-XX capsule. Decon as necessary and place into a safe and secure storage configuration.

7.5 Over Encapsulate Source(s)

I³ JLS Source Information

Theratron Source Drawer VS JLS Mark 1-68 source holder



USA/9215/B(U) Rev 15 Required:

- (1) Special Form Material
- (2) Contents must be secured in the drum assembly so as to restrict movement in any direction to less than 0.25 inch, by lead, steel, or tungsten full diameter plugs and spacers
- (3) In addition to the shielding provided by the shipping/transfer cask (S/TC) and S/TC cover, a minimum of 2 inches of lead, 2 inches of tungsten or 3 inches of steel shall be inserted between the source and the ST/C cover as axial shielding material in the drum assembly. This additional shielding material may be part of the plugs and spacers or part of the source drawer.

INIS' decision to remove source from holder was in order to meet these requirements.

Stop all Co60 hot cell and field service work activities

Complete reviews and risk assessments of all related procedures

Implement additional “independent” reviews

I³ Stop all similar work activities

Management terminated all future field service work activities

Amended the NRC license to remove field service activities from permitted operations

Terminate all Co-60 and source transfer procedures not planned for routine use – 34 documents

Evaluate the Risk Assessment and Safety Evaluation Process

Reviewed OP-QMS-012 Rev C Failure Mode Effects Analysis (FMEA) Procedure and determined the procedure addressed the risk assessment process

Completed an updated FMEA for cobalt operations, more from a cradle to grave perspective

Revised Radiation Safety Manual ALARA Committee & Evaluation Form

Strengthened risk assessment/safety assessment in the document change process

I³ F-77 Document Change Request Form Changes



International Isotopes Inc.

Document Change Request Form (DCR)

DCR No.	Re-routing ☐	Effective Date of Document:
TO BE COMPLETED BY ORIGINATOR		
(Use separate form for each document)		
☐ New Document	☐ Major Change	☐ Minor Change
☐ Grammatical/Formatting		
Submitted by:	Date	PRI
Document No.	Current Rev.	Business Segment
Document Title		
Other Documents Affected/Related		
Change Description:		
Reason for Change:		
Training Required?	Yes ☐ No ☐	Critical Training? Yes ☐ No ☐
Controlled Copy?	Yes ☐ No ☐	Binder Name:
Validation or Mock-Up Required?	Yes ☐ No ☐	Effectiveness Audit Required? Yes ☐ No ☐
Type of Validation or Mock-Up:		
Review required by RSO or ALARA and the following Areas:	☐ ADM ☐ EHS ☐ HR ☐ NUC ☐ QA ☐ RAD ☐ RSP ☐ PGX ☐ TRA ☐ SRC ☐ Other	

ALARA Chairperson:		
Does procedure implement or incorporate new or revised radiological controls?	Yes ☐	No ☐
Could this change increase the probability or severity of any radiological or safety event impacting personnel, facility or the environment/public?	Yes ☐	No ☐
Is an ALARA Committee Review required?	Yes ☐	No ☐
If the procedure changes radiological controls or effects risk but an ALARA Committee Review is not required explain in the space below:		
Signature: _____ Date: _____		

RSO or ALARA Chairperson Radiation Protection Program Evaluation:	
If procedure implements or incorporates new or revised radiological controls complete the section below:	
Does the revised document comply with regulatory requirements?	Yes ☐ No ☐
Does the revised document change the license conditions?	Yes ☐ No ☐
Does the revised document decrease the effectiveness of the Radiation Safety Program?	Yes ☐ No ☐
Is a formal Risk Assessment required?	Yes ☐ No ☐
Signature: _____ Date: _____	

1. Identifies magnitude of change, Major, Minor, Grammatical.
2. Require procedure review by RSO or ALARA in addition to affected sections.
3. ALARA Chair determines need for an ALARA Review.
4. ALARA Chair evaluates change against increase in probability or severity of an event.
5. Addresses formal risk assessment (using INIS FMEA process)



I³ F-77 Document Change Request Form Changes



International Isotopes Inc.

Document Change Request Form (DCR)

Review and Approval		Signature	Date	As Is	With Comments
Reviewer Name (to be completed by originator)	ALARA Committee				
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐

Comments (e.g. See Notes, Redlined in Drafts, etc. include additional sheets as necessary)	Initials	Date	Comments Resolved (initial)

ALARA Committee Comments	Initials	Date	Comments Resolved (Initial)

Document Control Information	
Number of Controlled Copies Distributed:	_____
Number of Official Documents Received at Document Control:	_____
Completed form and supporting documents are put into Master File	
Document Control (Print Name) _____	Signature _____
Date _____	Comments: _____

6. Rearranged Page 2, Review and Approval Section at top of page.
7. Added comment resolved column.
8. Added ALARA Committee Comments Section.

Completed form F-77 and handwritten comments on red-lined procedure with comment resolutions maintained in document history file.



Complete “Fresh” Risk Assessment Safety Evaluations of Co-60 and source handling OP’s and WI’s

6 ALARA review meetings conducted

21 procedures and work instructions reviewed to date

Some procedures received multiple reviews

2 walk throughs of procedures completed for ALARA committee

Several procedure reviews are still underway

I³ Corrective Actions - Continued

Implement additional “independent” reviews

Additional staff participation

Have contracted with Porter House Inc.

History of performance of independent reviews

Idaho National Laboratory

Savannah River Site

Mound

Nevada Test Site

Annual audit...Plus

- Other areas where they identify weakness or problems
- Participation on ALARA committee as appropriate
- Function as an independent auditor

I³ Conclusions and Considerations

- INIS does not dispute violation #1
- INIS requests NRC's consideration of the company's interpretation of permitted license activities in regard to violation #2
- INIS does request NRC consideration of the following when considering enforcement action
 - Overall performance of the INIS radiation safety program
 - INIS immediate and supplementary actions to try to reduce the consequences of the event
 - Additional timely corrective actions taken by INIS to prevent reoccurrence
 - INIS has already incurred significant financial impact from this event

Cancelations of over \$1 million in field service contracts

INIS expenditure time and over \$350,000 in internal costs for recovery

WA DOH civil penalty still pending

Possibility of future civil actions ²³against INIS