UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD
ARLINGTON TX 76011-4511

Licensee: International Isotopes, Inc.
Facility: Office in Idaho Falls, Idaho
License No.: 11-27680-01MD
Docket No.: 030-35486
EA-16-006

PREDECISIONAL ENFORCEMENT CONFERENCE SUMMARY

On May 3, 2016, representatives of International Isotopes, Inc. met with NRC personnel in the Region IV office in Arlington, Texas, to discuss the apparent violations identified in NRC Inspection Report Number 030-35486/2015-001. The conference was held at the request of the licensee.

The licensee presented a summary of the direct, contributing and root causes for the apparent violations and their corrective actions. The corrective actions discussed during the conference 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) performed training on the new and revised procedures; and 5) incorporating specific thresholds in procedures for when a full ALARA Committee review is required for specific procedures, designs, equipment, and processes. In addition, the licensee stated that they shared the significant lessons learned from the event with the industry at the Eastern Idaho Health Physics Society and have proposed to present the same at the Health Physics Society's Annual Meeting.

The attendance list and the licensee's partially redacted Power Point presentation are attached to this summary.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this summary and its enclosures will be made available to the Public.

Attachments:

1. Attendance List
2. Licensee Presentation

ATTENDANCE LIST

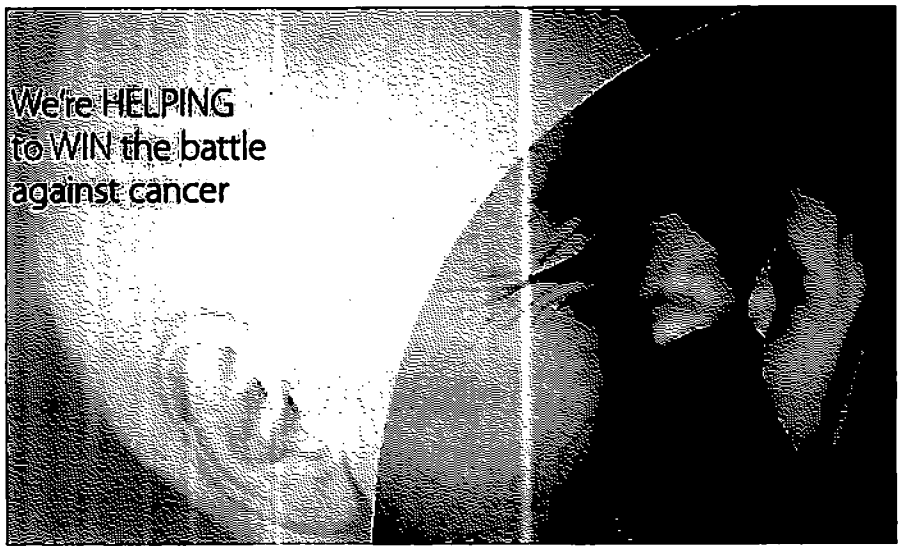
PREDECISIONAL ENFORCEMENT CONFERENCE

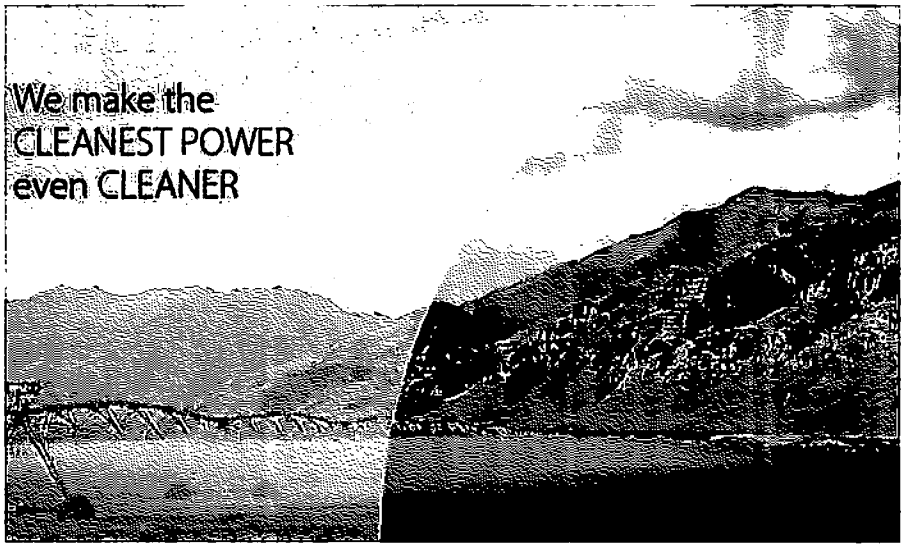
International Isotopes, Inc.

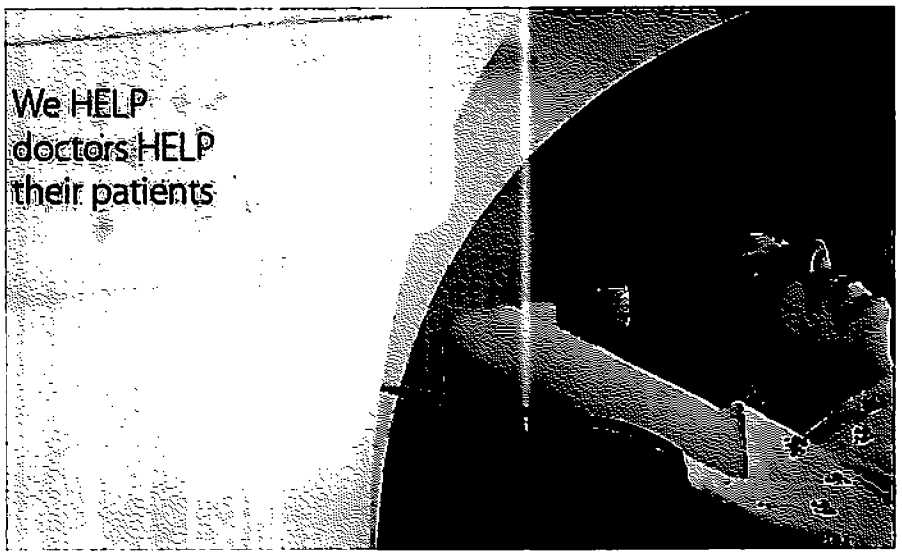
May 3, 2016

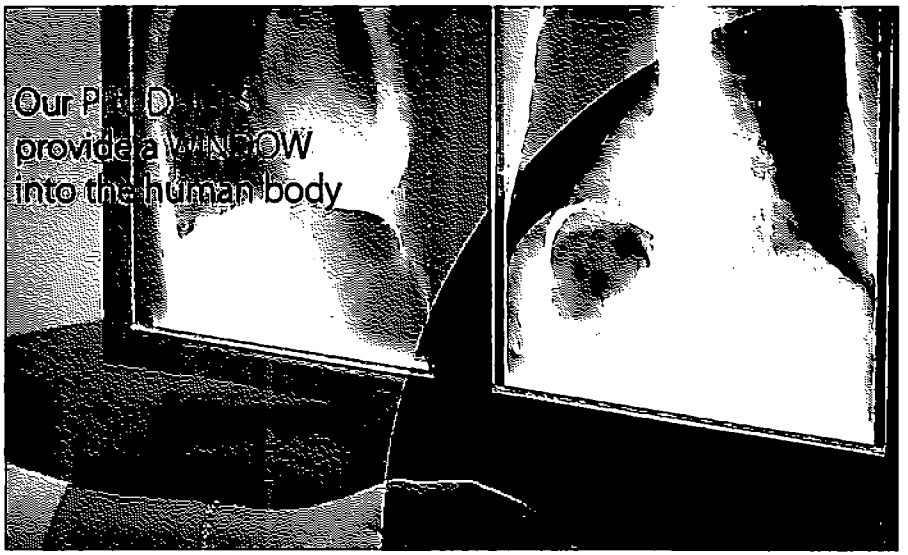
NAME	COMPANY / POSITION TITLE
JAMES L. THOMPSON	U.S. NRC, SR. INSPECTOR
Rachel S. Browder	U.S. NRC, Sr. Health Physicist
Ray Kellar	US NRC, Branch Chief
John Miller	International Isotopes Inc / RSO
STEVE LAFLIN	INIS CEO
Mark Shaffer	NRC / Director, DNMS
John Kramer	NRC / ACES Team Lead
Caleb vonEhr	NRC / Health Physicist (observing)
KARLA FULLER	NRC / RIV COUNSEL
SUE WOODS	NRC / OE
MICHELE BURGESS	NRC / NMSS
DAVID CYLKOWSKI	NRC / OGC
SOPHIE HOLIDAY	NRC / NMSS

International Isotopes Inc.









International Isotopes Inc.

Radiation Exposure Event

Of August 20, 2015

Investigation, Corrective Actions, and Considerations

Presented By: Steve Laflin

CEO International Isotopes Inc.

Agenda

- Brief Business Overview
- Set The Stage
- Description of the Event
- The Investigation and Dose Reconstruction
- Corrective Actions
- Comparison of INIS & NRC Reports
- INIS Event Response Considerations
- Concluding Points

Business Overview

Nuclear Medicine

Reference & Calibration Sources for PET & SPECT Imaging Equipment

Radiochemical & Radiopharmaceuticals

Precursors for Radiopharmaceutical Drug Products Such as I-131

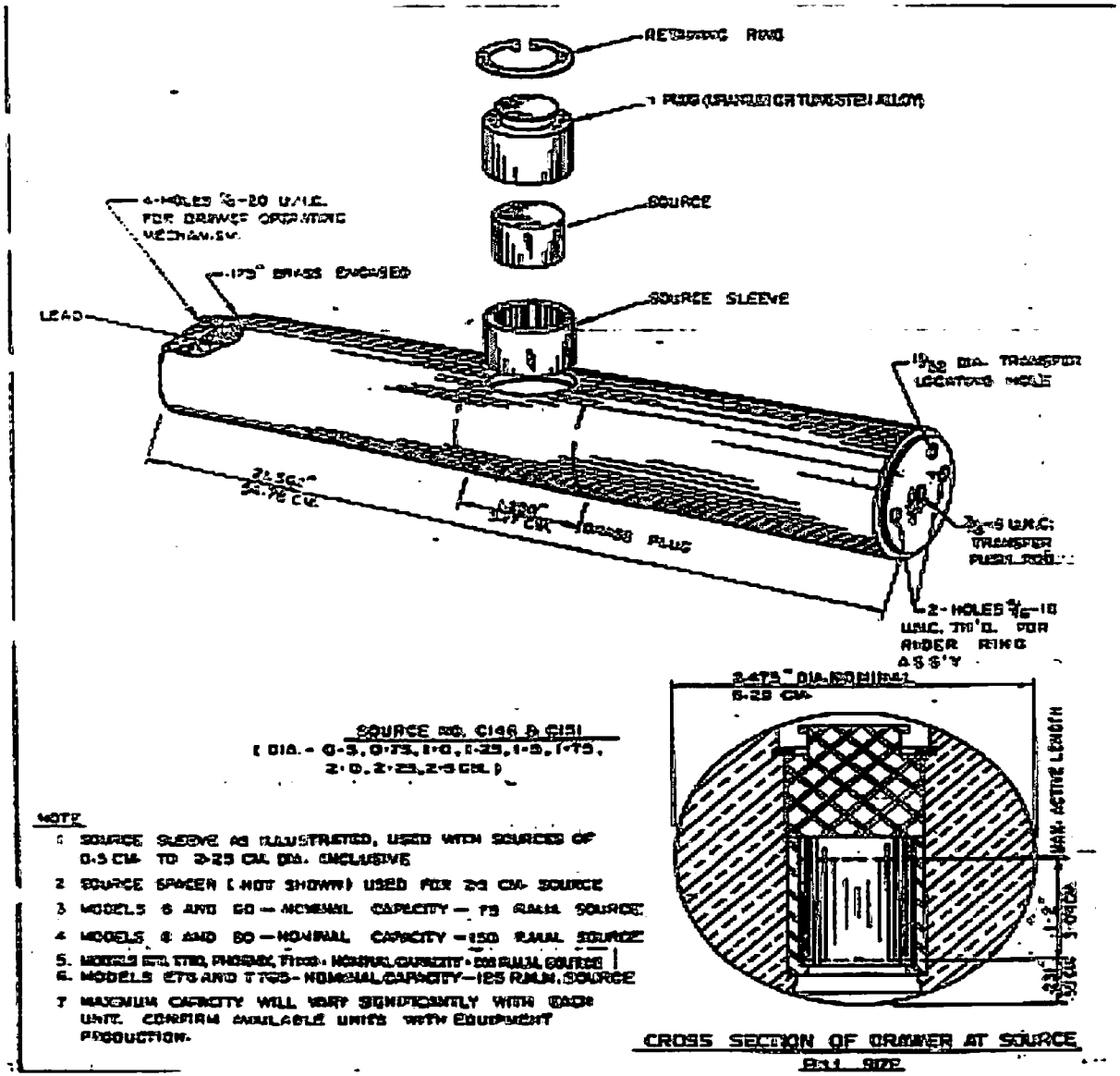
Radiological Services

Support Decommissioning Irradiator and Therapy Units Primarily DOE's OSRP

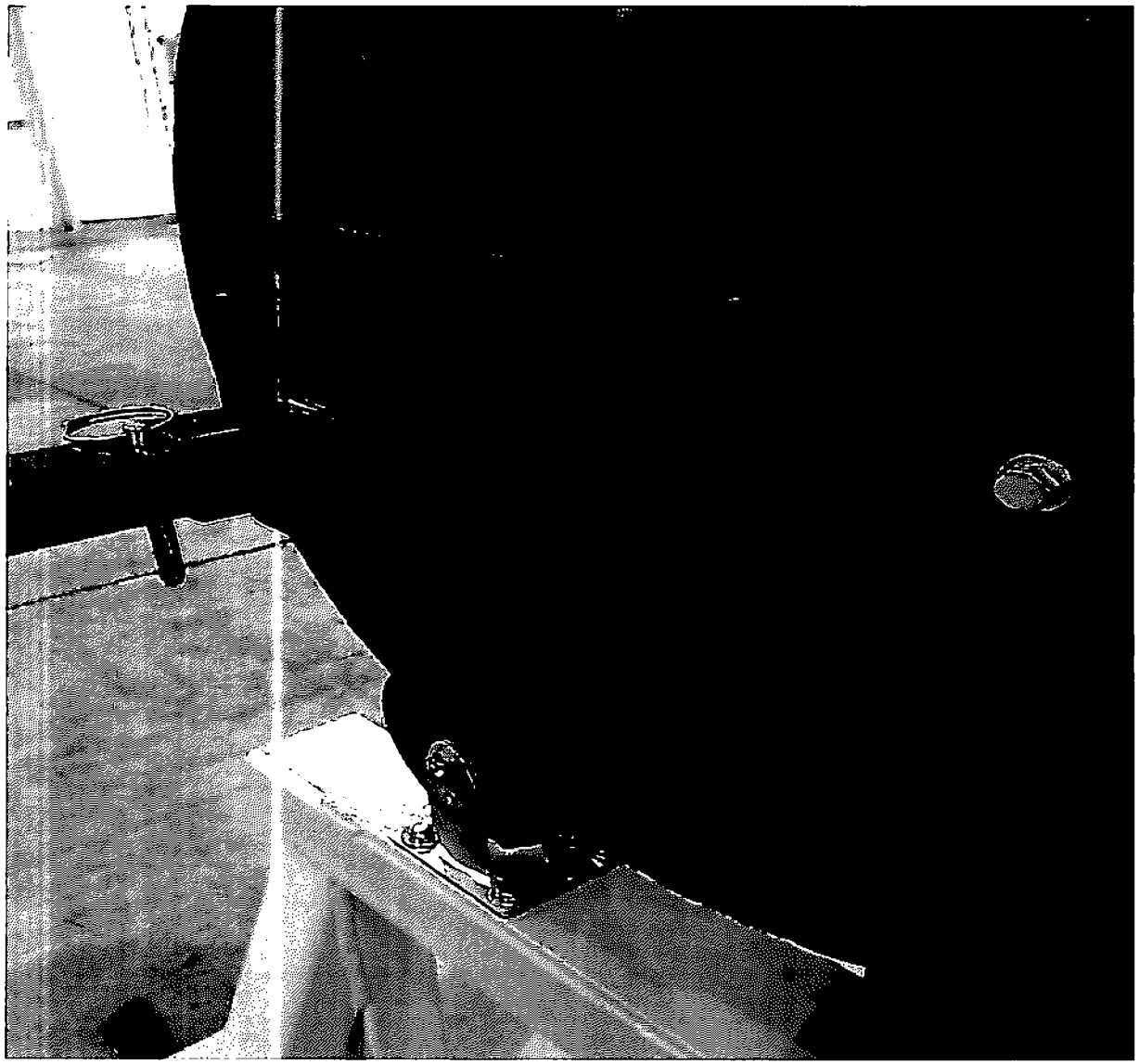
Cobalt Products

Raw Material & Finished Products For Radiation Therapy

Source Drawer



Source Drawer Blocking Device



SEQUENCE OF EVENTS

- The Event As Described by the Technician

And Then...

- The actual facts of the event shown by security video

Indications & Actions Continued

- Supervisor Investigates
- All Other Personnel ED Readings Normal (1-5 mRem)
- RCT Investigates - Technician ED Reading 5.62 Rem (Initially Not Disclosed)
- Management Informed
- NRC Emergency Operations Center Informed
  - WB gross estimate 15.8 Rem
  - 949 Rem possible estimate to left hand

Initial Actions and Investigation Steps

- Written statements collected from everyone involved
- Area set up photographed and positions measured
- Technician sent to local hospital for blood draw
- Baseline photographs taken of the technicians hands
- Dosimeters from all personnel in the area sent for emergency read – No Extremities
- Facility security system video reveals a different story!

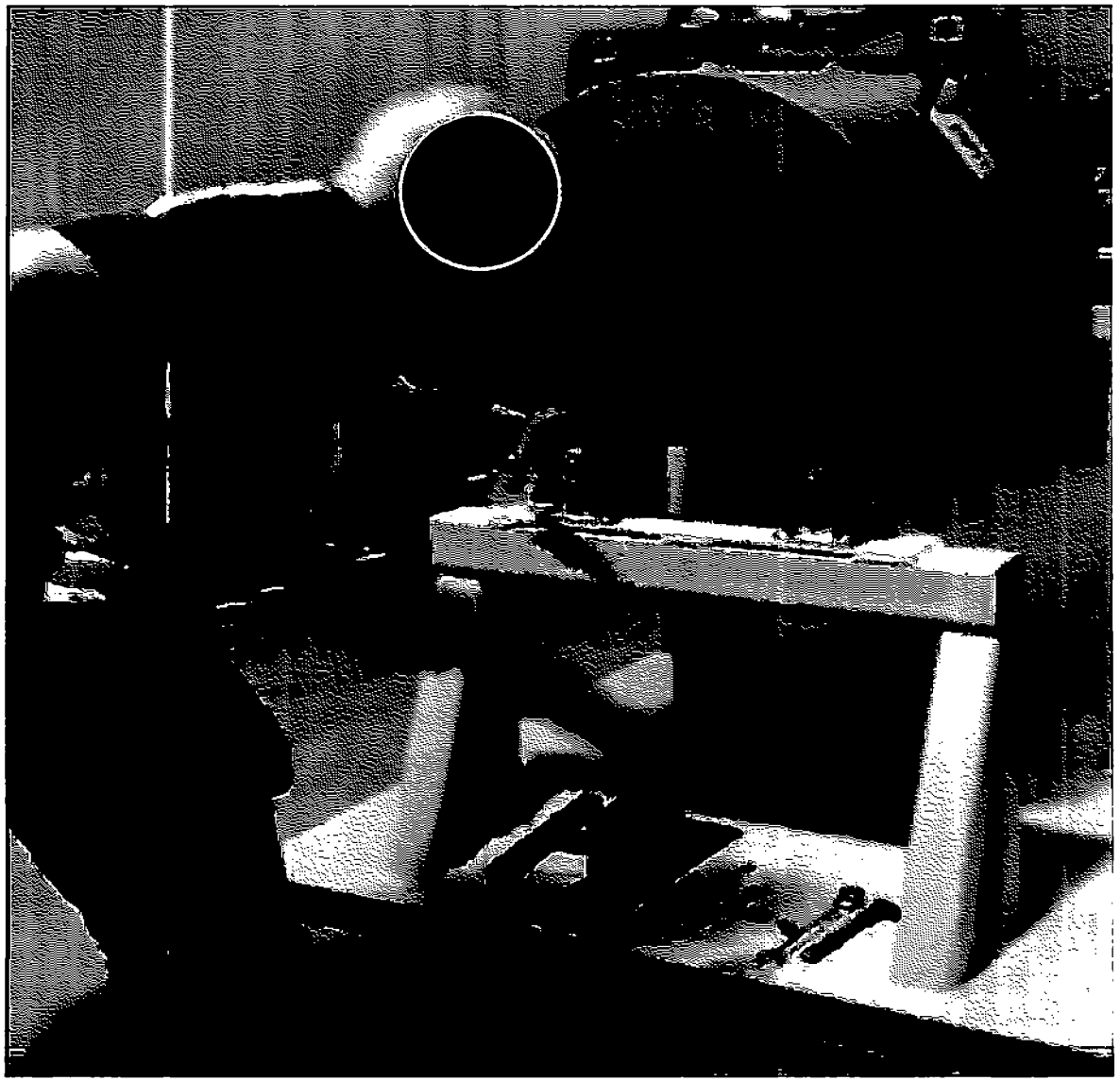
The Actual Event Continued

- The technician intentionally and completely removed the source drawer from the shield
- Mock-ups were conducted to replicate and confirm
- Security footage provided a good basis for modeling (Time stamps)
- Initial exposure estimates from RSO modeling
  - 7.2 Rem Whole Body
  - 37.1 to 49.1 Rem Extremities (Left hand)
- Next Day - results of OSL dosimetry – <u>201 Rem Whole body</u>

Subsequent Investigation Actions

- Based upon security video and mock-up daily photographic documentation of legs started
- Consultation with REAC/TS on blood work and exam protocol
- Daily photographs of hands and legs continued for 3 weeks
- Daily blood draws continued for one week – initial results "normal"
- Additional modeling made of the OSL dosimeter position
- No symptoms of radiation sickness

OSL and Whole Body Modeling



Investigation Actions Continued

- Company obtains an individual to perform an independent dose assessment
- Company contacts REAC/TS for performance of Cytogenetic Biodosimetry (8 days post event)
  - Utilizes lymphocytes from peripheral blood for assessment of doses to humans
  - Uses Dicentric Chromosome Analysis (DCA) – Considered the "gold standard" for dose estimation
  - Results compared to a linear-quadratic dose response curve
  - Can assess radiation exposures in the range from 0.25 Gy - 5 Gy (25 Rad – 500 Rad) 95% LCL
  - Cytogenetic Biodosimetry Results for the technician – <u>0.504 Gy (50 Rad)</u>

Shortcomings of Cytogenetic Biodosimetry

DCA is NOT good for estimating local or partial body non-uniform dose

All dose response curves for DCA are based upon uniform irradiations of small blood volume

Some modeling has been done of some non-uniform exposures but it is impossible to achieve any correlation at less than 2.5 Gy (250 Rad)

DCA dose assessment is only to be used as a "clinical screening tool" to determine if a dose may be of an acute medical concern

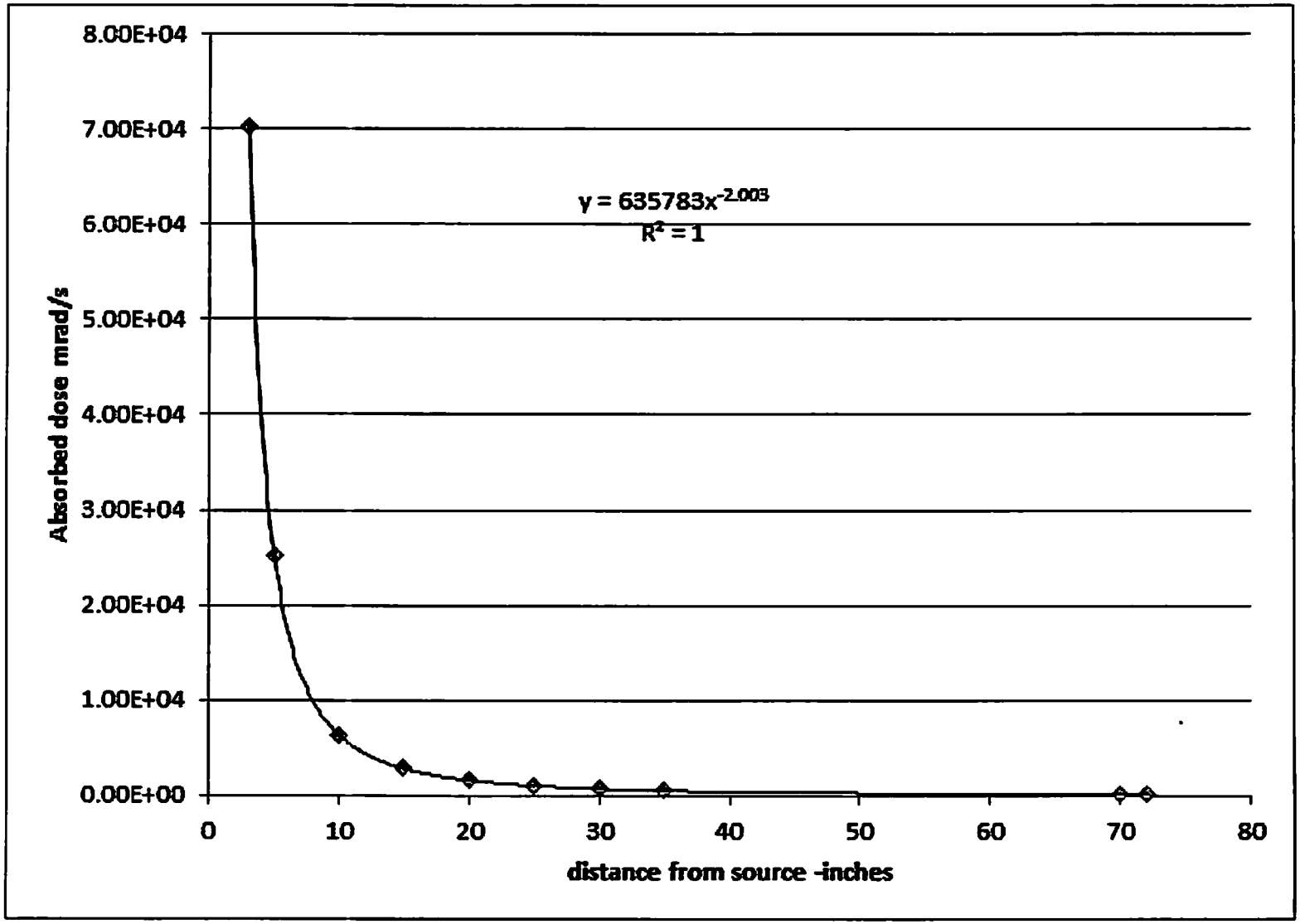
"I do not think it is appropriate to directly correlate dicentric assay results to whole body doses in the vast majority of accident scenarios involving non-uniform exposures to penetrating radiation". (Lead Health Physicist, REAC/TS)

Investigation Actions Continued

Results of independent dose assessment

Location	Absorbed Dose (rad)
Right Knee	2.6
Left Knee	10.4
Right hand	0.024
Left Hand	**38.2**
Right Ankle	1.2
Left Ankle	3.7
Waist	3.5
Sternum	**5.4**
Head lens of the eye	2.6

Dose Assessment



Final Dose Assessment

Whole body dose of 5.62 Rem (ED Reading)

Extremity dose of 38.4 Rem

Basis:

- Exposure time reduced from 5.5 to 4.3 seconds based upon frame by frame video analysis
- Modeled results to the ED comparable with the 5.62 Rem reading (within 20%)
- The ED was the only calibrated measurement device attached to the technicians torso
- Model of the OSL dosimeter confirmed a dose of 201 Rem could be collected in less than a second with the dosimeter hanging directly above the source
- Enhanced video images of security footage and mockup confirmed likely position of hands

Worth noting: NRC conducted independent modeling and did not dispute the Company findings and dose assignment

3 Weeks Post Event

Determination of Direct, Contributing, & Root Cause

- NUREG/CR-6751 "The Human Performance Evaluation Process"

- Barrier Analysis process selected
  - Determine the physical or management barriers in play
  - How did the barrier perform? (Pass/fail)
  - It if failed – WHY?
  - What was the effect of the failure?

Direct, Contributing, & Root Causes

- **Direct Cause** – Cognitive Error, loss of situational awareness or mental lapse
  - Very experienced technician
  - Distracted and hurrying through work
  - Had participated in multiple mock-ups with empty source drawers
  - NO MECHANICAL BLOCK OR VISIBLE WARNING PLACARD

- **Contributing Causes** – Training and inadequate procedures

- **Root Cause** –Poor coordination and work control
  - Multiple actions in progress in parallel
  - No morning or pre-job briefing
  - Two man rule not observed
  - NO STOP WORK ORDER GIVEN

Direct Cause

Direct Cause	DC #1	Corrective Action	LT or ST
Cognitive Error, loss of situational awareness			
No visible warning signs or placards	DC1	Develop and install highly visible warning placards on all surfaces of loaded containers.	LT
No "two person rule" for safety significant evolutions	DC2	Modify all source handling procedures and RWP's to require two people present to observe and verify actions when deemed important to safety.	LT
Need improved mechanical safety block	DC3	Review and revise all cask mechanical blocking plates to ensure they are designed to remain in place until casks are very close to mating for a transfer.	LT
	DC4	Review and revise all cask to cask source transfer procedures to ensure that the mechanical blocking plate is only removed as a last step and that the procedures include appropriate warnings.	LT
	DC5	Have an independent dose assessment completed for the technician.	ST
	DC6	Institute a "stop work" restriction on all cask to cask transfers until such time that all LT direct cause corrective actions are completed.	ST
	DC7	Complete an exposure estimate of the technician	LT
	DC8 (*)	Review and establish methods for determining appropriate ED alarm set points.	LT

I3 Contributing Cause

Contributing Cause	CC#	Corrective Action	LT or ST
Technician on the job training forms and positions descriptions should specifically include source transfer operations	CC5	Update the Position Description and on the job training forms to include coverage of the specific requirements for source handing in a cask to cask transfer.	LT
	CC6	Conduct training of all cobalt hot cell technicians and supervisors on changes to the position description and on the job training forms	LT
No specific procedure in use the source transfer	CC1	A procedure for source transfer specific to the shield and customer container involved in this event needs to be developed	LT
	CC2	Management should review current source transfer work activities and ensure appropriate procedures or work instructions are in place for all source transfer operations outside the hot cells.	LT

Contributing Cause

Contributing Cause	CC#	Corrective Action	LT or ST
Requirements for extremity dosimetry should be strengthened	CC3	Review and revise all radiation work permits (RWP's) dealing with source transfers and hot cell loading/unloading to ensure extremity dose monitoring is required at all times.	LT
Whole body dosimetry needs to be secured to the whole body	CC4	Revise all facility RWP's to stipulate that whole body dosimeters need to be attached in such a manner as to not allow more than 2 inches of movement.	LT
	CC7(*)	Conduct refresher training for all technicians on appropriate actions for response to a radiation area alarm.	

I3 Root Cause

Root Cause	RC #	Corrective Action	LT or ST
Poor coordination and control of work activities	RC1	Implement a mandatory management oversight requirement by either the CEO or RSO of all loaded cask handling procedures or cask to cask transfers until all LT root and direct cause corrective actions are completed.	ST
	RC2	Develop an administrative procedure for work coordination and control to include guidance on the conduct of pre-job briefings, requirements for written procedures, and stop work authority	LT
	RC3	Train supervisors on the new administrative work control procedure	LT
	RC4	Update the position description procedure for the operations manager to include specific work coordination and control requirements.	LT
	RC5	Develop an "on the job" qualification checklist for supervisors.	LT
	RC6	Complete "on the job" supervisor checklists for all supervisors.	LT

I³ Root Cause

Root Cause	RC #	Corrective Action	LT or ST
Failure to take immediate actions for ED alarms	RC7(*)	Conduct training to all company radiation workers on appropriate alarm response and immediate actions.	LT
Failure to take action to "Stop Work"	RC2	Develop an administrative procedure for work coordination and control to include guidance on the conduct of pre-job briefings, requirements for written procedures, and stop work authority.	LT
	RC7(*)	Repeated above	

Root Cause

Root Cause	RC #	Corrective Action	LT or ST
Lack of adequate ALARA reviews of procedures and equipment changes	RC8	Revise the administrative procedure and form for document change requests (DCR) to include a specific requirement to consider the need for ALARA or Safety committee review as a part of new document development or change	LT
	RC9	Implement a new process procedure, similar to the DCR process, for documenting the review of new equipment development and modifications (Equipment Change Request, "ECR") to existing equipment whenever such equipment could have a significant safety or ALARA implication.	LT
	RC10	Revise all technician on-the-job (OJT) training forms to include demonstration of understanding of the DCR and ECR process.	LT
	RC11	Conduct training for all technicians on all new procedures and forms.	LT

Alarm Response Changes

- DC8 – Review and establish methods for determining appropriate ED [RAM] alarm set points.

  ED's Dose = ALARM Dose Rate = ALERT

  Past practice:

  Defaults left at 80 mRem dose, 240 mRem/hr. dose rate

  Current Practice:

  RCT determines max dose and dose rate Hold Points for the RWP

  Dose alarm automatically calculated to 80% of max allowed

  Dose rate alert set at 90% of RWP hold point

  RAM's 500 mRem/hr. = ALERT 2000 mRem/hr. = ALARM

  Past Practice: Set annually at calibration

  Current Practice: Set annually, checked daily, set points adjusted with RSO concurrence

- CC7- Conduct refresher training for all technicians on appropriate actions for response to a radiation area alarm
- RC7-Conduct training to all company radiation workers on appropriate [ED] alarm response and immediate actions.

Conduct of Operations philosophy

Alarm Response – Conduct of Operations

- Set points are kept at meaningful values to avoid "spurious" alarms
  - Frequent or "expected" alarms breeds complacency
- Believe your indications
- Alarm = Take Immediate Actions

Comparison of INIS & NRC Reports

- Majority of the reports content are in agreement
- Root Cause determination difference
  - INIS – Management Coordination and Control of Work
  - NRC – Lack of Management oversight - Inadequate ALARA Committee Reviews
- Notation on difference of opinion on Root Cause
  - INIS ALARA Committee Membership same as Document review persons
  - Source removal was an overt act

Additional NRC Investigation Report Comments

- Changes to ALARA Committee review process must be sustainable in the long term
  - Permanent change to DCR & ECR process
  - All changes go to ALARA Chair for determination
- Weakness in the design and development process
  - Risk assessment and risk management included in Product and Equipment Development and Design control (OP-QMS-011) (Requires license amendment)
- Alarm response – "Conduct of Operations" philosophy
- INIS does not dispute the four apparent violations

INIS Event Response Considerations

- Senior management actions to stop all facility activities and initiate an investigation
- Conservative initial assessment and reporting to NRC
- Request for independent dose assessment
- Consultation with REAC/TS and additional dosimetry analysis
- Repeated communication and updates to NRC during the event investigation
- Timely completion of a thorough event investigation report
- Timely completion of listed corrective actions
- Additional measures to address risk assessment in design control

Concluding Points of Consideration

INIS believes the level of detail of corrective actions are commensurate with the significance of the event

INIS has implemented effective and lasting corrective actions in a timely manner to prevent reoccurrence

INIS has taken steps to benefit industry by sharing significant lessons learned from the event

- Eastern Idaho Health Physics Society Presentation
- Health Physics Society Annual Meeting continuing education (Proposed)

Consideration of our past 15 year license performance history

International Isotopes Inc.