RI - DNMS Licensee Event Report
Disposition

Licensee: West Virginia University Hospital

Event Description: Loss of Licensed Material

License No:	47-23066-02	Docket No:	03020233	MLER-RI:	2017-002
Event Date:	01/18/17	Report Date:	02/15/17	HQ Ops Event #:	52557

1. REPORTING REQUIREMENT

	10 CFR 20.1906 Package Contamination		10 CFR 30.50 Report
X	10 CFR 20.2201 Theft or Loss		10 CFR 35.3045 Medical Event
	10 CFR 20.2203 30 Day Report		License Condition
	Other		

2. REGION I RESPONSE

	Immediate Site Inspection	Inspector/Date	
	Special Inspection	Inspector/Date	
	Telephone Inquiry	Inspector/Date	
	Preliminary Notification/Report		Daily Report
X	Information Entered in RI Log	X	Review at Next Inspection
	Report Referred To:		

3. REPORT EVALUATION

X	Description of Event	X	Corrective Actions
X	Levels of RAM Involved	NA	Calculations Adequate
X	Cause of Event	X	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

NA

	Release w/Exposure > Limits		Deliberate Misuse w/Exposure > Limits
	Repeated Inadequate Control		Pkging Failure>10 rads/hr or Contamination>1000x Limits
	Exposure 5x Limits		Large# Indivs w/Exp>Limits or Medical Deterministic Effects
	Potential Fatality		Unique Circumstances or Safeguards Concerns

If any of the above are involved:

	Considered Need for IIT		Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

NA

	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
	Medical Consultant Used-Name of Consultant/Date of Report:
	Medical Consultant Determined Event Directly Contributed to Fatality
	Device Failure with Possible Adverse Generic Implications
	HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

See phone log. Review @ Next routine Inspection

___Non-Public Inspector Signature: Robin Elliott Date: 3/22/17

X Public-SUNSI REVIEW COMPLETE Branch Chief Initials: Date: 3/23/17

Location of File: G:\REFERENCE\BLANK FORMS\LER FORM.DOC

WestVirginiaUniversity.
RADIATION SAFETY DEPARTMENT

March 8, 2017

U.S. Nuclear Regulatory Commission
Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

License No: 47-23066-02
Docket No: 03020233
EIN: 52551

Summary

On January 18, 2017, WVU Radiation Safety Department (RSD) discovered that one Iodine-125 seed used in a Radioactive Seed Localization procedure was missing. The seed was implanted into the primary breast lesion on November 8, 2016 with an activity of 241 μCi. A second seed was also implanted into the patient's axilla lymph node on the same day. The surgery was completed on the same day and Radiation Safety staff picked up the 2 plastic vials from the case in question plus two other plastic vials from two other cases on November 9, 2016. An investigation determined that the seed arrived at the Pathology Gross Room but was likely inadvertently discarded in the trash.

Investigation

A patient was implanted with two seeds at different locations on November 8, 2016 at 1:30 pm. One seed was implanted in the primary breast lesion and the other into the axilla lymph node. Each seed was approximately 241 μCi at the time of implantation. Documentation shows that the seed placement was verified by mammogram or survey meter.

On the same day at approximately 4 pm the patient went to the operating room for surgery to remove the primary lesion and lymph node. The surgeon documented excision of two specimens with seeds contained within and released the specimens to be transported to the Breast Care Center (BCC) for mammo imaging.

BCC documentation indicates that the seed presence in the specimen was verified by image in the BCC though the record does not specify whether both specimens were imaged. However, after further investigation, mammo images were located for each specimen which clearly showed a seed contained within each specimen.

The specimens were then brought to the Gross Room for processing. Per Pathology RSL policy, they had indicated in the seed log book that 2 seeds were removed from specimens from the same case.

At pick up by Radiation Safety staff the following morning, the RSD staff member picking up seeds completed the seed verification process and completed the documentation in the Gross Room seed log book. The seeds were carried to the Radiation Safety radioactive waste area and placed in a designated area to await shipment back to the manufacturer.

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Rec'd for ROC 03/22/17

Radiation Surveys

Radiation surveys were completed in the Radiation Safety Department waste storage area and in the Gross Room; however readings showed radiation levels indistinguishable from background.

Surveys were also conducted on tissue blocks in the Pathology Department; however readings showed radiation levels indistinguishable from background.

Conclusion

It seems likely that the seed arrived in the Pathology Gross Room and was accidentally discarded in the trash. It seems unlikely that the seed would have been left in the specimen due to the fact that the specimens were submitted entirely to pathology to make tissue blocks and it more than likely would have been located in the tissue blocks during the radiation survey. The Pathology resident most likely did retrieve the seed from the specimen but unknowingly failed to place it into the plastic vial and it was subsequently discarded in the trash.

During pick up of the seeds by the Radiation Safety staff member, it is possible that during visual inspection a blue spacer that is implanted with the seed and that was in the plastic vial was mistaken for the seed as they are roughly the same dimensions and look very similar at certain angles. The radiation survey verification may have given false results due to the presence of the background radiation from the 3 other seeds present.

Corrective Actions

The Radiation Safety Department reviewed all processes pertaining to the I-125 seeds and has taken the following corrective action.

- Pathology will survey the specimen to assure that the seed has been removed and document the survey.
- After the seed has been placed in the vial Pathology will survey the vial and document the survey.
- Radiation Safety will check Pathology's log when they retrieve the seeds and during the quarterly audit.
- Radiation Safety will visually verify each source/vial in Pathology.
- Radiation Safety will complete a confirmation survey of each vial in the basement and record the survey reading. Survey results will be recorded on the new log sheet in the basement.

Sincerely,

Nasser Razmianfar
Director and Radiation Safety Officer

Haverkamp, Trisha

From: Elliott, Robin
Sent: Thursday, February 16, 2017 9:53 AM
To: Courtemanche, Steven
Cc: Haverkamp, Trisha
Subject: Event No 52551

Rep Org: WEST VIRGINIA UNIVERSITY HOSPITAL Licensee: WEST VIRGINIA UNIVERSITY HOSPITAL Region: 1 City: MORGANTOWN State: WV County: License #: 47-23066-02 Agreement: N Docket: NRC Notified By: NASSER RAZMIANFAR HQ OPS Officer: DONALD NORWOOD	Notification Date: 02/15/2017 Notification Time: 14:05 [ET] Event Date: 01/18/2017 Event Time: [EST] Last Update Date: 02/15/2017
Emergency Class: NON EMERGENCY 10 CFR Section: 20.2201(a)(1)(ii) - LOST/STOLEN LNM>10X	Person (Organization): RAY MCKINLEY (R1DO) NMSS_EVENTS_NOTIFIC (EMAI)

This material event contains a "Less than Cat 3" level of radioactive material.

Event Text

LOST IODINE-125 IMPLANT SEED

"In compliance with 10 CFR 20.2201(a), this report serves as notification of the loss of licensed material under West Virginia University Hospital Broad Scope License 47-23066-02.

"On January 18, 2017, the Radiation Safety Department discovered that one Iodine-125 seed used in a Radioactive Seed Localization (RSL) procedure was missing. The seed in question had been implanted on November 8, 2016 and contained 241 microCuries of I-125. The patient had surgery to excise the specimen with the seed on the same day as implantation.

"The specimen went to the Breast Care Center for imaging and then to the Pathology gross room where the seeds are removed and placed into plastic vials to await pick up by Radiation safety staff. Radiation Safety staff documented that the seed in question plus 3 others were picked up from the gross room on November 9, 2016 and taken to the radioactive waste storage area.

"The seed was discovered missing on January 18, 2017 during preparation of a return shipment of seeds to the manufacturer. WVU Radiation Safety promptly investigated the cause of the incident and performed thorough radiation surveys in the Pathology Gross room, radioactive waste storage area, and specimen blocks in Pathology, however all surveys were indistinguishable from background. WVU Hospital feels it is likely that the seed was extracted from the specimen in the gross room but was never placed into the plastic vial and subsequently ended up discarded in the gross room waste.

"During pick up by Radiation Safety, the seed was falsely identified by a visual verification as being present in the plastic vial. A blue plastic spacer, which comes preloaded in the syringe with the seed, may have been mistakenly identified as the seed due to its similar size and shape. WVU Hospital has instituted corrective actions to include more intense radiation surveys and better documentation of those surveys to prevent a future occurrence. In compliance with 10 CFR 20.2201(b), please expect a written report within the next 30 days for more details regarding this incident."

THIS MATERIAL EVENT CONTAINS A "LESS THAN CAT 3" LEVEL OF RADIOACTIVE MATERIAL

Sources that are "Less than IAEA Category 3 sources," are either sources that are very unlikely to cause permanent injury to individuals or contain a very small amount of radioactive material that would not cause any permanent injury. Some of these sources, such as moisture density gauges or thickness gauges that are Category 4, the amount of unshielded radioactive material, if not safely managed or securely protected, could possibly - although it is unlikely - temporarily injure someone who handled it or were otherwise in contact with it, or who were close to it for a period of many weeks. For additional information go to http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf

Steve,

FYI, Penny asked me to follow up on this event to make sure it gets closed out in NMED and an LER gets completed.

Thanks,

Robin L. Elliott
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