RI - DNMS Licensee Event Report Disposition

Licensee: Inova Loudoun Hospital, dtd 07/24/07

Event Description: Loss of I-125 Seed

License No: 45-16806-01 | Docket No: 03011072 | MLER-RI: 2007-019

Event Date: 07/24/07 | Report Date: 07/25/07 | HQ Ops Event #: 43522

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		Review at Next Inspection
	Report Referred To:		

3. REPORT EVALUATION

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

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

	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:	NA	

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

	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
	Medical Consultant Used-Name of Consultant/Date of Report: NA
	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

None

☐ Non-Public

☒ Public-SUNSI REVIEW COMPLETE

Inspector Signature: [signature] Date: 8/28/07

Branch Chief Initials: [signature] Date: 8/30/07

Location of File: G:\Reference\Blank Forms\LER FORM.wpd

Rev. 02/25/05

INOVA LOUDOUN HOSPITAL

Radiation Oncology Center
44035 Riverside Parkway, Suite 100
Leesburg, Virginia 20176

Tel 703-858-8850
Fax 703-858-8870

August 23, 2007

Samuel Collins
U.S.N.R.C., Region I
475 Allendale Road
King of Prussia, PA 19406

Re: Missing Seed Report, Inova Loudoun Hospital, NRC License 45-16806-01

Mr. Collins:

Enclosed is a report of a missing I-125 prostate seed for an administration that took place on July 25, 2007. Our physicist, Anne Patterson, who was assisting with the case, generated the report. The report also contains a change in policy that is intended to avoid a future recurrence.

If there are any questions please contact me at (703) 858-8850 or our RSO, Arnie Able at (301) 220-3580.

Sincerely,

Punam Dutt

Punam Dutt
Director of Oncology Services
Inova Loudoun Hospital

cc: Deidre Cahill
Director of Diagnostic Imaging

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July 25, 2007

Arnie Able, RSO
Inova Loudoun Hospital
c/o Associates in Medical Physics
7505 Greenway Center Drive
Greenbelt, MD 20770

Re: Lost I-125 Seed, Inova Loudoun Hospital, NRC License 45-16806-01

On July 24, 2007, upon counting the seeds left at the end of the case, it was noted that there were supposed to be 12 loose seeds remaining, but repeated seed counts revealed only 11 seeds. I checked the cap of the vial, and the lead container that held the vial. I checked the area where the seeds had been located during the case, and did not see the seed nor detect it with the survey meter. I had already done an area survey after the completion of the implant, but I repeated this survey in search of the missing seed. At no time during the case were the seeds removed from the vial; in fact, the cap remained on the vial throughout the case, and was not taken off until the final seed count was done.

I returned the remaining seeds to the Nuclear Medicine Hot Lab, where I interviewed the staff involved in handling seeds for the case, specifically Ralph Chilcott. He had done the seed assay earlier in the day, and he assured me that he assayed 12 seeds, and returned them all to the vial. We commenced a search for the seed in the hot lab, including a visual search and a detector search. We were using a Victoreen 450P meter, as well as a Radiation Alert Inspector meter. We searched for about one hour, without locating the seed either within the hot lab, nor in areas adjacent to the hot lab. I also surveyed the Nuclear Medicine staff, my assistant, and my own clothing and shoes. I surveyed the seed box and its contents.

At about 5:30 P.M., I decided to notify the RSO, Arnie Able, of the missing seed. I left him a voice mail and also sent an e mail. I returned to the hot lab and did another search, but again I was unable to locate the seed.

In accordance with the NRC regulations, specifically 10CFR20.221 (Reports of theft or loss of licensed material), the NRC was contacted on July 25, 2007. The NRC representative is Richard McKinley, in the King of Prussia office of the NRC (610-337-5102). He directed me to call the NRC Operations Center in Rockville, MD (301-816-5100) for the official telephone report. I contacted the Operations Center at approximately 3:45 P.M. on July 25, 2007. I was directed to report this incident in writing within 30 days.

The following is the information required by this regulation for the written report:

1. Description: One single Iodine 125 brachytherapy seed, manufactured by Best, Inc., activity approximately 0.34 millicuries.
2. Description of circumstances under which loss occurred: described above. I do not believe it was a theft of materials.
3. Statement of Probable Disposition: Most seed losses occur during direct seed handling procedures. As the only time the seeds were removed from the vial was during the assay in the Nuclear Medicine Hot Lab, I believe that the seed is somewhere in the hot lab itself. I do not believe the seed was lost in the operating room, as we never handled the loose seeds in that area. All seeds implanted in the patient were in preloaded needles, in seed strands. At no time were any loose seeds handled in the operating room.
4. Exposures of individuals to radiation: this is a single, very low activity source. I do not expect it to pose a health hazard to anyone who may be in the area where the seed is located.
5. Actions to recover the material: as described above. I have surveyed the hot lab twice; I do not believe that further searches will reveal the missing seed.
6. Procedures to ensure against a recurrence will be put in to action immediately. The change in current policy is as follows: We will count the loose seeds after returning them to the vial after the seed assay. We will also count the seeds before we remove them from the hot lab to take them to the operating room. We will also count the seeds after they are sterilized, then again at the end of the case. This will narrow down the possible locations of a lost seed to the hot lab, the operating room, or the sterilization area. We will inform all personnel involved in the seed program of this improved policy, as well as present it to the Radiation Safety Committee for discussion and approval.

Sincerely,

Anne S. Patterson

Anne S. Patterson, M.S.
Medical Physicist
Associates in Medical Physics

Hospital	Event Number: 43522
Rep Org: LOUDOUN HOSPITAL Licensee: LOUDOUN HOSPITAL Region: 1 City: LEESBURG State: VA County: License #: 45-16806-01 Agreement: N Docket: NRC Notified By: ANNE PATTERSON HQ OPS Officer: JASON KOZAL	Notification Date: 07/25/2007 Notification Time: 16:02 [ET] Event Date: 07/24/2007 Event Time: 15:30 [EDT] Last Update Date: 07/25/2007
Emergency Class: NON EMERGENCY 10 CFR Section: 20.2201(a)(1)(ii) - LOST/STOLEN LNM>10X	Person (Organization): PAT FINNEY (R1) ILTAB (E-MAIL) () CINDY FLANNERY (FSME)

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

Event Text

LOST I-125 SEED

The licensee was performing a prostate seed case requiring 12 loose I-125 seeds with an activity of .34 mCi each. The seeds were assayed in the licensee hot lab and transported to the operating room for the procedure. After completion of the procedure only 11 seeds were accounted for. The RSO was notified. The seed was verified to not be in the patient. The licensee completed search for the material throughout the operating room and hot lab with no success. The licensee contacted the NRC Region 1 representative.

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