RI - DNMS Licensee Event Report Disposition

Licensee: Jamison Health System, dtd 04/09/07

Event Description: Leaking Seed

License No: 37-0114603 Docket No: 03002977 MLER-RI: 2007-007

Event Date: 04/09/07 Report Date: 04/09/07 HQ Ops Event #:

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [X] Other 10 CFR 35.3067 Report of a leaking source
- [ ] 10 CFR 30.50 Report
- [X] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

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

3. REPORT EVALUATION

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

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [ ] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] 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)

- [ ] 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

[X] Non-Public Inspector Signature: Date: 5/1/07

[ ] Public-SUNSI REVIEW COMPLETE Branch Chief Initials: Date: 5/2/07

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

Rev. 02/25/05

North Campus
1211 Wilmington Avenue
New Castle, PA 16105-2595
Telephone: 724.658.9001

South Campus
1000 South Mercer Street
New Castle, PA 16101-4673
Telephone: 724.658.3511

Jameson Health System

Continuing the Tradition of Leadership in Community Health℠

13 April 2007

Pam Henderson
Chief, Medical Branch
Division of Nuclear Material Safety
United States Nuclear Regulator Commission, Region I
474 Allendale Road
King of Prussia, PA 19406-1415

Re: Licensd No. 37-01146-03, Report of Leaking Seed

Dear Ms. Henderson,

On Monday 4/9/07 I reported to Robert Ondo, RSO that we had discovered a possible leaking seed. The following description details the series of events.

Attachments 1 details the source ID Group No.'s and Attachment 2 indicates the equipment used as well as a brief descriptor of standard procedures.

Description:

On Monday 4/9/07, it was discovered that a possible leaking seed that was contained in one of our storage bottles that was being prepared for return shipment to Bard. A number of alcohol swab leak tests on the seeds in this bottle had indicated a reading 5 to 10 times higher than background counts in the Nuclear Medicine Well Counter. Based on the calibration that had been determined for this counter for I-125 the leakage was determined to be on the order of .020 microcuries. Following a thorough and comprehensive review of applicable NRC regulations, as well as several re-measurements to confirm reproducible data, it was determined that this was a reportable matter. Mr. Ondo and I then notified the NRC Operations Center on 4/11/07 at1120 HRS. The call was taken by Mr. Steve Sandin.

Shortly thereafter I spoke to Willie Lee of the NRC. In summary this is what I reported to him:

The shipping bottle contained leftover seeds from 7 implant patients or a total of about 150 seeds. I have since reviewed the data for this bottle. It contains 148 seeds. A

complete list of the Bard PSLs, seed counts and seed activity to date are attached. (Attachment 1) Initial counts per minute on an alcohol swab of this bottle read 570 and a second test later gave a reading of 1530. Calibration of the counter is .90 so actual dpm are 10 percent higher.
Background readings on the unit were 98cpm. The bottle containing the source was placed in a sealed leaded vial, which was then put in a sealed ziplock bag and placed back in the safe.

A number of other bottles with return seeds were also tested at the time and found to all be satisfactory.

Upon determining that a leaking source was present, a number of areas were also wiped to determine if there was any contamination anywhere else in the radioactive materials storage room. These areas were the seed counting area on the leaded shield, the table surrounding it, the safe, various seed handling devices, seed carriers, the bottle itself, and my hands. All areas were found to be at background.

A review of the seeds in the bottle showed that they came from seven different patients. I initially felt that the seeds from the patient PSL 71024 were not removed from the bottle during the counting, but Dineli Alahakone our other physicist, does remember counting these seeds in a small plastic dish. So all seeds were at one time or another outside of the bottle. In addition, she also remembers that I had a great degree of difficulty in removing 6 seeds from a stored cartridge for patient PSL 69838. These seeds were stuck in the cartridge, which is something that occasionally occurs with cartridges that are partially used. And they do take a certain degree of prying to get out.

The remaining seeds are of no exceptional note.

Action Taken:

After having spoken to Willie Lee on 4/11/07, it appeared that his interest, as well as ours was to make certain that no leaking seeds had been implanted into any patient. He asked me to do an inventory on everything I thought that could shed some light on this matter.

After speaking to Dineli, it seemed to me that possibly my initial suspicions were not correct and that it could in actuality be a seed for the other patient or actually any of the seven patients.

There did not appear to be any contamination on any site in the radioactive material storage area. All seeds that had been received had passed a Bard Leak test as well as package and primary container wipes done at Jameson when the seeds were received.

After having spoken to Willie Lee, I remember that it was likely that the primary shipping containers (in which the cartridges are shipped) were still on site and this was discovered to be so on 4/12/07.Six containers had patient names on them and the seventh

which had no label attached had to belong to PSL71091 by process of elimination among the various containers present.

The cartridges used for seed implantation are shipped in these metal containers. They contain a circular holder that keeps each cartridge in place vertically around the core of the container. As the seed holding cartridges are not covered, it is highly unlikely that any leaking source shipped to Jameson in these containers would not leave any measurable contamination on the inside surfaces of the container. On 4/12/07 all the containers were checked using alcohol swabs all across the various surfaces in the containers for all the listed patients. All counts were at background.

In addition, the alcohol swabs were also done on the dish on which PSL 71024 seeds were counted as well as the calibration chamber seed holders and these were also found to be background.

All seeds prior to implant have all been in their primary container, on the seed counting table, in the calibration chamber, and in the seed carrier used for transport. None of these areas shows any evidence of any contamination. It would therefore seem highly unlikely that any leaking seed or seeds had been in any of these areas prior to patient implantation. It seems most probable that whatever is leaking in the stored bottle is a seed or seeds that may have been corrupted following implant by some means that could only be determined by an examination of the seed surface that we are not able to perform.

I have listed all the various items that Willie Lee asked us to address on the following pages. Should you or he have any further questions you can reach me at UPMC/Jameson Cancer Center at 724-656-5870 or my cell at 724-561-2210. Mr. Robert Ondo, RSO can be reached at (724) 656-4123 or at rondo@jamesonhealth.org.

Sincerely,

Tony Combine MS
Medical Physicist

Robert A. Ondo B.S., C.N.M.T.
Radiation Safety Officer

Attachments.

c: Director, Office of Nuclear Material Safety
File copy
Radiation Safety Committee
Mr. Doug Danko

Patient Spreadsheet

ATTACHMENT 1

PSL #	Date Received	Source Group #	Leak Test (Bard) Date	Survey (mr/hr) surf	Survey (mr/hr) 1m	Background dpm	Outer Surface dpm	Primary Container dpm	implant date
67749	4/13/2006	I60149D24	4/3/2006	<.05	<.05	70	63	53	4/13/2006
69838	5/12/2006	I60202E50	5/3/2006	<.02	<.02	79	91	85	5/12/2006
		I60203B18	5/3/2006						
69839	5/8/2006	I60182B04	4/21/2006	0.03	0.02	159	231	178	5/12/2006
		I60185B39	4/25/2006						
71024	6/5/2006	I60241C16	5/23/2006	<.02	<.02	71	54	70	6/8/2006
71091	6/26/2006	I60241C16	6/14/2006	<.05	<.05	62	61	76	6/26/2006
74375	8/29/2006	60411A40	8/18/2006	<.05	<.05	75	57	77	9/4/2006
74641	9/15/2006	I60424A80	8/28/2006	<.05	<.05	73	68	68	9/15/2006

	# of remaining seeds	initial activity per seed mCi	present activity per seed mCi	present total contained activity mCi	4/12/07 wipe dpm primary shipping container
67749	13	0.36	0.0059	0.13	60
69839	22	0.36	0.0075	0.28	79
69838	23	0.36	0.0081	0.32	77
71024	37	0.36	0.0103	0.65	60
71091	18	0.425	0.0155	0.48	79
74375	21	0.36	0.0296	1.06	61
74641	14	0.36	0.0348	0.83	52
total	148			3.73	bkgd 60

Attachment 2

Equipment – Jameson Hospital Brachytherapy Program

Standard Imaging Model HDR 1000 Plus Well Type Ionization Chamber #A993364
Date of Last Calibration 01/03/06

Ludlum 14C survey meter 173077 with probe 44-9 #pr176942
Date of last Calibration 02/22/07

Ludlum Model 3 #224460 with scintillation probe pr 236057
Date of last calibration 01/03/07

Ludlum Well Counter 2200 (Nuclear Medicine Department)

Standard Procedures for Source Receipt and Use

Jameson Hospital only uses I-125 seeds (prostate and lung implants) or Pd-103 seeds (prostate implants) in its bracytherapy program. All seeds ordered by the hospital are received by the Nuclear Medicine department. Physicists from the UPMC/Jameson Cancer Center in New Castle do incoming surveys on the packages which consist of an external survey or radiation levels done with the Ludlum 14c or in its absence one of the calibrated Nuclear Medicine survey intsruments. In addition wipe tests are done of the box and primary container and these are counted in the Ludlum Well Counter in Nuclear Medicine.

Sources are then inventoried by the physicists and a calibration check of source activity is done using the HDR 1000 Plus well.

Prior to implant procedures sources are taken to the OR in shielded carriers where they are autoclaved prior to implant use. Procedures are done using real-time planning by the physicist and dosimetrist and OR nurse keep a running tab on sources used throughout the procedure with the physicist so that an accurate count is kept on the sources. At the end of the procedure all source counts are to agree. Following the procedure a survey is done of the patient (exposure rate at 2 cm, bedside and at 1 meter) and of the entire OR area using the Ludlum 14c or equivalent survey meter. Remaining seeds are autoclaved and taken back to the radioactive material storage room for counting. Seed count is compared to expected seed count and seeds are then stored for decay and then return. Should the seed count not agree (which has not happened due to the redundancy of the checks) the physicist is charged with resolving the discrepancy.

Seeds are stored for 6 months to a year and then returned to the manufacturer. Seeds are leak tested using alcohol swabs, packaged and surveyed according to transport regs and returned by Fed Ex.