

RI - DNMS Licensee Event Report Disposition

Licensee: Pottstown Memorial Medical Center
 Event Description: Loss of I-125 seed

License No: 37-03906-d Docket No: 03003035 MLER-RI: 2007-017
 Event Date: 7/17/07 Report Date: 7/27/07 HQ Ops Event #: None

1. REPORTING REQUIREMENT

<input type="checkbox"/>	10 CFR 20.1906 Package Contamination	<input type="checkbox"/>	10 CFR 30.50 Report
<input checked="" type="checkbox"/>	10 CFR 20.2201 Theft or Loss	<input type="checkbox"/>	10 CFR 35.3045 Medical Event
<input type="checkbox"/>	10 CFR 20.2203 30 Day Report	<input type="checkbox"/>	License Condition
<input type="checkbox"/>	Other: <u>< 1000 x APC quantity</u>		

2. REGION I RESPONSE

<input type="checkbox"/>	Immediate Site Inspection	Inspector/Date	
<input type="checkbox"/>	Special Inspection	Inspector/Date	
<input checked="" type="checkbox"/>	Telephone Inquiry	Inspector/Date	
<input type="checkbox"/>	Preliminary Notification/Report	<input type="checkbox"/>	Daily Report
<input type="checkbox"/>	Information Entered In RI Log	<input checked="" type="checkbox"/>	Review at Next Inspection
<input type="checkbox"/>	Report Referred To:		

3. REPORT EVALUATION

<input checked="" type="checkbox"/>	Description of Event	<input checked="" type="checkbox"/>	Corrective Actions
<input checked="" type="checkbox"/>	Levels of RAM Involved	<input type="checkbox"/>	Calculations Adequate
<input type="checkbox"/>	Cause of Event	<input type="checkbox"/>	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/>	Release w/Exposure > Limits	<input type="checkbox"/>	Deliberate Misuse w/Exposure > Limits
<input type="checkbox"/>	Repeated Inadequate Control	<input type="checkbox"/>	Pkging Failure > 10 rads/hr or Contamination > 1000x Limits
<input type="checkbox"/>	Exposure 5x Limits	<input type="checkbox"/>	Large# Indivs w/Exp > Limits or Medical Deterministic Effects
<input type="checkbox"/>	Potential Fatality	<input type="checkbox"/>	Unique Circumstances or Safeguards Concerns
<input type="checkbox"/>	If any of the above are involved:	<input type="checkbox"/>	Considered Need for AIT
<input type="checkbox"/>	Considered Need for IIT	Decision/Made By/Date: _____	

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

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

6. SPECIAL INSTRUCTIONS OR COMMENTS

Non-Public Inspector Signature: [Signature] Date: 8/2/07
 Public-SUNSI REVIEW COMPLETE Branch Chief Initials: [Signature] Date: 8/2/07

610-337-5269

POTTSTOWN HEALTHCARE CORPORATION

FAX TRANSMITTAL SUMMARY

DATE: 7.27.07

TO: Richard McKinley

Receiver's Phone #

FROM: Denise Shantz

Receiver's Fax #

Sender's Phone # 610-327-7485

Sender's Fax # 610-970-3194

Number of Pages (Including this form):

Comments:

Accounts of events

Denise Shantz 610-327-7485

Lisa Goulet 610-327-7794

Thanks

PLEASE NOTE: If you do not receive all of the pages indicated above, call as soon as possible to inform sender.

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Instructions to the authorized receiver: Please complete this statement of receipt and return to sender via the above fax number.

I, _____, verify I have received _____ (# of pages, including this form)

I-125 seed Narrative

- 7/5/07 Seed order faxed to manufacturer for a total of 76 I-125 seeds, .345mCi each on implant date, including a usable calibration seed from same batch, loaded in Mentor 20 cartridges, assayed, and sterilized. To be shipped 7/13 for delivery 7/16/07.
- 7/13 Seeds arrived via Fed-Ex
Seeds delivered to Nuc. Med. from Receiving Dept.
Nuclear Medicine Technologist receives package and does appropriate wipe test. Package opened, contents(foil folder flat pack & documents) removed and placed into shielded storage in Nuclear Medicine hot lab.
Packaging surveyed and discarded.
- 7/16 Receipt of seed order logged into Radiation Oncology source inventory, 76 I-125 seeds, .345 mCi each for implant on Mr. RH on 7/17 @12:30 pm.
- 7/17 Foil Folder Flat pack containing sources and documents taken to OR for case by the dosimetrist.
Seal broken on sterilized flat pack and cartridges containing seeds are dropped onto scrub table for scrub nurse to verify seed count before start of case.
Dosimetrist asks the Radiation Oncology Physicist about additional documents and labels in packet for a single seed other than the 76 in the foil flat pack. The physicist states that it indicates that there is a separate container with a single seed in it.
A total of 69 seeds are implanted into Mr. RH, 7 seeds are sterilized and returned to storage in Nuc. Med. Hot lab. Dosimetrist looks in storage for any shielded container containing a single seed, none found. 5:30PM
- 7/18 Dosimetrist asks Nuclear Medicine technologist if there was more than one container in the package received for Mr. RH. "Nothing in the box other than the the materials for the return of excess seeds, the flat foil folder with Mr.RH's label on it, and the packet of papers." "The box was thrown out because we already have one to ship seeds back in."
Dosimetrist explains concern that an additional seed was shipped according to the paperwork but that it isn't in any of the containers that we have.
Dosimetrist phones customer service at Core Oncology/ Mills Biopharmaceuticals,LLC @(405)525-3141 to inquire as to the calibration seed being included in the total number of 76 ordered for the case or separate as indicated by the paper work in the package?" The answer was that they would have to check and call me back. Richard Brancaleone the marketing rep. for the company would also be informed and call the Dosimetrist later. Mr. Brancaleone phoned to state that the calibration seed may have been included in the batch to be used for the case, he would speak to all parties involved in manufacture and shipment and call back in afternoon.

Late Afternoon 7/18

Mr. Brancalone & Robyn Stump from Core Oncology conference call to the Dosimetrist, Lisa Goulet CMD, to ask "did I go through every layer of packing foam in the box?" "A small pill bottle size pig (shielded container) with a calibration seed in it was sent. It was probably in the 3rd layer of foam packing." Lisa stated that she personally didn't open the box and instructed them to speak to the Nuc. Med. Technologist, Denise because she did receive the box. Denise is phoned by Rich and Robyn and states that she found no other container in the box and that that box had been discarded. It is assumed that the calibration seed which was .345 mCi of activity at noon on implant date 7/17/07 was discarded.

Rich phones Lisa to discuss course of action.

Lisa states that "the Physicist needs to be informed and advise us as to appropriate measure of action. We will making formal recommendations as to changes needed for labeling and shipping packaging of the seeds. We would request a response in writing from Core Oncology stating that they will cooperate with us in an effort to avoid a problem in the future.

7/19 S. Lo PHD (Radiation Onc. Physicist) informed of all happenings. He advised to inform Jay Yoder the Physicist for the Radiology Department.

Mr. Yoder is paged.

Mr. Yoder phones back "Recommends we call NRC and write a narrative stating the chain of events to be sent as a report as required by the NRC." He suggested that Dr. Lo phone Nuc. Med. for a copy of the regulations for report of a lost or stolen source.

Dosimetrist informs Dr. Lambo, Director of Radiation Oncology.

Denise phones Lisa "Don't call the NRC yet, we have 30 days to report a lost or stolen source." "I am going to the compactor to see if boxes from Friday went to the dump yet, will call you back."

Dosimetrist informs Radiation Onc. Administrator, Peg Neese RN of chain of events and that Denise is trying to locate the box.

Denise is unable to find the box at the hospital.

Dosimetrist begins to compose a narrative.

7/23 Denise travels to the trash dump to try to exhaust all chances of recovering the box from Coloplast/Core. The box is not found.

7/25 **Suggested Corrective Action:**

- 1) Package seeds in a smaller box which is clearly labeled to deliver directly to Nuclear Medicine Department and includes a bright colored notice inside it if there is more than one container in the box.
- 2) Place all shielded containers on the same level inside the foam packing material so as to limit the chance of missing one when unpacking the box.

- 3) Have a dedicated space in the Nuclear Medicine Hot Lab to place all isotopes and accessories used for Radiation Oncology treatment so as to avoid a small shielded container or paperwork from getting lost in the bottom of the large shielded bins which presently contain sharps containers and nuclear medicine supplies.
- 4) Avoid order of a calibration seed as long as the assay is being performed at the radio-pharmacy.
- 5) Continue diligent compliance with the radiation safety guidelines for handling of radioisotopes.

Denise Shantz's account
Wednesday, July 25, 2007

On Friday, July 13, 2007, I received a package from Anazoa Health with one packet of 76 I¹²⁵ seeds. The package was surveyed and wiped. I opened the box, removed the cardboard, the foam, and the packet of seeds. Seeds were placed in a shielded holding area and entered into the Dose Manager. The box was discarded into the trash.

On Wednesday, July 18, 2007 at 2:00pm, Lisa Goulet, PMMC's Radiation Dosemitrist informed me that a calibration seed was sent with the order. On Wednesday, July 18, 2007 at 3:15pm, I received a call from Rich Brancaleone a Sales Representative who informed me that the calibration seed was placed on the lower level of the box between the fourth and fifth layer of foam.

On Thursday morning, July 19, 2007, I informed Dr. Brian Solomon, PMMC's Radiation Safety Officer and Jay Yoder, PMMC's consultant physicist. Jay informed me to do everything I could to retrieve the box. I then notified Bill O'Neill, Environmental Supervisor to get in touch with Mascaro Trucking to see if it was possible to go through the compactor on site. Mascaro Trucking agreed to come Friday at 3:00PM.

On Friday, July 20, 2007, at 3:00pm, my manager, Paula Lenane and I went through the trash compactor on the hospital site. We did not find the box.

On Monday, July 23, 2007 at 9:00am, I followed the compactor to the dumping site. The contents of the compactor were distributed to an isolated area and were separated by a landfill attendant, while my manager and I observed. The box was not found.

After I returned to the department on Monday July 23, 2007, I called Rich again to ask him how the seeds were packaged. He gave me the phone number of Maureen Krause of Core Oncology. I spoke to her and she informed me that the calibration seed was in a three pound lead shield. I told that there was no lead shield was in the box. She told me she would confirm this packaging with her supervisor. She called me back and told me it was a smaller lead shield located next to the packet of seeds. I told her that there was no lead pig next to the seeds.

On the morning of Tuesday, July 24, 2007, I spoke with Cara Ogle of Core Oncology who informed me that she would check on the packaging and call me back. She left a message for me on voice mail after I left for the day.

On Wednesday, July 25, 2007, Cara's message stated that the calibration seed was on the second layer of foam next to the packet of seeds in a cut out area of foam.

Originally when I opened the box, I lifted out the cardboard, the first layer of foam. I removed the packet of seeds. I went through the remaining layers of foam. There were no contents besides the packet of seeds also there was no lead pig located next to the packet of seeds.