

## RI - DNMS Licensee Event Report Disposition

Licensee:	Bon Secours DePaul Medical Center		
Event Description:	Missing Sealed Source		
License No:	45-00986-01	Docket No:	(300302)
Event Date:	08/06/07	Report Date:	09/25/07
		MLER-RI:	2007-025
		HQ Ops Event #:	

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 _____		

2. REGION I RESPONSE

<input type="checkbox"/>	Immediate Site Inspection	Inspector/Date	
<input type="checkbox"/>	Special Inspection	Inspector/Date	
<input type="checkbox"/>	Telephone Inquiry	Inspector/Date	
<input type="checkbox"/>	Preliminary Notification/Report	<input type="checkbox"/>	Daily Report
<input checked="" 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 <i>N/A</i>
<input checked="" type="checkbox"/>	Cause of Event	<input type="checkbox"/>	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<i>N/A</i>	<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)

<i>N/A</i>	<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

<input type="checkbox"/> Non-Public	Inspector Signature: _____	Date: <i>10/2/07</i>
<input checked="" type="checkbox"/> Public-SUNSI REVIEW COMPLETE	Branch Chief Initials: _____	Date: _____

RECEIVED  
REGION 1

2007 OCT -1 AM 10: 54



**BON SECOURS**  
**DEPAUL MEDICAL CENTER**  
Bon Secours Health System

David P. Setchel  
Vice President / Operations

September 25, 2007

United States Nuclear Regulatory Commission  
Washington, DC 20555-0001

Dear Nuclear Regulatory Commission Official,

The Purpose of this letter is to report a missing Barium-133 Calibration Sealed Source, June-August 2007

**Background:**

Lead Nuclear Medicine Technologist Shannon Riley ordered a Ba-133 "E-Vial" source from Radiology Services of Hampton Roads (RSHR) on June 6, 2007. Pharmacist Thanh Huynh took the order.

Sealed sources are ordered infrequently by this hospital because of their long half-life. This source was replacing a reference source more than 20 years old. Reference sources have customarily been received in the manufacturer's original packaging materials with return shipping instructions for disposal of the spent source enclosed. This is necessitated by the difficulty in disposing of long-lived radioactive sources. The only cost effective way to dispose of these sources is to return the old source to the manufacturer of the replacement source. Though not mandatory, the original packaging materials for the replacement source have traditionally been used to return the spent source to the manufacturer for disposal.

**Incident:**

On August 6, 2007 it was discovered that the replacement source ordered 2 months earlier was not in our sealed source inventory. Only the envelope containing the calibration certificate, return shipping instructions and a shipping label were discovered in a drawer in the hot lab. The return shipping instructions indicated placing the used source in the original package. The "depleted source return kit", referred to by RSHR, contained only a single instruction page and a shipping label, not the customary cardboard box with Styrofoam insert.

Shaunna Hassell then called RSHR to inquire about the missing source. Thanh Huynh, PharmD responded that the source was shipped to DePaul Medical Center (DMC) in an "ammo can" shipping case (DOT 7A shipping case) with our daily back-up doses and Technetium-99m calibration sources on the afternoon of June 11, 2007 (Monday) according to his documents and memory. It should be noted that we have never before received a sealed source in this manner nor did we receive notice from RSHR that the source was being delivered with our regular back-up shipment. Usually, this back-up shipment is delivered to the hospital hot lab by the RSHR courier where it remains until the next morning when it is surveyed and entered into our inventory. RSHR was called

NOT sent in the original packaging but was, indeed, sent with the back-up doses in the DOT 7A shipping case as originally stated.

On this particular evening, staff Nuclear Medicine Technologist Shaunna Hassell was called back to the hospital for an emergency procedure according to our records. Shaunna remembers checking in the back-up shipment for use in the procedure but does not recall seeing the Ba-133 E-Vial in the shipping case. Staff Nuclear Medicine Technologist Berline Waterfield is usually the first employee to arrive each morning. She checks in the morning shipment and any other unopened shipments that arrived during the evening. She does not recall seeing the E-Vial in any of the shipping cases. All DMC Nuclear Medicine Department technologists were thoroughly questioned by Tom Walsh, Radiology Director and Conwell Boccia, Radiology Manager. None of the staff recalls seeing the missing E-Vial.

As the investigation continued, several possibilities were considered:

1. DMC Nuclear Medicine Department did not receive the missing E-Vial. The source may have been inadvertently delivered to another facility. Although not common, we have on occasion received shipments intended for other facilities. RSHR agreed to contact each of their customers in this regard.
2. DMC Nuclear Medicine Department did indeed receive the missing E-Vial. The fact that we were in receipt of the calibration certificate and return shipping instructions lends credence to this possibility.
  - A. The missing E-Vial may have been misplaced in DMC Nuclear Medicine. Multiple, thorough department searches by staff and management failed to locate the source. The missing E-Vial is not in DMC Nuclear Medicine Department.
  - B. The missing E-Vial may have been discarded in the DMC Nuclear Medicine Department radioactive trash. This hospital decays all radioactive trash to background activity on-site. Spent syringes & dose vials are not returned to RSHR for disposal. Technetium radioactive trash is stored separately from long-lived radioactive trash. The long-lived radioactive trash on site encompassed the time frame of the incident. The Technetium radioactive trash did not encompass the time frame of the incident. All radioactive trash on-site was searched visually and with a sensitive survey instrument. The biohazard waste vendor for DMC was contacted. The vendor monitors biohazard waste for radiation. No radiation was noted coming from this facility. DMC returns all lead to RSHR. No lead is ever thrown away by DMC. The E-Vial would necessarily have been removed from its lead shield to be discarded in the "hot trash". DMC Nuclear Medicine Technologists are very familiar with E-Vials. The DMC Nuclear Medicine dose calibrator is checked with three different E-Vials a minimum of once daily. Only Certified Nuclear Medicine Technologists handle radioactive trash in DMC Nuclear Medicine. It is extremely unlikely that the E-Vial was discarded in the hospital radioactive trash.
  - C. During the time when RSHR indicated the source had been sent in its original packaging, the possibility that the new source was somehow returned to RadQual (manufacturer) was considered. Additional inquiries with Radqual revealed that the E-Vial was shipped in the same container with a Cobalt-57 sheet source for another facility. Both sources were placed on the same order by RSHR. Radqual has special shipping containers that can accommodate up to four sources in addition to the sheet source. The Radqual representative stated that the two sources would have been shipped in separate boxes if the orders were placed

separately. RadQual stated that sources have been inadvertently returned to them in the past but that did not happen in this case.

- D. DMC Nuclear Medicine staff may have overlooked the E-Vial in its lead shield due to the unusual delivery circumstances. DMC Nuclear Medicine Technologists were not expecting the E-Vial to arrive with a back-up shipment, which was opened late at night for an emergency procedure. Since the E-Vial envelope was in the shipping case with the back-up doses, a technologist may have removed the envelope from the case without opening it, not realizing its importance. Other leads being returned to RSHR in the same case may have obscured the E-Vial from view. Due to the low activity and shielding of the reference source, routine radiation monitoring of the return case may not have revealed a source within. In this situation, the E-Vial would have been inadvertently returned to RSHR. Some hospitals return their spent dose vials and syringes to RSHR for disposal. It was considered that a RSHR courier might be unfamiliar with E-Vials and perhaps had discarded it, thinking it to be ordinary radioactive trash. This possibility was discussed with RSHR and they agreed to conduct a search of their facilities. If DMC Nuclear Medicine did indeed receive the missing E-Vial, this is most likely what happened.
3. DMC Nuclear Medicine returns some back-up dose shipments to RSHR unopened. These are small cardboard boxes containing two shielded multi-dose vials of Technetium Pertechnetate and Technetium Macro Aggregated Albumin. The back-up doses in this incident were not packaged in this manner according to RSHR.

#### Analysis of Events and Action Taken to Prevent Future Events

A thorough examination of the incident has resulted in the following conclusions and recommendations:

1. Conclusions.
  - A. The primary reason for the loss was the unusual delivery circumstances.
  - B. The Nuclear Medicine Department should have noticed that the source had not arrived much sooner than August 6, 2007.
  - C. Communications within the Nuclear Medicine Department and with RSHR were not optimal.
2. Recommendations/Actions:
  - A. When reference sources are ordered, inquiry will be made by DMC Nuclear Medicine to determine the expected arrival date. All staff will be notified that a sealed source is on order and will be on alert for its arrival.
  - B. All future sealed source orders from DMC Nuclear Medicine will be placed separately with the manufacturer by RSHR, not combined with orders from other facilities.
  - C. Future shipments of sealed sources will be delivered to DMC Nuclear Medicine in their original packaging materials with calibration certificate and return shipping instructions enclosed as is customary.
  - D. Any paperwork received by DMC Nuclear Medicine in shipping cases will be immediately examined for importance before being stowed.

- E. The entire contents of all shipping cases being returned to RSHR will be inspected visually for appropriate disposal before being closed up and surveyed. The contents of all lead containers will be removed and inspected before being returned to RSHR.
- F. Communication between RSHR and DMC Nuclear Medicine Department concerning delivery of reference sources will be improved, especially if there is something unusual about the delivery.

If you should have any questions or need additional information, please contact David Setchel at 757-889-5098.

Sincerely,

Handwritten signature of Robert T. Mariano, M.D. in black ink, with a circled 'MD' at the end.

Robert T. Mariano, M.D.  
Radiation Safety Officer

Handwritten signature of David P. Setchel in black ink.

David P. Setchel  
Vice President of Operations