

FEB - 8 1994

Docket No. 030-01845

License No. 20-02215-01

Boston University Medical Center  
ATTN: Victor Evdokimoff, CHP  
Director, Radiation Protection  
88 East Newton Street  
D-604  
Boston, Massachusetts 02118-2394

Dear Mr. Evdokimoff:

Subject: Routine Inspection No. 030-01845/93-001

This letter refers to your January 4, 1994 correspondence, in response to our December 20, 1993 letter.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:  
Jenny M. Johansen



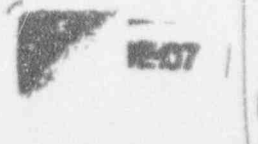
Jenny M. Johansen, Chief  
Medical Inspection Section  
Division of Radiation Safety  
and Safeguards

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cc:  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Massachusetts

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
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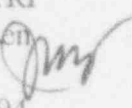
Boston University Medical Center

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bcc:  
Region I Docket Room (w/concurrences)

DRSS:RI  
Mann/gc 

2/4/94

DRSS:RI  
Johansen 

2/8/94



Boston University  
Medical Center

Radiation Protection  
Office

88 East Newton Street, D 604  
Boston, Massachusetts 02118-2394  
617 638-7052

US Nuclear Regulatory Commission  
Attn: Document Control Desk  
Washington, D.C. 20555

January 4, 1994

Reply to a Notice of Violation

Gentlemen:

This is in response to a notice of violation (Docket No: 030-01845). We reported by telephone to David Mann of Region I NRC on October 7, 1993, a loss of 1 millicurie of P-32 shielded in lead. Subsequently we submitted a written report on October 26, 1993 (enclosure) to Region I headquarters. This self-reported violation was identified during a routine inspection on November 16-19, 1993 at Boston University Medical Center. In response to Appendix A instructions responding to this alleged violation, we are furnishing the following information:

1) Reason for the Violation:

Refer to page 6 of our October 26, 1993 letter that was previously submitted (Items 3,4,5).

2) Corrective Steps Taken:

Refer to page six of our October 26, 1993 letter that was previously submitted (Items 1,2,5,6,7). In addition, we confirm all retraining for Pulmonary Center was completed by December 6, 1993. This incident was reported to the Radioisotope Committee on November 9, 1993 and December 2, 1993. The Committee considered corrective actions taken to that date as appropriate and imposed further conditions on the Pulmonary Center in order to maintain exposures ALARA.

3) Corrective Steps That will be Taken:

a) All radioisotope permit holders will be notified of this violation with steps taken to minimize future occurrences (See Item 7 October 26, 1993 letter). Lessons learned will be incorporated in present and future training and retraining for radioisotope users.

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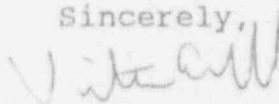
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b) Pulmonary Center will restructure existing radioisotope permits under a plan approved by the Radioisotope Committee.

4) Date When Full Compliance Achieved:

February 21, 1994.

Sincerely,



Victor Evdokimoff, CHP  
Director Radiation Protection, BUMC

cc: Region I Administrator  
Dr. Wotiz, Chairman RSC



# Boston University Medical Center

## Radiation Protection Office

88 East Newton Street, D-604  
Boston, Massachusetts 02118-2399  
617-638-7052

USNRC  
Region I  
475 Allendale Rd.  
King of Prussia, PA. 19406  
Attn: David Mann

October 26, 1993

Gentlemen,

This is a followup to our telephone conversation on October 7, 1993 where I reported a loss of 1 millicurie P-32 dCTP vial shielded in lead. This loss occurred at Boston University Medical Center under license no. 20-02215-01.

The most likely scenario is that the 1 mCi P-32 was contained in a dry ice styrofoam container inside the final shipping package. It was totally covered in dry ice and not obvious upon inspection by a researcher. This package was discarded from the laboratory on Friday afternoon October 8, 1993 and removed by Housekeeping on Monday morning at approximately 8 AM. The trash containing this lost byproduct material passed through our radiation detectors before being discarded into the institution's dumpster. These detectors are set up to locate nuclear medicine patient excreta in trash and/or red bag waste but are not capable of detecting P-32 encased in lead. The dumpster was removed at 9AM Monday and brought to a transfer station in central Massachusetts. The radioactivity was not detected at this transfer station. Our waste and other facilities waste was segregated, scanned and commingled and then loaded onto contracted trailers for disposal. According to the waste hauler, it is impossible to know where our waste went since these trucks go to different facilities (landfills and incinerators) located in different states. In addition, waste capacity changes daily and could result in a truck being diverted to a different facility within Massachusetts or other states such as New York. By Tuesday morning, October 5, 1993 the disposal was final according to our waste hauler. We did not confirm this loss until Thursday morning October 7th, having been notified by the laboratory on Wednesday afternoon October 6th of a missing 1 mCi P-32 vial.

VMC

Corrected copy  
V. Erdoskinoff  
11/3/94

9A80 1120 295

### Public Health Significance

We conclude this loss of 1 millicurie of P-32 does not represent a significant public health hazard. Since the material was shielded in lead, external exposure is minimized. Surveys of the returned empty dumpster indicated no contamination or exposure. In addition no other landfill/waste operator notified us of any radioactivity detected from this institution. The final fate of this package is either buried under tons of trash or incinerated probably with complete volatilization to pollution equipment and/or discharge from stack outlet.

### Description of Incident

1) Two requisitions from the Pulmonary Center were brought to our office on 9/30/93. Both were coded for the same permit holder and involved respectively 1 mCi dCTP P-32 and 500 uCi ATP P-32. The RPO approved both orders. Since both separate requisitions for P-32 were under the same permit holder and for the same vendor, the purchasing agent combined both orders on one purchase order to save on shipping charges. The permit holder was notified that both orders would be arriving on 10/1/93 in one box.

2) On the morning of 10/1/93 the two P-32 vials arrived in one box at BUMC. It was inspected and surveyed. The lab was notified of the combined radioisotope vials.

Enclosed is the laboratory's description of the incident with their recommendations and my actions leading to the NRC call on 10/8/93.

7

VME

Dated: October 7, 1993

Radiation Protection Office,  
BUMC

Dear sir,

Re: Missing vial of radioisotope (32p).

Further to my conversation of yesterday afternoon, I am writing to report the incidence pertaining to a vial of 32p (1mCi quantity) which has been missing from our laboratory. My discussion with the people involved in this incidence reveals the following sequence of events:

1. The above said isotope was ordered on September 30 by my assistant Akil Gulamhussein.
2. The product was received by Radiation Protection Office (RPO) on October 1 alongwith another vial with similar isotope (500 uCi) which had been separately ordered by Jyhchang Jean. Since both the products were from the same company (ICN), the products were shipped together in single container.
3. The RPO informed our office in K-603 on Morning of October 1. The messages were accordingly passed on to both Mr. Gulamhussein and Mr. Jean. Mr. Gulamhussein could not pick the package right away. However, in the meantime, Mr. Jean called Dr. Akihide Itoh with the understanding that the radioactive products were for himself and Dr. Itoh, and requested Dr. Itoh to walk to RPO and pick the package.
4. At the RPO, Dr. Itoh realized that the package was for Mr. Jean and Mr. Gulamhussein and not for Mr. Jean and Dr. Itoh. However, RPO let Dr. Itoh pick the package since he said that he knew Mr. Jean.
5. Dr. Itoh brought the package to K-626 around 2-3 PM and left it on Mr. Jean's bench.
6. In the meantime, Dr. Reiko Katsui noticed the package on Mr. Jean's bench and decided to take care of the radioactivity. She took out the vial containing 500 uCi of isotope (meant for Mr. Jean) and stored it properly in -20 freezer. She did not know there was a second isotope in the package. She handed rest of the box to Mr. Jean and told him that she had stored his isotope in the -20 freezer.
7. Jean apparently trashed the box on the afternoon of October 1.
8. On October 4, Mr. Gulamhussein asked Mr. Jean regarding his 32p isotope and was told that the isotope was for Mr. Jean and Dr. Itoh. Accordingly, Mr. Gulamhussein got confused and assumed that his order had not arrived and did not search for it.

The above information is all I could gather from various people involved in this incidence.

It would seem that no single person was responsible for the loss of the 32p. However, changes in operating procedures at several stages could avert a similar occurrence in the future. These include: 1)

The company should clearly label the package containing more than a single order; 2) RPO should clearly label package with a warning that there is more than one order in the package; 3) although it may be difficult to enforce, RPO should give orders only to the named individual or their designee; and 4) all investigators should be instructed to thoroughly search all isotope package to make certain all isotope have been removed.

We would be happy to discuss our our suggestions and the specifics of this case with you.

Sincerely,

Ann Marie Roberts



Notified 3:00 PM on Wednesday, October 6, 1993 by Rishi lab about missing 1 mCi P-32 vial in lead alleged to have been disposed of unknowingly in trash on last Friday afternoon. Vial buried in dry ice in styrofoam box inside shipping container. Trash delivered to Stoughton St. dumpster last Monday. Verified by Housekeeping that dumpster containing the trash from K-6 was removed Monday morning.

#### Actions

- 1) Told P.I. on 10/6 to verify from all parties involved that P-32 vial is missing. Two persons missing who may know something about vial. Lab will contact them. One away in Vancouver.
- 2) Sent Darin Goodwin from our staff to lab to search for missing vial on 10/6/93.
- 3) Requested written chronology from lab on events that contributed to missing vial.
- 4) Notified R. Rodel on 10/6 to inquire likelihood of finding removed dumpster. E.L. Harvey waste hauler confirmed dumpster brought to their facility, waste surveyed, transferred to contracted trucks and sent either to landfill or incinerator in Massachusetts, New York or other states. If buried it could be under 30 tons of trash. E.L. Harvey stated it is impossible to know where the waste is since it is commingled and put into contracted trucks which go to different locations according to their contracts or changing daily waste space. Thus this waste could not be traced and ultimate disposal is done.
- 5) Notified Chairman RSC on 10/6 about situation and need to notify NRC if extensive search could not locate vial. Need to resolve within 24 hours.
6. Lab confirmed on Thursday morning 1 mCi P-32 is missing.
7. Notified Chairman RSC of item #6.
8. Told Purchasing not to combine separate P.O.'s in one box anymore.
9. Notified David Mann of NRC on Thursday around 1:00 PM about incident.

*V. Evd*  
V. Evdokimoff  
10/8/93

JAN 12 1994

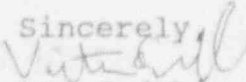
Further Action and Remedial Action

- 1) On October 7, 1993 the RPO suspended the Pulmonary Center from ordering radioisotopes until I could further discuss with the three individuals involved their recollection of the events that lead up to the loss of 1 millicurie of P-32.
- 2) Reviewed entire approval, ordering, receipt and pick up policies of Radiation Protection Office with staff. Determined procedures still appropriate as we handle over 3000 packages a year without incident. This is the first instance of this type of loss that has occurred in the last 16 years.
- 3) After discussion with individuals involved, I determined wrong permit codes used. Requested entire center to update individuals authorized under different permits (6).
- 4) Determined similarity of names, (Aki and Akil) and communication issues contributed to this event. I determined that actions taken represented good intentions on Purchasing and the lab's part. My judgement that this was not an example of gross negligence however improvements are necessary. Thus, The laboratory bears the responsibility for this loss.
- 5) I told the Purchasing Department not to combine separate radioisotope orders for same permit holders. Although the motive of saving money is noble, greater probability of mix ups is possible. This however has been rarely done in the past.
- 6) When I received revised list of Pulmonary Center permits on 10/12, I lifted suspension.
- 7) Determined after discussions with lab personnel and RPO staff that mandatory retraining would be required for all permit holders and authorized users under each Pulmonary Center permit. This should take place within the next two weeks. Those not completing retraining will not be allowed to use radioisotopes. Retraining will review important radiation safety topics plus lessons learned from the loss of 1 mCi P-32.

These include:

- a) Using correct permit codes
- b) Verifying all radioactive packages are empty especially dry ice packages
- c) Communications (ordering, package pickup, delivery to user, etc.)
- d) Opening and removing radioactive sources from someone else's package.

Sincerely,

  
Victor Evdokimoff

Director Radiation Protection, BUMC

cc: Dr. Wotiz