RI - DNMS Licensee Event Report Disposition

Licensee: Dept of Health & Human Services, NIH

Event Description: Loss of Material

License No: 19-00296-10 Docket No: 0300178 MLER-RI: 2006-051

Event Date: 12/04/06 Report Date: 12/22/06 HQ Ops Event #: 43067

1. REPORTING REQUIREMENT

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

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date
- [ ] Special Inspection — Inspector/Date
- [X] Telephone Inquiry — Inspector/Date: Gabriel 12/26/06
- [ ] 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
- [X] Levels of RAM Involved
- [X] Cause of Event
- [X] Corrective Actions – see also e-mail dated 1-17-07
- [ ] Calculations Adequate
- [X] Additional Information Requested from Licensee — Corrective actions see response in e-mail

4. N/A 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. N/A 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

☐ Non-Public

☒ Public-SUNSI REVIEW COMPLETE

Inspector Signauture: [signature] Date: 1/7/07

Branch Chief Initials: [signature] Date: 1/18/07

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

Rev. 02/25/05

U.S. NUCLEAR REGULATORY COMMISSION TELEPHONE CONVERSATION RECORD	Date: 12/26/06 Time: 9:50 a.m.

Mail Control or Report No(s).	NA	License No(s). 19-00296-10	Docket No(s). 03001786

Name of Licensee:	Department of Health and Human Services, National Institutes of Health
Name of Participant(s):	a) Cathy Ribaudo, Chief, Materials Control and Analysis Branch, NIH Division of Radiation Safety (DRS) b) Sandy Gabriel, NRC Region I
Telephone No.	301-496-5774
Subject: (NOTE: This will be used as the Documents Title in ADAMS)	Event Notification Report 43061 (loss of 250 uCi of P-32)
Summary:	I called to follow up to the report, called in on December 22, 2006, of the loss of 250 uCi of P-32 that was identified on December 4. Cathy said that Bob Zoon, DRS Director/RSO, is on vacation this week. She is aware of the event and report. She said that NIH DRS staff performed a detailed review of the event and determined that the cause was human error on the part of the AU who failed to remove the third vial from the package. Other than this event, the AU has history of good performance. Bob Zoon plans to submit a written report to the NRC Region I office upon his return on January 2, 2007. Region I will follow up to this event during the next on-site inspection, due in late 2007.
Action Required:	File in ADAMS. Review during next inspection.

Document Availability:	X **Publicly Available**		___ Non-Publicly Available	
X Non-Sensitive	___ Non-Sensitive Copyright	___ Sensitive	___ Sensitive Copyright	
___ Immediate Release	X Normal Release		___ Delay Release Date	
Prepared & SUNSI Review Completed By:	S. Gabriel	***/ RA /***	Date: 12/26/06	

Other Nuclear Material	Event Number: 43061
Rep Org: NATIONAL INSTITUTE OF HEALTH Licensee: NATIONAL INSTITUTE OF HEALTH Region: 1 City: BETHESDA State: MD County: License #: 19-00296-10 Agreement: Y Docket: NRC Notified By: ROBERT ZOON HQ OPS Officer: BILL HUFFMAN	Notification Date: 12/22/2006 Notification Time: 13:32 [ET] Event Date: 12/01/2006 Event Time: [EST] Last Update Date: 12/22/2006
Emergency Class: NON EMERGENCY 10 CFR Section: 20.2201(a)(1)(ii) - LOST/STOLEN LNM>10X	Person (Organization): RAY POWELL (R1) ROBERT PIERSON (NMSS)

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

Event Text

LOST VIAL CONTAINING PHOSPHORUS-32

"This is a report of the loss of licensed material in accordance with 10CFR20.2201.

"1. The licensed material consisted of a single packaged vial of Alpha-Adenosine Triphosphate (a-ATP) which contained 250 microcuries (9.25 MBq) of Phosphorus-32 (Half-life=14.3 days). The product is supplied by GE Healthcare, product number PT10160. The volume of the product was 25 microliters.

"2. On December 1, 2006 a box containing three separate shielded vials of the product described in (1) above was delivered to a technician in the Clinical Research Center, 5th floor, Room 3288. Some time later, the Authorized User [AU] unpacked the box, but only retrieved two of the three product packages from the dry ice within the Styrofoam chest, because the third package was below the remaining dry ice. The AU then defaced the radioactive materials labels on the delivery box and placed the box containing the remaining vial for pickup as regular trash. The AU did not discover the error until December 4, 2006, too late to attempt retrieval from the regular trash dumpster.

"3. The disposition of the material is to the regular trash stream through the Montgomery Country, MD refuse transfer station in Rockville, MD.

"4. We have no reason to believe that this loss of licensed material resulted in exposure to anyone. The P-32 labeled ATP is in a very small volume of liquid, shielded by a sturdy Lucite plastic vial shield, encased in a sealed vinyl plastic outer containment. Furthermore, that assembly was in a thick-walled Styrofoam box within the cardboard delivery box. It is highly unlikely that, during the process of transport to, and through the transfer station that the P-32 would have leaked out of containment.

"5. No action was taken to recover the material due the circumstances of loss and the time between loss and discovery of the loss.

"6. No procedures have been modified as a result of this incident. The package insert clearly delineated to the AU that there were 750 microcuries of Alpha-ATP-32 in the shipment, in accordance with what the AU ordered, indicating that three items should have been retrieved from the dry ice. The loss was the result of human error."

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

JAN 3 2007

Administrator
Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License No. 19-00296-10

This is a written report of the loss of licensed material in accordance with 10CFR20.2201. Telephone report number 43061 was made on December 22, 2006.

1. The licensed material consisted of a single packaged vial of Alpha-Adenosine Triphosphate (α-ATP) which contained 250 microcuries (9.25 MBq) of Phosphorus-32 (Half-life=14.3 days). The product is supplied by GE Healthcare, product number PT10160. The volume of the product was 25 microliters.

2. On December 1, 2006 a box containing three separate shielded vials of the product described in (1) above was delivered to a technician in the Clinical Research Center, 5th floor, Room 3288. Some time later, the Authorized User unpacked the box, but only retrieved two of the three product packages from the dry ice within the Styrofoam chest, because the third package was below the remaining dry ice. The AU then defaced the radioactive materials labels on the delivery box and placed the box containing the remaining vial for pickup as regular trash. The AU did not discover the error until December 4, 2006, too late to attempt retrieval from the regular trash dumpster.

3. The disposition of the material is to the regular trash stream through the Montgomery Country, MD refuse transfer station in Rockville, MD.

4. We have no reason to believe that this loss of licensed material resulted in exposure to anyone. The P-32 labeled ATP is in a very small volume of liquid, shielded by a sturdy Lucite plastic vial shield, encased in a sealed vinyl plastic outer containment. Furthermore, that assembly was in a thick-walled Styrofoam box within the cardboard delivery box. It is highly unlikely that, during the process of transport to, and through the transfer station that the P-32 would have leaked out of containment.

5. No action was taken to recover the material due the circumstances of loss and the time between loss and discovery of the loss.

6. No procedures have been modified as a result of this incident. The package insert clearly delineated to the AU that there were 750 microcuries of Alpha-ATP-32 in the shipment, in accordance with what the AU ordered, indicating that three items should have been retrieved from the dry ice. The loss was the result of human error.

Please contact me if you or your staff have questions or need additional information. I may be reached at 301-496-2254 or by email at zoonr@mail.nih.gov.

Sincerely

Robert A. Zoon, M.E., M.S.
Radiation Safety Officer, NIH

cc: Dr. Ira Levin, Chair, RSC
Dr. Alfred Johnson, Director, ORS

From: "Zoon, Robert (NIH/OD/ORS) [E]" <zoonr@ors.od.nih.gov>
To: "Sandra Gabriel" <SLG2@nrc.gov>
Date: 01/17/2007 9:03:25 AM
Subject: RE: Question regarding your report of lost material, 43061

Dear Sandy,

Yes - two senior HP's from my staff investigated this incident, the Area HP and the DRS Training Coordinator. Both refreshed the AU regarding proper package opening procedures, as well as confirming that she understood those procedures.

Bob

-----Original Message-----
From: Sandra Gabriel [mailto:SLG2@nrc.gov]
Sent: Friday, January 12, 2007 2:55 PM
To: Zoon, Robert (NIH/OD/ORS) [E]
Subject: Question regarding your report of lost material, 43061

Bob:

We received your written report dated 1/3/07, following up to your telephone report on 12/22/06.

Item 6 of your written report said the loss of the vial of P-32 was the result of human error and no procedures have been modified as a result of this incident. Please provide one additional piece of information: what action did you take to assure this authorized user does not repeat the error? For example did you re-train the authorized user about the requirements of your package receipt procedure?

Thank you,
Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I

CC: "Ngutter, Laurenti (NIH/OD/ORS) [E]" <ngutterl@ors.od.nih.gov>, "Mercer, Tom (NIH/OD/ORS) [E]" <mercert@ors.od.nih.gov>

Mail Envelope Properties (45AE2C92.72F : 0 : 42799)

Subject:	RE: Question regarding your report of lost material, 43061
Creation Date	01/17/2007 9:02:56 AM
From:	"Zoon, Robert (NIH/OD/ORS) [E]" <zoonr@ors.od.nih.gov>
Created By:	zoonr@ors.od.nih.gov

Recipients

nrc.gov
kp1_po.KP_DO
SLG2 (Sandra Gabriel)

ors.od.nih.gov
mercert CC (Tom (NIH/OD/ORS) [E] Mercer)
ngutterl CC (Laurenti (NIH/OD/ORS) [E] Ngutter)

Post Office	**Route**
kp1_po.KP_DO	nrc.gov
	ors.od.nih.gov

Files	**Size**	**Date & Time**
MESSAGE	1058	01/17/2007 9:02:56 AM
Mime.822	2709	

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard

Junk Mail Handling Evaluation Results

Message is eligible for Junk Mail handling
This message was not classified as Junk Mail

Junk Mail settings when this message was delivered

Junk Mail handling disabled by User
Junk List is not enabled
Junk Mail using personal address books is not enabled
Block List is not enabled