General Information or Other	Event Number: 43443
Rep Org: NEW YORK STATE DEPT. OF HEALTH Licensee: UNKNOWN Region: 1 City: TROY State: NY County: License #: Agreement: Y Docket: NRC Notified By: ROBERT DANSEREAU HQ OPS Officer: STEVE SANDIN	Notification Date: 06/25/2007 Notification Time: 16:45 [ET] Event Date: 06/19/2007 Event Time: [EDT] Last Update Date: 06/26/2007
Emergency Class: NON EMERGENCY 10 CFR Section: AGREEMENT STATE	Person (Organization): RAY POWELL (R1) JACK DAVIS (FSME)

Event Text

AGREEMENT STATE REPORT INVOLVING HIGHER THAN PRESCRIBED DOSE DELIVERED

The following notification was received from the State of NY Bureau of Environmental Radiation Protection via fax:

"AS Agency -New York State Department of Health

"Event Report - ID # NYS DOH 07-002

"Licensee Name and License Number - Withheld as per NYS Law

"Event Date - June 19, 2007

"Event Type - Medical Event

"Event Description:

"A medical event involving yttriurn-90 Zevalin (Ibritumomab Tiuxetan) for treatment of non-Hodgkin's lymphoma was reported to NYS DOH by telephone on June 22, 2007. The authorized physician user (AU) approved a dosage of 29 mCi for treatment on June 19, 2007, however a dose of 36.7 mCi was administered.

"This Zevalin patient (A) was scheduled to receive treatment at the hospital on June 19, 2007. The radiopharmacy prepared the dose but observed that the assay from the supplier was approximately 10 mCi higher than their assay. They reviewed their data including their most recent calibration of the dose calibrator with a NIST traceable syringe standard. They decided to use their NIST traceable calibration factor and associated assay. The dose was dispensed and the patient was treated.

"Another Zevalin patient (B) was scheduled for treatment on June 20, 2007. In preparing patient B's dose the radiopharmacy observed the same condition as with patient A's assay. At this point they realized they had a problem and patient B's dose was not dispensed. An investigation began.

"The radiopharmacy identified the error. They used an AEA Technology QSA Inc. model SIM.SY2 (Sealed Source Registry No. MA-1059-S-360-S) to calibrate their Capintec CRC-15R dose calibrator as well as the hospital's dose calibrator. This source is specifically designed to calibrate Capintec CRC-15R units for yttrium 90 assays. The calibration source label has an assay of 20mCi (740 MBq) of strontium 90/ytrrium 90 and a calibration date of Nov. 14, 2004. However, the source certificate lists the yttrium 90 'Equivalent Activity' as 30.68 mCi (1135 MBq), which is the value that should have been used for the calibration. Apparently the certificate was not available (misplaced?) on June 8 &10 for the calibration. The radiopharmacy used the decay-corrected value from the label rather than a decay-corrected value of the certificate's 'Equivalent Activity'. Since the same calibration error was performed on the hospital's dose calibrator, the hospital's assay matched up with that of

A/2

the radiopharmacy and with the intended dosage.

"The patient's daughter and the referring physician were notified on the day after discovery. The treating physician is assessing situation and the possible effects to the patient.

"Intended dose - 29 mCi
"Delivered dose - 37.6 mCi
"Date of treatment - 6/20/07
"Date of error discovered - 6/20/07
"Isotope/drug - yttrium-90/Zevalin
"Reported/notification dates:
"Patient/patient rep. - 6/20/07
"Referring MD - 6/20/07
"NYS DOH - 6/22/07
"Cause: Dose calibrator calibration error
"Effect - patient's condition and effects are being assessed
"Investigation - RCA required
"Initial Written report due 6/29/07"

* * * UPDATE AT 1107 EDT ON 6/26/07 FROM FSME (FLANNERY) TO JASON KOZAL VIA EMAIL * * *

"This event (EN43443) has been reviewed and determined to be a reportable medical event."

A "Medical Event" may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

Full Report

08/11/2009

Item Number: 070390 **Last Updated:** 09/20/2007

Narrative:

The licensee reported that a patient received 1358 MBq (36.7 mCi) of Y-90 Zevalin (Ibritumomab Tiuxetan) for non-Hodgkin's lymphoma instead of the prescribed dose of 1073 MBq (29 mCi). The radiopharmacy prepared the dose but observed that the assay from the supplier was approximately 370 MBq (10 mCi) higher than their assay. They reviewed their data, including their most recent calibration of the dose calibrator with a NIST traceable syringe standard. They decided to use their NIST traceable calibration factor and associated assay. The dose was dispensed and the patient was treated. Another patient was scheduled to receive a similar treatment the next day and assay results of the dose revealed the same discrepancy. At that point, the licensee realized there was a problem and the second dose was not dispensed. The radiopharmacy identified the error. They had used an AEA Technology QSA source (model SIM.SY2) to calibrate their Capintec dose calibrator (model CRC-15R) as well as the hospital's dose calibrator. This source is specifically designed to calibrate Capintec CRC-15R units for Y-90 assays. The calibration source is labeled with an assay of 740 MBq (20 mCi) of Sr-90/Y-90 and a calibration date of 11/14/2004. However, the source certificate lists the Y-90 equivalent activity as 1135 MBq (30.68 mCi), which is the value that should have been used for the calibration. Apparently, this certificate was not available for the 6/8 and 6/10/2007 calibration. The radiopharmacy used the decay-corrected value on the source label rather than a decay-corrected value from the certificate's equivalent activity. Since the same calibration error was performed on the hospital's dose calibrator, the hospital's assay matched the radiopharmacy's and with the intended dosage. The patient's daughter and the referring physician were notified of the incident. Corrective actions taken by the licensee included using the source certificate information to perform the dose calibrator calibration.

Event Date: 06/19/2007 **Discovery Date:** 06/20/2007 **Report Date:** 06/22/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NR	Name:	NR
NRC Docket Number:	NA	City:	NR
NRC Program Code:	NA	State: NY	Zip Code: NR
Responsible NRC Region:	1		

Site of Event:

Site Name: NR
State: NY

Additional Involved Party:

License Number:	NA	Name:	NA
NRC Docket Number:	NA	City:	NA
NRC Program Code:	NA	State: NA	Zip Code: NA
Responsible NRC Region:	NA		

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	N
Consultant Hired:	N	Event Closed by Region/State:	N

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2
Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 06/20/2007

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: IBRITUMOMAB TIUXETAN
Radionuclide: Y-90 Activity: 36.7 mCi 1357.9 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: IBRITUMOMAB TIUXETAN
Radionuclide: Y-90 Activity: 29 mCi 1073 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 26.6
% Dose is Less Than Prescribed: NA
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: NR Activity: 0.0367 Ci 1.3579 GBq
Model Number: NA
Serial Number: NA

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(ii) - Total dosage delivered differs from prescribed by 20% or more or falls outside the prescribed range; and results in a dose that differs from prescribed by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43443	06/29/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070918	09/20/2007		DCH	AGREEMENT STATE LETTER

"Robert E. Dansereau"
<red07@health.state.ny.us>
09/18/2007 01:19 PM

To Dante.Huntsman@inl.gov, "James Kottan" <JJK@nrc.gov>
cc "Donna Janda" <DMJ@nrc.gov>, red07@health.state.ny.us
bcc
Subject Re: Fwd: Information request for NMED item 070390

Please note that we cannot provide identifiers (license name, license number, address, etc.) for medical events. NYS law prohibits the release of such information.

The corrective action was to use the source certificate information to perform the dose calibrator calibration.

The authorized physician user (AU) approved a dosage of 29 mCi for treatment on June 19, 2007, however a dose of 36.7 mCi was administered.

Robert E. Dansereau
Chief, Radioactive Materials Section
Bureau of Environmental Radiation Protection
NYS Department of Health - Rm 530
547 River Street
Troy, NY 12180-2216
Phone (518)402-7590
FAX (518)402-7585
red07@health.state.ny.us

"James Kottan"
<JJK@nrc.gov>

09/18/2007 02:39 PM

To <red07@health.state.ny.us>
cc "Donna Janda" <DMJ@nrc.gov>
Subject Fwd: Information request for NMED item 070390

Bob,

As per our phone discussion, see the forwarded e-mail. Any questions, let me know.

Best Regards,
Jim

----- Message from Unknown on Thu, 13 Sep 2007 10:35:11 -0600 -----

To: jjk@nrc.gov

cc: dmj@nrc.gov

Subject: Information request for NMED item 070390

We need additional information to complete the NMED record identified below. The additional information is needed to meet the minimum requirements of STP Procedure SA-300 (available at the NRC/STP web site, www.hsrd.ornl.gov/nrc/home.html). In order to promptly complete the NMED record, we request a reply at your earliest convenience, but no later than 60 days from the date of this request.

NMED Item No.: 070390
State Event No.: Information received via the NRC Event Notification 43443.
Licensee/Reporting Party: NR
License Number: NR
Event Date: 6/19/2007

ADDITIONAL INFORMATION REQUESTED

What was the city of the licensee's/company's residence?
What was the license number?
What was the licensee's/company's name?
What was the Site of Event- Site Name?

What corrective action(s) were taken by the licensee to prevent a recurrence?

What was the determined dose given to the patient?

Thank you for your help,

Dante Huntsman
NMED Project
Dante.Huntsman@inl.gov