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|General Information or Other                               |Event Number: 39707|
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| REP ORG: NEW YORK STATE DEPT. OF HEALTH                |NOTIFICATION DATE: 03/27/2003| |
|LICENSEE: NOT AVAILABLE                                  |NOTIFICATION TIME: 17:40[EST]|
|   CITY:                                               |REGION: 1 |EVENT DATE: 03/27/2003|
|   COUNTY:                                             |STATE: NY |EVENT TIME: [EST]|
|LICENSE#: NOT AVAILABLE                                |AGREEMENT: Y |LAST UPDATE DATE: 03/27/2003|
| DOCKET:                                               |-----+
|                                                         |PERSON          ORGANIZATION|
|                                                         |PAMELA HENDERSON      R1|
|                                                         |E. WILLIAM BRACH      NMSS|
+-----+
| NRC NOTIFIED BY: ROBERT DANSEREAU (FAX)                |
| HQ OPS OFFICER: HOWIE CROUCH                           |
+-----+
|EMERGENCY CLASS:          NON EMERGENCY                 |
|10 CFR SECTION:          |
|NAGR                      AGREEMENT STATE               |
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EVENT TEXT

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| AGREEMENT STATE REPORT - MEDICAL MISADMINISTRATION     |
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| The following information was received from the New York State Department of
| Health, Bureau of Environmental Radiation Protection:
|
| "This notice is in regard to a medical misadministration involving a Novoste
| Beta-Cath IVB 3.5F system, Model A1767 with AEAT Model SIC W.2 source train.
| The event occurred on March 25, 2003.
|
| "Two attempts to advance the source train into the delivery catheter were
| unsuccessful. A third (and final) attempt resulted in the source train
| becoming stuck in the patient's femoral artery, somewhere in the lower groin
| area. The sources could not be returned to the base unit. The treatment team
| then removed the catheter, with the source extended, and placed these items
| into the emergency bailout box.
|
| "The licensee estimated that the patient received an exposure of 250 Rads to
| an area of the femoral artery in the lower groin area. The oncologist and
| cardiologist decided not to proceed with IVB treatment of this patient.
| Hospital staff concluded that the misdirected radiation exposure would not
| have a significant health effect on the patient.
|
| "This event meets the reporting requirements in 10 NYCRR 16. The facility
| will investigate the circumstances, procedures, training, history of use,
| etc., and will submit a written report within 7 days. The device, including
| catheter and hydraulic attachment (syringe) will be sent to the vendor for
| evaluation."
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A/3

Full Report

08/11/2009

Item Number: 030259

Last Updated: 04/10/2003

Narrative:

The New York Department of Health reported that during an intravascular brachytherapy (IVB) treatment the source train became stuck in the patient's femoral artery, somewhere in the lower groin area. The event involved a Novoste Beta-Cath IVB 3.5 Fr device (model A1767) with an AEA Technology Sr-90 source train (model SICW.2) that contained an activity of 2.96 GBq (80 mCi). During the procedure on a 76-year-old woman, two attempts to advance the source train into the delivery catheter were unsuccessful. A third attempt resulted in the source train becoming stuck in the patient's femoral artery. The source train could not be returned to the base unit. The treatment team then removed the catheter with the source train extended and placed it into the emergency bailout box. The licensee estimated that the patient received an exposure of 250 cGy (rad) to an area of the femoral artery in the lower groin area. The oncologist and cardiologist decided not to proceed with IVB treatment of this patient. The licensee will investigate the circumstances, procedures, training, history of use, etc. pertaining to this event. The IVB device, including the catheter and hydraulic attachment, has been sent to the vendor for evaluation. The State plans to conduct an on-site investigation.

Event Date: 03/25/2003

Discovery Date: 03/25/2003

Report Date: 03/27/2003

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:

EQP - EQUIPMENT

MD2 - MEDICAL EVENT

Event Cause:

EQP

Cause: DEFECTIVE OR FAILED PART

Old Cause: DEFECTIVE OR FAILED PARTS

MD2

Cause: DEFECTIVE OR FAILED PART

Old Cause: DEFECTIVE OR FAILED PARTS

Corrective Actions Information:

Action Number: Corrective Action:

EQP

1 EQUIPMENT RETURNED TO MANUFACTURER FOR REPAIR OR DISPOSAL

MD2

1 EQUIPMENT RETURNED TO MANUFACTURER FOR REPAIR OR DISPOSAL

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, INTRAVASCULAR

Organ: GROIN

Radiopharmaceutical: NA

Radionuclide: SR-90 Activity: 80 mCi 2960 MBq Dose: 250 rad 2.5 Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: NR

% Dose is Less Than Prescribed: NA

Effect on Patient:

Patient Number: 1A

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, INTRAVASCULAR

Organ: HEART

Radiopharmaceutical: NA

Radionuclide: SR-90 Activity: 80 mCi 2960 MBq Dose: 0 rad 0 Gy

Intended:

Therapeutic Procedure: BRACHY, INTRAVASCULAR

Organ: HEART

Radiopharmaceutical: NA

Radionuclide: SR-90 Activity: 80 mCi 2960 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 100

Effect on Patient:

Source of Radiation:

EQP

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): SR-90
Manufacturer: AEA TECHNOLOGIES Activity: 0.08 Ci 2.96 GBq
Model Number: SICW.2
Serial Number: NR

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): SR-90
Manufacturer: AEA TECHNOLOGIES Activity: 0.08 Ci 2.96 GBq
Model Number: SICW.2
Serial Number: NR

Device/Associated Equipment:

EQP

Device Number: 1

Device Name: INTRAVASCULAR BRACHY UNIT Model Number: A1767
Manufacturer: NOVOSTE Serial Number: NR

MD2

Device Number: 1

Device Name: INTRAVASCULAR BRACHY UNIT Model Number: A1767
Manufacturer: NOVOSTE Serial Number: NR

Reporting Requirements:

EQP

Reporting Requirement: 30.50(b)(2)(ii) - old - (SUPERSEDED) EQUIPMENT IS DISABLED OR FAILS TO FUNCTION AS DESIGNED WHEN THE EQUIPMENT IS REQUIRED TO BE AVAILABLE AND OPERABLE WHEN IT IS DISABLED OR FAILS TO FUNCTION.

MD2

Reporting Requirement: 35.3045(a)(1)(i) - Total dose delivered that differs from the prescribed dose by 20% or more; and differs from the prescribed dose 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.

Reporting Requirement: 35.3045(a)(3) - Dose to the skin, organ, or tissue, other than the treatment site, that exceeds the prescribed dose by 0.5 Sv (50 rem) and 50% or more (excluding permanently implanted seeds that migrated from the treatment site).

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN39707	04/01/2003		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML030920724	04/10/2003		DCH	PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN103009	04/10/2003		DCH	PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE

DCS No.: 99999999030325

Date: April 2, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-I-03-009

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region I staff on this date.

Facility

New York State Department of Health Licensee

Licensee Emergency Classification

Notification of Unusual Event

Alert

Site Area Emergency

General Emergency

Not Applicable

Docket No.: NA

License No.: Agreement State Licensee

SUBJECT: MEDICAL EVENT INVOLVING NOVOSTE BETA-CATH
INTRAVASCULAR BRACHYTHERAPY SYSTEM

On March 27, 2003, at 5:40 p.m., the New York State Department of Health notified the NRC Operations Center that a medical misadministration involving a Novoste Beta-Cath Model A1767 Intravascular Brachytherapy (IVB) system with Model SIC W.2 source train (approximately 80 millicuries of Sr-90) occurred at a State licensee on March 25, 2003. New York State law prohibits the release of any identifying information of the patient or the facility involved in a medical misadministration.

During an IVB procedure on a 76-year old woman, two attempts to advance the source train into the delivery catheter were unsuccessful. The third attempt resulted in the source train becoming stuck in the patient's femoral artery, somewhere in the lower groin area. Since the sources could not be returned to the base unit, the treatment team removed the catheter, with the sources extended, and placed these items into the emergency bailout box.

The licensee estimated that the patient received a dose of 250 rads to an area of the femoral artery in the lower groin area. The oncologist and cardiologist decided not to proceed with the IVB treatment of this patient. The licensee concluded that the radiation dose to the wrong treatment site would not have a significant health effect on the patient. The facility will investigate the circumstances, procedures, training, and history of use and will submit a written report to the State by April 4, 2003. The device, including catheter and hydraulic attachment (syringe) have been sent to the vendor for evaluation. Upon receipt and review of the licensee's report, the State plans an on-site investigation.

The New York Department of Health concurs with the contents of this notification. Region I is prepared to respond to media inquiries.

This information is current as of 2:00 p.m. on April 2, 2003

Contact: Duncan White
610-337-5042

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DATE	4/2/03	4/2/03	4/2/03		