Uncertain-Reportable Medical Events

The following data was gathered from the Nuclear Material Events Database (NMED) on October 27, 2010 in response to a request from Congressman Markey dated October 26, 2010.

Specifically, the data in this report respond to the Congressman's question "For each of the previous 5 years 2005-2010, please provide the number of times in which the NRC was made aware that the therapeutic and diagnostic medical use of radioactive materials was investigated, questioned, or identified as being at odds with the original medical treatment plan, but was ultimately not designated as a 'medical event'."

The following table lists the number of NMED event records that are designated as uncertain-reportable medical events. The NMED contractor has not yet been determined whether these events are medical events per 10CFR 35.3045. More event information is required to complete that process. Note that an NMED event record may involve more than one patient or procedure. For example, in a review of past procedures, a hospital discovered that prostate brachytherapy seeds were incorrectly positioned in five patients over the last three years. This information is typically included in a single NMED event record. Thus, a single NMED event record may actually include multiple medical events.

NMED Records of Uncertain-Reportable Medical Events

Year	Events
2005	-
2006	-
2007	-
2008	-
2009	1
2010*	2
Total	**3**

*Note that calendar year 2010 is not yet complete.

The following section contains the NMED event record for each of the 3 events. The manufacturer and model number information for IAEA Category 1-3 sources and devices was redacted.

Full Report

10/28/2010

Item Number: 100310

Last Updated: 06/21/2010

Narrative:

A medical facility in New York reported that a patient with prostate cancer was improperly implanted with I-125 brachytherapy seeds on 5/26/2010. The patient was prescr bed 14,500 cGy (rad) and implanted with 112 brachytherapy seeds. Each seed contained approximately 13.32 MBq (0.36 mCi) of I-125. It was determined that 22 seeds were placed outside the prostate gland, inferior to the gland by 5.4 cm and in the perineum. According to the medical physicist's calculations, the prostate gland received a D90 dose of 14,000 cGy (rad). Initial indication is that the misplacement was a result of misidentification of the prostate gland by the radiation oncologist who performed the procedure. Ultrasound and C-arm fluoroscopy systems were used to aid with positioning the seeds. It appears that the patient's colon was not properly prepared, which caused poor ultrasound imaging. In addition, a Foley catheter was not inserted into the bladder, which made bladder localization difficult. A post implant confirmatory fluoroscopic image was obtained and the radiation oncologist observed that the sources were outside the prostate. On 5/28/2010, a post implant CT scan was performed, which confirmed the seed locations and allowed for a calculation of the Dose-Volume Histogram to the perineum of 1,000 cGy (rad). The State of New York is tracking the incident as number NYDOH-10-01.

Event Date: 05/26/2010 **Discovery Date:** 05/28/2010 **Report Date:** 05/28/2010

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
Respons ble 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
Respons ble NRC Region:	NA		

Other Information:

NRC Reportable Event:	U	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	Investigation:	N
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: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 32.4 mCi 1198.8 MBq Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 40.32 mCi 1491.84 MBq Dose: 14500 rad 145 Gy

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

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: NR Activity: 40.32 Ci 1491.84 GBq
Model Number: NR
Serial Number: AGGREGATE

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46009	06/21/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

Item Number: 100174

Last Updated: 06/29/2010

Narrative:

The University of Maryland reported a potential medical event involving a gamma knife treatment performed on 1/27/2010. The gamma knife unit [redacted] serial #4322) contained 95.46 TBq (2,580 Ci) of Co-60. It was determined that the patient helmet moved approximately 2 cm. The University stated that due to the posterior location of the tumor, the right anterior frame post interfered with the helmet. To allow for treatment, the neurosurgeon removed the anterior right post from the head frame. As a result, the pin from the left anterior post slipped superiorly about 2 cm. The University stated with a high level of confidence that the slippage occurred after the treatment and did not result in any dose to an unintended area. They believe the patient received 95% of the intended 1,800 cGy (rad) dose. The patient was informed of the incident on 1/27/2010. The Maryland Department of Health is investigating the incident.

Event Date: 01/27/2010 **Discovery Date:** 01/27/2010 **Report Date:** 02/09/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MD-07-014-05	Name:	UNIVERSITY OF MARYLAND
NRC Docket Number:	NA	City:	BALTIMORE
NRC Program Code:	NA	State: MD	Zip Code: 21201
Respons ble NRC Region:	1		

Site of Event:

Site Name: BALTIMORE
State: MD

Additional Involved Party:

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

Other Information:

NRC Reportable Event:	U	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: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 01/27/2010

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 2580000 mCi 95460000 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 2580000 mCi 95460000 MBq Dose: 1800 rad 18 Gy

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

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: NR Activity: 2580 Ci 95460 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 4322

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
MD100006	04/12/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR100623	06/29/2010		DCH	AGREEMENT STATE LETTER

Item Number: 090885

Last Updated: 12/23/2009

Narrative:

Cookeville Regional Medical Center reported a possible therapeutic medical event that occurred while a patient was being treated with three sealed sources of Cs-137 on 12/15/2009. The three sources had a total activity of 6.48 GBq (175 mCi) and were contained in a vaginal applicator. The patient was elderly and heavily sedated. The applicator was inserted and after 20 minutes of treatment, the nurse checked on the patient and noticed the applicator outside of the treatment location. The applicator was placed into a lead pig. The patient may have received a maximum dose of 76 cSv (rem) to the thigh area. The Tennessee Division of Radiological Health is tracking the incident as number TN-09-155. The INL has requested additional information for this event.

Event Date: 12/15/2009 **Discovery Date:** 12/15/2009 **Report Date:** 12/17/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TN-R-71026-D10	Name:	COOKEVILLE REGIONAL MEDICAL CENTER
NRC Docket Number:	NA	City:	COOKEVILLE
NRC Program Code:	NA	State: TN	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: COOKEVILLE
State: TN

Additional Involved Party:

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

Other Information:

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2
Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA

Radionuclide: CS-137	Activity:	175 mCi	6475 MBq	Dose:	NR rad	NR Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA

Radionuclide: CS-137	Activity:	175 mCi	6475 MBq	Dose:	NR rad	NR Gy

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

Patient Number: 1A

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: LEG

Radiopharmaceutical: NA

Radionuclide: CS-137 Activity: 175 mCi 6475 MBq Dose: 76 rad 0.76 Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: NR

% Dose is Less Than Prescribed: NA

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137

Manufacturer: NR Activity: 0.175 Ci 6.475 GBq

Model Number: NR

Serial Number: AGGREGATE

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: APPLICATOR Model Number: NR

Manufacturer: NR Serial Number: NR

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45579	12/23/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE